Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Approval

Protectol® GA 50

Product types 6, 11, 12

Glutaraldehyde as included in the Union list of approved active substances

Case Number in R4BP: BC-MQ026829-10

Evaluating Competent Authority: Finland

Date: 14/05/2018

Table of Contents

1 CONCLUSION

The Finnish CA proposes the authorisation of the biocidal product Protectol GA 50 as in-can preservative (PT6), preservative in oilfield applications (PT11) and a slimicide (PT12) for industrial and professional use. The biocidal product Protectol GA 50 contains 48.5-52.5% the active substance glutaraldehyde in aqueous solution. Protectol GA 50 is used for perservation of multiple product types under PT6: Detergents, cleaning fluids, paints, raw materias for production of paints, plastic and glues, additives used in the paper industry and auxiliaries used in the leather and textile production. These products treated with Protectol GA 50 contain a concentration of 0.001-0.0979% of glutaraldehyde. In PT11 Protectol GA 50 is used in preservation of hydrotesting fluids and in production and injection water in oil field applications in a concentration of 0.001-0.2% glutaraldehyde. In PT12 Protectol GA 50 is used as slimicide in the corresponding oil field applications and in paper industry as a slimidice in paper machine wet-end and de-inking. In all oilfield applications the use concentration of glutaraldehyde ranges in 0.001-0.2%. In paper industry the use concentration is in the range of 0.0005-0.02% glutaraldehyde. Uses of three different BPR product types were categorised in 11 different use groups (Use #1, 2, 3, 4, 5 for PT6, Use #6 and 7 for PT11 and Use #8, 9, 10 and 11 for PT12).

The physico-chemical properties and the safety relevant physico-chemical properties have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

The required validated analytical methods for determination of glutaraldehyde in the product and for determination of glutaraldehyde in air have been provided.

The justifications considering method requirement for detection of glutaraldehyde in soil, in animal tissues and in food or feedstuffs have been accepted.

The product demonstrated efficacy against bacteria and yeasts. Based on the submitted efficacy data it was observed that usually higher concentrations are required against fungi than bacteria or yeast to achieve efficacy. For use in detergents/cleaning fluids and auxillaries in leather and textile industry the claim against yeasts could not be accepted because growth in the untreated control was not achieved. For use in detergents/cleaning fluids and as slimicides in paper industry the claim against fungi could not be accepted because growth in the untreated control was not achieved. Use in water-based polymer emulsions (waxes, polishes) could not be accepted at all because growth in the untreated control was not achieved for any target species in the submitted efficacy study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated for any of the uses in PT6.

The minimum concentrations of above mentioned ranges were supported by efficacy data on at least one target species (e.g. bacteria) per use category, except for PT12 in paper industry where a minimum of 0.0046% of glutaraldehyde was validated by acceptable efficacy data. Based on the big variety of uses within the BPR product types it was considered necessary to state in the SPC that microbiological tests to prove adequacy of preservation should be undertaken by the user of Protectol GA 50 to determine the effective dose of the preservative for the specific matrix/location/system.

It was also required in the SPC that users shall be guided to consult the manufacturer of the preservative product in the determination of efficacy concentrations for their end-use if needed.

No unacceptable risks were identified in the risk assessment for human health for the Protectol GA 50 in the application of the Protectol GA 50 for preservation in the professional use when suitable personal protective equipment is used. No unacceptable risks were identified during handling of articles/formulations preserved with Protectol GA 50 in the professional or non-professional use. Appropriate personal protective equipment is required for certain uses when handling articles/formulations preserved with Protectol GA 50 in the professional use but not in the non-professional use.

Safe use in PT 6 and 12 could be identified for all environmental compartments as far as the emissions were led to the sewage treatment plant (STP). However, the use as preservative in the textile (PT 6.3.2) and leather industry (PT 6.3.3) requires the following risk mitigation measure (RMM): Waste water must be treated according to industry standards defined in the respective BAT documents. In addition, Protectol GA 50 must not be used as slimicide (PT 12) in pulp or paper mills with direct release to surface water or seawater. The following RMM is assigned: Application in the paper industry is only allowed when waste water is purified at least biologically before discharge to surface water.

Unacceptable risk was identified for preservation of paints and coatings (PT 6.2) when direct release to soil took place. Therefore, the following RMM is needed: The person responsible for the placing on the market of paints/coatings directly preserved with Protectol GA 50 shall ensure that the label of paints/coatings provides the following information: In order to avoid soil contamination during spray application of the treated articles (paints and coatings) cover ground adjacent to the wall with plastic sheet unless the ground is impermeable hardstanding. The groundwater concentrations were shown to be less than the trigger in Directive 98/83/EC. Direct release of Protectol GA 50 to surface water resulted in an acceptable risk.

Aggregated exposure of the PT 6 did not result in an unacceptable risk. Other uses than PT 6 were not relevant for the aggregated exposure as they are released to a bigger waste water treatment plant (PT 12 uses in pulp and paper mills) or they are released directly to seawater (oilfield uses).

Protectol GA 50 was also evaluated as preservative (PT 11) and slimicide (PT 12) in the oilfield uses. Both uses are covered by the PT 12 scenarios. Safe uses could be identified when taking into account degradation of glutaraldehyde. An obligation to measure the glutaraldehyde concentration in the discharge water is set to all oilfield uses. Glutaraldehyde concentration shall not exceed 0.2 mg/L in the hydrotesting fluids or produced water to be disposed to the sea.

The active substance glutaraldehyde is a candidate for substitution in accordance with Article 10(1)(b) of BPR. The comparative assessment has been perfomed by the eCA and a comparative assessment report has been produced. According to the comparative assessment, there is no adequate chemical diverisity of the active substances in PT6, PT11 or PT12 and it is not pertinent to conduct further investigations. The comparative assessment was finalised at the screening phase.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

2.1.1.2 PT06: Preservatives for products during storage (Preservatives) used for paper additives

Identifier[1]	**Country (if relevant)**
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Austria
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Belgium
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Finland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	France
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Germany
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Italy
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Netherlands

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[1] Please fill in here the identifying product name from R4BP.

Identifier[1]	**Country (if relevant)**
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, BIM CC 3250, BIM MC 4946, BIM MP 4850	Norway
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Poland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Portugal
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Spain
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850, BIM MC 4950	Sweden
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Switzerland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, BIM CC 3250, BIM MC 4946, BIM MP 4850	United Kingdom

2.1.1.3 *PT06: Preservatives for products during storage (Preservatives) used for all other uses*

Identifier[2]	**Country (if relevant)**
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Austria
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Belgium

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[2] Please fill in here the identifying product name from R4BP.

Identifier[2]	Country (if relevant)
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Finland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	France
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Germany
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Italy
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Netherlands
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Norway
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Poland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Portugal
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Spain
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Sweden
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Switzerland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	United Kingdom

2.1.1.4 PT11: Preservatives for liquid cooling and processing systems (Preservatives)

Identifier[3]	Country (if relevant)
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Denmark
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Netherlands
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Norway
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	United Kingdom

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[3] Please fill in here the identifying product name from R4BP.

2.1.1.5 PT12: Slimicides (Preservatives): oilfield related uses only

Identifier[4]	**Country (if relevant)**
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Denmark
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Netherlands
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	Norway
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF	United Kingdom

2.1.1.6 PT12: Slimicides (Preservatives): paper production process

Identifier[5]	**Country (if relevant)**
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Austria
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Belgium
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Finland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	France
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Germany
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL	Italy

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[4] Please fill in here the identifying product name from R4BP.

[5] Please fill in here the identifying product name from R4BP.

Identifier[5]	**Country (if relevant)**
50 B, BIM CC 3250, BIM MC 4946, BIM MP 485	
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Netherlands
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, BIM CC 3250, BIM MC 4946, BIM MP 4850	Norway
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Poland
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Portugal
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850	Spain
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, FennoSan GL10B, FennoCide GL 50 B, BIM CC 3250, BIM MC 4946, BIM MP 4850, BIM MC 4950	Sweden
Protectol® GA 50, Myacide® GA 50, Protectol® GA 50 OF, BIM CC 3250, BIM MC 4946, BIM MP 4850	United Kingdom

2.1.1.7 Authorisation holder

Name and address of the authorisation holder	**Name**	BASF SE
	Address	Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany
Authorisation number	Not yet available	
Date of the authorisation	Not yet available	
Expiry date of the authorisation	Not yet available	

2.1.1.8 *Manufacturer(s) of the products of the family*

Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany
Location of manufacturing sites	Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany

2.1.1.9 *Manufacturer(s) of the active substance(s)*

Active substance	Glutaraldehyde
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany
Location of manufacturing sites	Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany

2.1.1.10 *Distributor of the Biocidal Product:*

BTC Europe GmbH (BASF trading company, BASF group company)
BASF Österreich GmbH, Austria
BASF Belgium Coordination Center, Belgium
BASF A/S, Denmark
BASF Oy, Finland
BASF France, France
BASF SE, Germany
BASF Italia S.p.A., Italy
BASF Nederland B.V.H., The Netherlands
BASF AS, Norway
BASF Polska Sp. z.o.o., Poland
BASF Portuguesa S.A., Portugal
BASF Española S.L., Spain
BASF AB, Sweden
BASF Schweiz AG, Switzerland
BASF plc, UK
And other BASF affiliates

For further information please refer to chapter 3.6 (Confidential Annex).

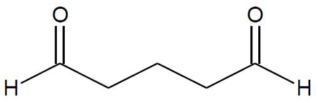
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Glutaraldehyde
IUPAC or EC name	1,5-Pentanedial
EC number	203-856-5
CAS number	111-30-8
Index number in Annex VI of CLP	605-022-00-X
Minimum purity / content	48.5 – 52.5% in aqueous solution*
Structural formula	

* theoretical dry weight specification: minimum purity is 95.0 % (wt), aqueous solution due to stability reasons

2.1.2.2 Candidate(s) for substitution

The active substance Glutaraldehyde is a candidate for substitution in accordance with Article 10(1)(b) of BPR due to classification according to Regulation (EC) No 1272/2008 as a respiratory sensitiser. Public consultation has taken place and the received comments have been included in the CAR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[6]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Glutaraldehyde	1,5-Pentanedial	Active substance	111-30-8	203-856-5	50*
(**)	(**)	Non-active substance[7]	(**)	(**)	(**)

* Range of 48.5% – 52.5% was set at active substance approval.
(**) Please refer to the confidential annex for further details.

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family[2]

This is not applicable as the dossier describes a biocidal product, not a biocidal product family.

2.1.2.5 Information on technical equivalence

Not applicable because the source of active substance is the same as was evaluated for inclusion in the Union list of approved active substances. Please refer to section 2.1.2.

2.1.2.6 Type of formulation

AL – Any other liquid.

2.1.3 Hazard and precautionary statements[8]

Classification and labelling of the products of the family according to the 9th ATP of Regulation (EC) 1272/2008

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[6] Please delete as appropriate.

[7] Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

[8] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Hazard category	Acute Tox 3
Hazard statement	H301: Toxic if swallowed.
Hazard category	Acute Tox 2
Hazard statement	H330: Fatal if inhaled.
Hazard category	Skin Corr. 1B
Hazard category	Eye dam. 1
Hazard statement	H314: Causes severe skin burns and eye damage.
Hazard category	Resp. Sens. 1
Hazard statement	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Hazard category	Skin Sens. 1A
Hazard statement	H317: May cause an allergic skin reaction
Hazard category	Aquatic chronic 2
Hazard statement	H411: Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H301: Toxic if swallowed. H330: Fatal if inhaled. H314: Causes severe skin burns and eye damage. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317: May cause an allergic skin reaction H411: Toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract.

Precautionary statements	included in the label: P260: Do not breathe dust / mist/ vapours/ P280: Wear protective gloves/protective clothing/eye protection/face protection. P284: [In case of inadequate ventilation] wear respiratory protection. P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician P403+P233: Store in well-ventilated place. Keep container tightly closed. P405: Store locked up. further precautionary statements in the SDS: P264: Wash with plenty of water and soap thoroughly after handling. P270: Do no eat, drink or smoke when using this product. P271: Use only outdoors or in well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P342+P311: If experiencing respiratory symptoms: Call a doctor. P360: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. P362 + P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage. P501: Dispose of contents/ container to…
Note	EUH071: Corrosive to the respiratory tract.

Justification for the environmental classification: Glutaraldehyde is classified as H400 (M=1) and H411 (harmonised classification, ATP09). The classification of Protectol GA 50 is based on the study on green algae (Scenedesmus subspicatus) with a product with identical composition to Protectol GA 50 (50 % aqueous solution of glutaraldehyde). In the risk assessment of glutaraldehyde algae were shown to be the most sensitive species to glutaraldehyde (Doc IIA, Table 4.3.3).

Aquatic toxicity tests are to be preferred for the classification of mixtures (CLP regulation, Annex I, Part 4, Fig. 4.1.2).

Because the ErC50 of the algae test is 1.2 mg/L, there will be no classification of Protectol GA 50 in category Acute 1 (CLP, Annex I, Part 4, 4.1.3.3.3.).

Classification as Aquatic chronic 2 is based on the same study. The NOEC is 0.05 mg/L (glutaraldehyde is readily biodegradable) (CLP, Annex I, Part 4, Table 4.10).

The active substance glutaraldehyde and Protectol GA 50 are identical 50 % aqueous solutions of glutaraldehyde. All ecotoxicological tests on the active substance were done on the 50 % glutaraldehyde, but the test result was converted to 100 % glutaraldehyde. Glutaraldehyde is not stable over 50 % and does not exist as 100 % substance.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Protectol® GA 50 is used for the control of gram positive and gram-negative bacteria, yeasts and fungi responsible for spoilage, deterioration, gas evolution, odour, colour/ pH/ viscosity changes, disintegration of formulations, slime and corrosion.

Microbiological tests to prove adequacy of preservation should be undertaken by the user of Protectol® GA 50 in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, the manufacturer of the preservative product shall be consulted.

The highest dosage recommendation for PT6 was obtained aiming to make sure that the glutaraldehyde concentration in the treated article is below the concentration limit for classification for sensitization (0,1 % w/w). As the commercial specification is 50-51 % glutaraldehyde in Protectol GA 50 (titration) and the applicant wants to give round values of Protectol GA 50 dosage recommendations for the sake of simplicity + taking 51% GA content into account + applying a little safety, the stated glutaraldehyde upper limits are obtained.

In the consultation of cMSs it was discussed if the intended use in PT6 should be considered curative but it was concluded by BPR Coordination Group members that related to PT6 there is no claim as "curative" for this product.

The highest dosages for the PT11/12 uses are either determined by the risk assessments or by commercial experience/feedback from customers on how the biocidal product is used e.g. in paper mills or hydrotesting with "dirty" and hot test water in real oilfield applications where degradation of glutaraldehyde takes place.

Table 1. Use #1 – Preservation of detergents and cleaning fluids and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage: PT 6.1 Detergent and cleaning fluids
Where relevant, an exact description of the authorised use	preservation of detergents and cleaning fluids (laundry products, laundry softener, liquid dishwashing products, hard surface cleaners and raw materials for use in detergent and cleaning applications)
Target organism (including development stage)	bacteria
Field of use	Indoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	100-1958 mg Protectol® GA 50 per kg (0.005-0.098% a.s.); double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, BE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, CH, UK
Authorisation	YES

2.1.4.2 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.3 Use-specific risk mitigation measures

please refer to chapter 2.1.5 General directions for use

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.7 Use description

Table 2. Use#2 – Preservation of wax and polymer emulsions and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	Preservative for water-based polymer emulsions polishes, car polishes, waxes)
Target organism (including development stage)	-
Field of use	Indoor and outdoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg (0.003-0.098% a.s.); double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial and trained professional
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, BE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, CH, UK
Authorisation	NO, because growth in the untreated control was not achieved for any target species in the submitted efficacy study.

2.1.4.8 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.9 Use-specific risk mitigation measures

please refer to chapter 2.1.5 General directions for use

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.13 Use description

Table 3. Use #3 – Preservation of water based products used in the paper industry (PT06)

Product Type	PT06 - Preservatives for products during storage: PT 6.3.1 Paper production
Where relevant, an exact description of the authorised use	Preservation of additives used in the production of paper
Target organism (including development stage)	bacteria and yeasts
Field of use	Indoor Examples of additives to be preserved are inorganic slurries ($CaCO_3$ and kaolin), cellulose (pulp), polymers, pigment dispersions, starch.
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	20 – 1958 mg biocidal product per kg (0.001-0.098% a.s.); double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, BE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, CH, UK
Authorisation	YES

2.1.4.14 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.15 Use-specific risk mitigation measures

RPE (2.5 % penetration), coated coverall and gloves are required while loading and unloading slurry tanks if slurries are not pumped in automatic procedures

2.1.4.16 *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

please refer to chapter 2.1.5 General directions for use

2.1.4.17 *Where specific to the use, the instructions for safe disposal of the product and its packaging*

please refer to chapter 2.1.5 General directions for use

2.1.4.18 *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

please refer to chapter 2.1.5 General directions for use

2.1.4.19 *Use description*

Table 4. Use #4 – Preservation of paints and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage: PT 6.2 Paints and coatings
Where relevant, an exact description of the authorised use	Preservation of paints and raw materials for the production of paints, plastic and glues (pigments, polymer and pigment dispersions, inorganic slurries used as fillers)
Target organism (including development stage)	bacteria and yeasts
Field of use	Indoor and outdoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg (0.003-0.098% a.s.); double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial and (trained) professional
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, BE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, CH, UK
Authorisation	YES

2.1.4.20 *Use-specific instructions for use*

please refer to chapter 2.1.5 General directions for use

2.1.4.21 *Use-specific risk mitigation measures*

The label of the paint to which this product is added must indicate following risk mitigation measures: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least TN3, EN 14605; coverall material to be specified by the authorisation holder within the product information; 10 % penetration each) and RPE (10 % penetration) for painting using spray application; The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: In order to avoid soil contamination during spray application of the treated articles (paints and coatings) cover ground adjacent to the wall with plastic sheet unless the ground is impermeable hardstanding. For rolling/brush application no PPE is required but use of gloves is recommended.

2.1.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.25 Use description

Table 5. Use #5 – Preservation of additives for the production of leather and textile (PT06)

Product Type	PT06 - Preservatives for products during storage: PT 6.3.2 Textile production PT 6.3.3 Leather production
Where relevant, an exact description of the authorised use	Preservation of additives for production of leather and textiles
Target organism (including development stage)	bacteria
Field of use	Indoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg (0.003-0.098% a.s.); double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial

Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, BE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, CH, UK
Authorisation	YES

2.1.4.26 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.27 Use-specific risk mitigation measures

During textile and leather treatment, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a protective impermeable coverall (at least TN3, EN 14605; coverall material to be specified by the authorisation holder within the product information; 5 % penetration. Waste water must be treated according to industry standards defined in the respective BAT documents.

2.1.4.28 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.29 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.30 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.31 Use description

Table 6. Use #6 – Preservation of hydrotesting fluids in oil field applications (PT11)

Product Type	PT11 - Preservatives for liquid-cooling and processing systems
Where relevant, an exact description of the authorised use	The product is intended to prevent microbially induced deterioration and corrosion in pipelines, vessels, boilers etc. during pressure tests after construction or maintenance
Target organism (including development stage)	deterioration and corrosion inducing bacteria

Field of use	Outdoor
Application method(s)	single dose of liquid to the testing water *via* automated pumps and dosing lines
Application rate(s) and frequency	25 – 4000 mg Protectol® GA 50 per L water (0.001-0.2% a.s.), double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single addition to the fluids
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	DK, NL, NO, UK
Authorisation	YES

2.1.4.32 Use-specific instructions for use

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in hydrotesting fluids. This concentration can be achieved either by slow release and/or long retention times resulting in degradation of glutaraldehyde and/or by dilution and/or by addition of sodium bisulphite at pH 5 (release after at least 20 minutes) or addition of sodium hydroxide to pH 12 (release after at least 10-16 hours) as degradation aids. Hydrotest water containing up to 750 mg/L glutaraldehyde can be used for re-injection.
Run lab test to determine the soiling dependent dosage and degradation rate in use.

2.1.4.33 Use-specific risk mitigation measures

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in hydrotesting fluids. To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.37 Use description

Table 7. Use #-7 – Preservation of production and injection water in oilfield applications (PT11)

Product Type	PT11 - Preservatives for liquid-cooling and processing systems
Where relevant, an exact description of the authorised use	The product is intended to prevent microbially induced deterioration and corrosion in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems, and during pipeline pigging and scraping operations
Target organism (including development stage)	Deterioration and corrosion inducing bacteria
Field of use	Outdoor
Application method(s)	addition to water phases *via* automated pumps and dosing lines
Application rate(s) and frequency	Add 25-1500 mg Protectol® GA 50 per liter water (0.001-0.075% a.s.) once per week for injection water and production water re-injection, pipeline and storage tank uses with a dosing time of 1-6 hours or daily over 2 hours. Dose rate: max. 1500 mg/L Protectol® GA 50 per liter water daily with a dosing time of 1 hour or weekly max. 1500 mg/L Protectol® GA 50 with a dosing time of 2 hours or max. 1200 mg/L for 6 hours every two weeks or other dosing regimens resulting in same or lower daily average concentrations. If Protectol® GA 50 is added to produced water intended to be disposed to the sea, dose min. 25 mg/L - max. 36 mg/L Protectol® GA 50 daily with a dosing time of 2 hours or weekly 25 mg/L – max 260 mg/L Protectol® GA 50 with a dosing time of two hours or other dosing regimens resulting in the same or lower daily average concentrations. Contact time of min. 24 hours should be observed before discharge. Use double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	DK, NL, NO, UK
Authorisation	YES

2.1.4.38 Use-specific instructions for use

If Protectol® GA 50 is added to the production water intended to be disposed to the sea and not re-injected, use retention time of at least 24 hours (dependent on degradation rate) in order to achieve sufficient degradation. Run lab test to determine the soiling/degradation rate dependent dosage. Check glutaraldehyde degradation to determine the water release rate when releasing into seawater and/or the in-situ dilution at the outlet with water necessary and/or the rate of glutaraldehyde degradation.

2.1.4.39 Use-specific risk mitigation measures

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in production water. To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.40 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.41 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.42 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.43 Use description

Table 8. Use #8 – Slimicide for hydrotesting fluids in oilfield applications (PT12)

Product Type	PT12 – Slimicides (Preservatives) PT12.2 Oil extraction processes
Where relevant, an exact description of the authorised use	Avoid microbially induced corrosion and spoilage by destroying biofilms in pipelines, vessels, boilers etc. during pressure tests after construction or maintenance
Target organism (including development stage)	biofilm forming bacteria
Field of use	Outdoor
Application method(s)	single dose of liquid to the testing water *via* automated pumps and dosing lines
Application rate(s) and frequency	25-4000 mg Protectol® GA 50 per L water (0.001-0.2% a.s.), the minimum effective concentration tested for biofilm 312.5 mg Protectol® GA 50 per kg after 4 h or 20 mg Protectol® GA 50 per kg after 24 h.; double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank; single addition to the fluids

Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	DK, NL, NO, UK
Authorisation	YES

2.1.4.44 Use-specific instructions for use

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in hydrotesting fluids. This concentration can be achieved either by slow release and/or long retention times resulting in degradation of glutaraldehyde and/or by dilution and/or by addition of sodium bisulphite at pH 5 (release after at least 20 minutes) or addition of sodium hydroxide to pH 12 (release after at least 10-16 hours) as degradation aids. Hydrotest water containing up to 750 mg/L glutaraldehyde can be used for re-injection.
Run lab test to determine the soiling dependent dosage and degradation rate in use.

2.1.4.45 Use-specific risk mitigation measures

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in hydrotesting fluids. To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.46 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.47 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.48 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.49 Use description

Table 9. Use #9 – Slimicide for production and injection water in oilfield applications (PT12)

Product Type	PT12 – Slimicides (Preservatives) PT12.2 Oil extraction processes

Where relevant, an exact description of the authorised use	The product is intended to avoid microbially induced corrosion and spoilage by destroying biofilms in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations.
Target organism (including development stage)	biofilm forming bacteria
Field of use	Outdoor
Application method(s)	addition to water phases *via* automated pumps and dosing lines
Application rate(s) and frequency	Add 25-1500 mg Protectol® GA 50 per liter water (0.001-0.075% a.s.) once per week for injection water and production water re-injection, pipeline and storage tank uses with a dosing time of 1-6 hours or daily over 2 hours. The minimum effective concentration tested for biofilm is 312.5 mg Protectol® GA 50 per kg after 4 h or 20 mg Protectol® GA 50 per kg after 24 h. Dose rate: max. 1500 mg/L Protectol® GA 50 per liter water daily with a dosing time of 1 hour or weekly max. 1500 mg/L Protectol® GA 50 with a dosing time of 2 hours or max. 1200 mg/L for 6 hours every two weeks or other dosing regimens resulting in same or lower daily average concentrations. If Protectol® GA 50 is added to produced water intended to be disposed to the sea, dose min. 25 mg/L - max. 36 mg/L Protectol® GA 50 daily with a dosing time of 2 hours or weekly 25 mg/L – max 260 mg/L Protectol® GA 50 with a dosing time of two hours or other dosing regimens resulting in the same or lower daily average concentrations. Contact time of min. 24 hours should be observed before discharge. Use double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	DK, NL, NO, UK
Authorisation	YES

2.1.4.50 Use-specific instructions for use

If Protectol® GA 50 is added to produced water intended to be disposed to the sea and not re-injected, use retention time of at least 24 hours (dependent on degradation rate) in order to achieve sufficient degradation. Run lab test to determine the soiling/degradation rate dependent dosage. Check glutaraldehyde degradation to determine the water release rate when releasing into seawater and/or the in-situ dilution at the outlet with water necessary and/or the rate of glutaraldehyde degradation.

2.1.4.51 Use-specific risk mitigation measures

If discharged into seawater 0.2 mg/L glutaraldehyde must not be exceeded in the production water. To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.52 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.53 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.54 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.55 Use description

Table 10. Use #10 – Slimicide for paper industry, wet end (PT12)

Product Type	PT12 – Slimicides (Preservatives) PT12.1 Paper industry
Where relevant, an exact description of the authorised use	For use as paper slimicide for continuous paper production, for slime control/prevention for process water and short-term protection of wet stock during machine shut down.
Target organism (including development stage)	biofilm forming bacteria
Field of use	Indoor
Application method(s)	automatic dosing into the white-water circuit, head box or machine chest
Application rate(s) and frequency	shock dose: 92 mg/L to 400 mg/L Protectol® GA 50 (0.0046-0.02% a.s.) Intermittent dosage: Add Protectol® GA 50 at 92 mg/L to 300 mg/L (0.0046-0.015% a.s.) for a period of up to 1 hour. Repeat intermittent dosage every 6-8 hours; double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank. A shock dose is used to gain control in case of severe microbial infection and the dosage is lowered when control is

	achieved. The shock dosing and intermittent dosage regime was already described and agreed on in the CAR for glutaraldehyde (2014), e.g. p. 156.
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, DE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, UK
Authorisation	YES

2.1.4.56 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.57 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least TN3, EN 14605; coverall material to be specified by the authorisation holder within the product information; 10 % penetration) and RPE (2.5 % penetration) while cleaning/maintenance work on pulp tanks. Ensure low level of containment. Application in the paper industry is only allowed when waste water is purified at least biologically before discharge to surface water.

To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.58 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.59 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.60 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.4.61 Use description

Table 11. Use #11 – Slimicide for paper industry, de-inking (PT12)

Product Type	PT12 – Slimicides (Preservatives): PT12.1 Paper industry
Where relevant, an exact description of the authorised use	For papermill de-inking use Protectol® GA 50 for the control of slime and microbial release of catalase enzyme interfering with the de-inking process during paper recycling.
Target organism (including development stage)	biofilm forming bacteria
Field of use	Indoor
Application method(s)	automatic dosing
Application rate(s) and frequency	92 mg/L to 250 mg/L Protectol® GA 50 (0.0046-0.013 % a.s.), 4 times per day lasting 30 minutes, directly to the water circuit of the deinking plant; double amount of the pre-diluted product in case of pre-dilution to 24 % glutaral with water in a pre-tank
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.
Concerned MS	AT, DE, FI, FR, DE, IT, NL, NO, PL, PO, ES, SE, UK
Authorisation	YES

2.1.4.62 Use-specific instructions for use

please refer to chapter 2.1.5 General directions for use

2.1.4.63 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least TN3, EN 14605; coverall material to be specified by the authorisation holder within the product information; 10 % penetration) and RPE (2.5 % penetration) while cleaning/maintenance work on pulp tanks.

Application in the paper industry is only allowed when waste water is purified at least biologically before discharge to surface water.
To avoid the development of resistance: in addition to the requirements in the general instructions for use, check the efficacy of the product on site. If needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

2.1.4.64 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

please refer to chapter 2.1.5 General directions for use

2.1.4.65 Where specific to the use, the instructions for safe disposal of the product and its packaging

please refer to chapter 2.1.5 General directions for use

2.1.4.66 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

please refer to chapter 2.1.5 General directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

For the control of micro-organisms responsible for spoilage, deterioration, gas evolution, odour, colour/ pH/ viscosity changes, disintegration of formulations, slime and corrosion. Protectol® GA 50 should be added directly to the water phase where adequate mixing will ensure quick dissolution. In hot process, allow the temperature to fall below 40 °C prior to addition.
Microbiological tests to prove adequacy of preservation should be undertaken by the user of Protectol® GA 50 in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

2.1.5.2 Risk mitigation measures

When connecting pump to Protectol® GA 50 drum wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coated coverall (at least TN3, EN 14605; coverall material to be specified by theauthorisation holder within the product information; 10 % penetration), eye protection and RPE (2.5 % penetration; APF 40).

To avoid the development of resistance: Always read the label or leaflet before use and follow all the instructions provided. The authorisation holder should report any observed incidents related to the efficacy to the Competent Authorities (CA). The user should ensure general cleanliness and hygiene during application. The user should prevent as far as possible the release of the biocide into the environment to avoid non-effective concentrations in the environment which might select for resistance in the environment. If resistance does occur, the user should consider cycling between different active substances.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects may include:
Skin and eye contact: Irritation to severe burns of the skin and eyes. May induce eye lacrimation, skin sensitization and/or allergic dermatitis.
Mouth contact/ingestion: Irritation to corrosion of the gastrointestinal tract. May include nausea, vomiting, ulceration of the esophagus and/or stomach with subsequent perforation, hematemesis and/or internal bleeding.

Inhalation/aspiration: Irritation to corrosion of the respiratory tract. May include coughing, rhinitis, coryza, epistaxis, pulmonary oedema, bronchospasm, respiratory distress and/ or asthma.
Other clinical manifestations may include; headache, tachycardia, palpitations, hypotension and depression of the CNS.

First aid instructions:
Relocate individual form contamination site/ source; remove all contaminated clothing avoiding exposure to yourself and/ or others.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.
IF INHALED: Remove person to fresh air and keep confortable for breathing. Keep the person calm, maintain body temperature, monitor breathing, start artificial respiration if necessary. Immediately call a POISON CENTER/doctor.
IF ON SKIN (or hair): Wash skin with plenty of water without rubbing.
IF IN EYES: Rinse immediately with water at least for 15 minutes under running water with eyelids held open. Always check and remove contact lenses.
Immediately call a POISON CENTER/doctor.
Take off contaminated clothing and wash it before reuse.
If symptoms persist or worsen seek medical advice/attention.NEVER give anything by mouth to an impaired or unconscious individual, place in recovery (left sideways) position with the knees bent and transport to a healthcare centre, bring the label or container if possible.

Never leave an intoxicated individual unattended!

Advice for medical and healthcare personnel:
Monitor vital signs for at least 24 hours and provide symptomatic and supportive treatment following local protocols.
In case of ingestion evaluate realization of endoscopy and immediate dilution and/or decontamination.
The use of ipecac syrup is contraindicated.
If inhaled, administer a corticosteroid from a controlled/ metered dose inhaler.
No known antidote is currently available.
Pulmonary oedema prophylaxis. Medical monitoring for at least 24 hours.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents to hazardous or special waste collection point.
Incinerate in suitable incineration plant, observing local authority regulations.
Contaminated packaging should be emptied as far as possible; then it can be passed on for recycling after being thoroughly cleaned.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a well-ventilated place. Keep container tightly closed.
Keep under inert gas.
Storage temperature: ≤ 25°C
Shelf-life: 12 months if stored at $\leq 25^{o}$C.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Iso tank container	3-33 m³	Stainless steel (with no inliner)	Stainless steel	Industrial	Yes
IBC	1100 kg	HDPE	Butterfly valve, HDPE	Industrial	Yes
drum	230 kg	HDPE or steel/PE inliner	Screw plugs HDPE	Industrial, professional	Yes
drum	60 kg	Steel/PE	Plug PE or PP	Industrial, professional	Yes
bottle	1 kg	Glass or PE	PP or PE screw cap	Only for sampling!	yes

2.1.8 Documentation

2.1.8.1 *Data submitted in relation to product application*

New studies on the product have been submitted for the application for product authorisation of Protectol® GA 50. Core data such as efficacy effects, physico-chemical properties, storage stability and the analytical method of determination of the a.s. in the biocidal product have been investigated.

Complete information details on the references are given at the end of the document in the list of studies of section 3.1.

2.1.8.2 *Access to documentation*

The applicant is BASF SE, who is the data owner of the active substance dossier that supported the approval of glutaraldehyde for use as a Product Type 2, 3, 4, 6, 11, and 12. Therefore, no letter of access is required.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 12. Use #1 – Preservation of detergents and cleaning fluids and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	preservation of detergents and cleaning fluids such as (but not limited to) laundry products, laundry softener, liquid dishwashing products, hard surface cleaners and raw materials for use in detergent and cleaning applications
Target organism (including development stage)	gram-positive and gram-negative bacteria and fungi, including yeasts and moulds
Field of use	Indoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	100-1958 mg Protectol® GA 50 per kg; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 13. Use #2 – Preservation of wax and polymer emulsions and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	Preservative for water-based polymer emulsions (e.g. but not limited to polishes, car polishes, waxes, etc.)
Target organism (including development stage)	gram-positive and gram-negative bacteria and fungi, including yeasts and molds
Field of use	Indoor and outdoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial and trained professional
Pack sizes and packaging material	Please see the relevant section.

Table 14. Use #3 – Preservation of water based products used in the paper industry (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	Preservation of chemicals (including but not limited to inorganic slurries, organic dispersions, polymers, pigments, inks, cellulose, starch, glues, pulp etc.) used in the production of paper
Target organism (including development stage)	gram-positive and gram-negative bacteria and fungi, including yeasts and moulds

Field of use	Indoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	add once 20 – 1958 mg biocidal product per kg; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 15. Use #4 – Preservation of paints, glues and raw materials thereof (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	Preservation of paints and raw materials for the production of paints, plastic and glues such as (but not limited to) pigments, polymer and pigment dispersions, inorganic slurries used as fillers etc.
Target organism (including development stage)	gram-positive and gram-negative bacteria and fungi, including yeasts and molds
Field of use	Indoor and outdoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial and (trained) professional
Pack sizes and packaging material	Please see the relevant section.

Table 16. Use #5 – Preservation of auxiliaries used in leather and textile industry (PT06)

Product Type	PT06 - Preservatives for products during storage
Where relevant, an exact description of the authorised use	Preservation of auxiliaries such as (but not limited to) organic emulsions e.g. leather re-fattening agents, pigment and polymer dispersions etc. used in the leather and textile production
Target organism (including development stage)	gram-positive and gram-negative bacteria and fungi, including yeasts and moulds
Field of use	Indoor
Application method(s)	Incorporated during manufacture
Application rate(s) and frequency	50 – 1958 mg Protectol® GA 50 per kg; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single application
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 17. Use #6 – Preservation of hydrotesting fluids in oil field applications (PT11)

Product Type	PT11 - Preservatives for liquid-cooling and processing systems
Where relevant, an exact description of the authorised use	The product is intended to prevent microbially induced deterioration and corrosion in pipelines, vessels, boilers etc. during pressure tests after construction or maintenance
Target organism (including development stage)	deterioration and corrosion inducing gram-positive and gram–negative bacteria
Field of use	Outdoor
Application method(s)	single dose of liquid to the testing water *via* automated pumps and dosing lines
Application rate(s) and frequency	25 – 4000 mg Protectol® GA 50 per L water, double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single addition to the fluids
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 18. Use #7 – Preservation of production and injection water in oilfield applications (PT11)

Product Type	PT11 - Preservatives for liquid-cooling and processing systems
Where relevant, an exact description of the authorised use	The product is intended to prevent microbially induced deterioration and corrosion in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations
Target organism (including development stage)	Deterioration and corrosion inducing gram-positive and gram–negative bacteria
Field of use	Outdoor
Application method(s)	addition to water phases *via* automated pumps and dosing lines
Application rate(s) and frequency	Add 25-1500 mg Protectol® GA 50 per liter water once per week for injection water and production water re-injection, pipeline and storage tank uses with a dosing time of 1-6 hours or daily over 2 hours. If Protectol® GA 50 is added to produced water intended to be disposed to the sea, use 36 mg Protectol® GA 50 per liter water daily for 2 hours or weekly 260 mg/L Protectol® GA 50 dosed over 2 hours. Use double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 19. Use #8 – Slimicide for hydrotesting fluids in oilfield applications (PT12)

Product Type	PT12 – Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	Prevent biofilm formation in pipelines, vessels, boilers etc. during pressure tests after construction or maintenance
Target organism (including development stage)	biofilm forming gram-positive and gram-negative bacteria
Field of use	Outdoor
Application method(s)	single dose of liquid to the testing water *via* automated pumps and dosing lines
Application rate(s) and frequency	25-4000 mg Protectol® GA 50 per L water; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank; single addition to the fluids
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 20. Use #9 – Slimicide for production and injection water in oilfield applications (PT12)

Product Type	PT12 – Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	The product is intended to prevent biofilm formation in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations.
Target organism (including development stage)	biofilm forming gram-positive and gram-negative bacteria
Field of use	Outdoor
Application method(s)	addition to water phases *via* automated pumps and dosing lines
Application rate(s) and frequency	Add 25-1500 mg Protectol® GA 50 per liter water once per week for injection water and production water re-injection, pipeline and storage tank uses with a dosing time of 1-6 hours or daily over 2 hours. If Protectol® GA 50 is added to produced water intended to be disposed to the sea, use 36 mg Protectol® GA 50 per liter water daily for 2 hours or weekly 260 mg/L Protectol® GA 50 dosed over 2 hours. Use double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank.
Category(ies) of users	Industrial

Table 21. Use #10 – Slimicide for paper industry, wet end (PT12)

Product Type	PT12 – Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	For use as paper slimicide for continous paper production, for slime control/prevention for process water and short-term protection of wet stock during machine shut down.

Target organism (including development stage)	biofilm forming gram-positive and gram-negative bacteria, fungi
Field of use	Indoor
Application method(s)	automatic dosing into the white-water circuit, head box or machine chest
Application rate(s) and frequency	shock dose: 10 mg/L to 400 mg/L Protectol® GA 50 Intermittent dosage: Add Protectol® GA 50 at 10 mg/L to 300 mg/L for a period of up to 1 hour. Repeat every 6-8 hours; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

Table 22. Use #11 – Slimicide for paper industry, de-inking (PT12)

Product Type	PT12 – Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	For papermill de-inking use Protectol® GA 50 for the control of slime and microbial release of catalase enzyme interfering with the de-inking process during paper recycling.
Target organism (including development stage)	biofilm forming gram-positive and gram-negative bacteria, fungi
Field of use	Indoor
Application method(s)	automatic dosing
Application rate(s) and frequency	10 mg/L to 250 mg/L Protectol® GA 50, 4 times per day lasting 30 minutes, directly to the water circuit of the deinking plant; double amount in case of pre-dilution to 24 % glutaral with water in a pre-tank
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
Physical state at 20 °C and 101.3 kPa	Pesticide Assessment Guidelines, Subdivision D, 63-3	Glutaraldehyde 50% aq. solution	Free flowing liquid	-	BASF 4217-F(02) (1999) key study
Colour at 20 °C and 101.3 kPa	Pesticide Assessment Guidelines, Subdivision D, 63-2	Glutaraldehyde 50% aq. solution	Water clear Clear colourless liquid	-	BASF 4217-F(02) (1999) key study
Odour at 20 °C and 101.3 kPa	Pesticide Assessment Guidelines, Subdivision D, 63-4	Glutaraldehyde 50% aq. solution	Sweetish	-	BASF 4217-F(02) (1999) key study
Acidity / alkalinity	CIPAC Method MT 75; potentiometric measurement	Glutaraldehyde 50% aq. solution	pH 3.7 at 23 °C	-	BASF 07L00094 (2007) key study
	CIPAC Method MT 75; potentiometric measurement CIPAC Method MT 31, potentiometric titration	Glutaraldehyde 50% aq. solution	pH 5.9 at 23 °C Acidity 0.10g/100g (calc. as H_2SO_4)	This value has obtained for a dilution, not for the neat product.	BASF 07L00060 (2007) key study
	Pesticide Assessment Guidelines, Subdivision D, "Series 63", pH (63-12)	Glutaraldehyde 0.5% aq. solution	pH 4.77 at 24.9 °C	-	BASF 4217-F(02) (1999) key study
Relative density / bulk density	Pesticide Assessment Guidelines, Subdivision D, 63-7	Glutaraldehyde 50% aq. solution	Relative density 1.13 g/cm^3 at 20 °C	-	BASF 4217-F(02) (1999) key study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
	Internal Dr. Wolman standard, comparable to OECD 109 (buoyancy method, hydrometer)	Glutaraldehyde 50% aq. solution	Density 1.13 g/cm^3 at 20 °C	-	Dr. Wolman GmbH (1987)/BASF SE supporting study
	German Standard DIN 51757	Glutaraldehyde 50% aq. solution	Density 1.13 g/cm^3 at 20 °C	-	BASF 92A03264 (1992) supporting study
Storage stability test – Accelerated storage	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Stability (Guideline 63-13), Storage stability (Guideline 63-17)	Glutaraldehyde 50% aq. solution	Stability (Guideline 63-13): C_{D0} 49.2% $C_{D14\text{ (elevated temp.)}}$ 48.2% $C_{D14\text{ (stainless steel)}}$ 50.7% $C_{D14\text{ (copper)}}$ 49.4% $C_{D14\text{ (iron III oxide)}}$ 49.7% $C_{D14\text{ (cupric acetate)}}$ 50.4% $C_{D14\text{ (light)}}$ 47.0% $C_{D14\text{ (light control)}}$ 49.5% $C_{D14\text{ (galvanised steel)}}$ 50.4% $C_{D14\text{ (aluminium)}}$ 50.6% $C_{D14\text{ (zinc acetate)}}$ 42.5%	Stable when stored for 14 days under the following conditions: ambient temperature (ca. 21°C), metals (galvanized steel, stainless steel, copper, and aluminium), and metal ions (iron, copper, and aluminium). Loss of active ingredient occurred when stored exposed to light and zinc ions.	BASF 4217-F(02) (1999) supporting study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
			$C_{D14\text{ (aluminium tartrate)}}$ 53.3% Storage stability (Guideline 63-17): $C_{D0\text{ (ambient)}}$ 49.2% $C_{12M\text{ (plastic)}}$ 49.0% $C_{12M\text{ (steel)}}$ 48.2% Evaluated temp.: $C_{D33\text{ (plastic)}}$ 45.4% $C_{D33\text{ (steel)}}$ 44.1%	Stable for ca. 12 months at ambient temperature for both plastic and stainless steel containers. Loss of active ingredient was observed after 33 days at elevated temperature (ca. 54°C) for both types of containers, with the greatest loss in the stainless-steel containers.	
	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Accelerated storage stability (Guideline 63-17)	Glutaraldehyde 50% aq. solution	<u>Ambient temp.:</u> C_{d0} 49.4% $C_{d35\text{ (plastic)}}$ 49.5% $C_{d35\text{ (stainless steel)}}$ 49.9% <u>c. 38°C:</u> $C_{35\text{ (plastic)}}$ 49.1% $C_{35\text{ (stainless steel)}}$ 49.0%	Stable for 35 days at ambient and elevated (ca. 38 °C) temperatures in both plastic and stainless-steel containers No changes of appearance, colour or	BASF 4712-F(01) (1999) supporting study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				viscocity was observed after any of these studies.	
	CIPAC MT 46.3/ GIFAP Monograph 17 (for accelerated storage stability studies); appearance (physical state, colour and odour), stability of the original test item container, weight change of the test item container, content of active ingredient has been investigated following well-described guideline study	Glutaraldehyde 50.8% aq. solution	C_0 = 51.0% pH_0 = 3.79 C_{8w} = 49.8% pH_{8w} 3.60 No changes to appearance, colour or odour were observed. No changes to container shape or size were observed.	Test substance is thermally stable at 40 °C ± 2 °C for 8 weeks.	BASF S15-04190 (2015) key study
Storage stability test Long term storage at ambient temperature	Guidance on information requirements Version 1.0 July 2013, page 147	Glutaraldehyde 50% aq. solution	C_0 = 51.0% C_{24M} = 49.5% pH_0 = 3.79 pH_{24M} = 3.47 No changes to appearance, colour or odour were observed.	The test substance is thermally stable at 20 °C ± 2 °C for 24 months. Only minor changes of the determined parameters were observed after storage.	BASF S15-04191 / EX15/020 (2016) key study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
			No changes to container shape, size or weight were observed.		
Storage stability test Low temperature stability test for liquids	CIPAC MT 39.3, CIPAC MT 185	Glutaraldehyde 50.8% aq. solution	The substance is stable at 0 °C for 7 days	-	BASF S15-04192 (2015) key study
Effects on content of the active substance and technical characteristics of the biocidal product Light	-	-	FennoCide GL 50 B, Protectol GA 50 OF, BIM MP 4850, Myacide GA 50, BIM MC 4946, FennoSan GL 10 B, BIM CC 3250	-	-
Effects on content of the active substance and technical characteristics of the biocidal product Temperature and humidity	OECD 111 and 113	Glutaraldehyde 50% aq. solution	OECD 111: $C_{0(at\ pH4)}$= 49.6% $C_{5D(at\ pH4)}$=49.2% $C_{0(at\ pH7)}$= 50.1% $C_{5D(at\ pH7)}$=45.5% $C_{0(at\ pH9)}$= 49.2% $C_{5D(at\ pH9)}$=11.6% OECD113: C_{D0}= 48.8% $C_{D14(at\ 55^{o}C)}$ =51.4%	The test substance is stable with respect to the OECD Guideline 113	BASF O/93/9932 (1993) key study
	DIN 51007	Glutaraldehyde 50% aq. solution	Tot. exot. energy c. 250 J/g(<300 J/g)	-	BASF SIK-Nr. 15/2089 (2015) key study
	OECD Guideline 113 (Screening Test for Thermal Stability and Stability in Air)	Glutaraldehyde 50% aq. solution	Substance is thermally not stable at	-	BASF SIK-Nr. 04/2080 (2004) key study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
			temperatures ≥ 85 °C		
	Expert judgement	Glutaraldehyde 50% aq. solution	Substance is thermally not stable at temperatures > 100 °C	-	BASF BPD ID A3.10_02 (2006) key study
	German Standard DIN 51007	Glutaraldehyde 50% aq. solution (ca. 0.3 % methanol)	Substance is thermally not stable at temperatures ≥ 110 °C	-	BASF SIK-No. 98/0231 (1998) key study
	-	-	-	The product is an aqueous solution thus the test does not need to be performed. For the tests on thermal stability see IUCLID Section 3.4.2.1.	-
Effects on content of the active substance and technical characteristics of the biocidal product	-	-	-	See studies mentioned under 'Storage stability test – accelerated storage'	BASF PGA 10 (2004)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
Reactivity towards container material	Experience in use	Glutaraldehyde 50% aq. solution	Material Compatibility: Yes/No Carbon Steel: No Stainless Steel types 304, 304L, 316 and 316L: Yes Iron: No Titanium: Yes Copper-Nickel Alloy: No Nickel: Yes Aluminium: No Copper: No Nickel-Chromium-Molybdenum Alloys: Yes Fiberglas-reinforced plastics: Yes PVC: Yes Polyethylene:Yes Baked Phenolics: Yes	Rubber linings can swell when in contact with BASF glutar-aldehyde products and should therefore not be used. The same is true for many other natural and synthetic rubber materials. Special care should be taken when choosing gasket materials. The use of incompatible materials may lead to product leakage or material failure. PTFE is recommended for all gaskets.	BPD ID A3.17_02 key study
	Annex A of ADR/ Class 8; IATA-DGR 3.8.2.4;	Glutardialdehyde 50% aq. solution	Carbon steel: No local corrosion rate > 240 µm/year	According to REACH and the Regulations for Transport of Dangerous	BASF 215.1153 TB01 (2015) key study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
	IMDG-Code, Class 8, 2.1.4.3; 49 CFR § 173; CLP-Regulation (EU) No. 1272/2008 and UN Recommendations on the Transport of Dangerous Goods;		Al 7075-T6: No local corrosion rate > 240 µm/year	Goods Protectol GA 50% (glutardialdehyd 50%) has to be classified as non-corrosive.	
Wettability	-	-	-	Since the biocidal product is liquid, the wettability does not need to be performed.	-
Suspensibility, spontaneity and dispersion stability	-	-	-	Since the biocidal product is not solid, none of these tests needs to be performed.	-
Wet sieve analysis and dry sieve test	-	-	-	Since the biocidal product is not solid, none of these tests needs to be performed.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	-	Since the biocidal product is an aqueous solution of glutaraldehyde, these tests do	-

Property	**Guideline and Method**	**Purity of the test substance % (w/w)**	**Results**	**Remarks/ Justification**	**Reference**
				not need to be performed.	
Disintegration time	-	-	-	Since the biocidal product is liquid, this test does not need to be performed.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	-	Since the biocidal product is liquid, these tests do not need to be performed.	-
Persistent foaming	-	-	-	The test has not been carried out since Protectol GA 50 is not surface active and of low viscosity. In addition, the biocidal product is not a spray application.	-
Flowability/Pourability/Dustability	-	-	-	Since the biocidal product is an aqueous solution of glutaraldehyde, these tests do not apply.	-
Burning rate — smoke generators	-	-	-	Since the biocidal product	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				is not a smoke generator, this test does not need to be performed.	
Burning completeness — smoke generators	-	-	-	Since the biocidal product is not a smoke generator, this test does not need to be performed.	-
Composition of smoke — smoke generators	-	-	-	Since the biocidal product is not a smoke generator, this test does not need to be performed.	-
Spraying pattern — aerosols	-	-	-	Since the biocidal product is not an aerosol, this test does not need to be performed. In addition, the biocidal product is not a spray application.	-
Physical compatibility	-	-	-	The biocidal product is not intended to be used with other	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				products including other biocidal products. Hence, no information is submitted about its compatibility with other products.	
Chemical compatibility	-	-	-	The biocidal product is not intended to be used with other products including other biocidal products. Hence, no information is submitted about its compatibility with other products.	-
Degree of dissolution and dilution stability	CIPAC MT 46.3/ GIFAP Monograph 17 (for accelerated storage stability studies); appearance (physical state, colour and odour), stability of the original test item	Glutaraldehyde 50.8% w/w aq. solution	Test substance is thermally stable at 40 °C ± 2 °C for 8 weeks.	The biocidal product is already a dilution. In addition, studies carried out with a 24% glutaraldehyde aqueous solution	BASF S15-04186 (2015) key study

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
	container, weight change of the test item container, content of active ingredient has been investigated following well-described guideline study			indicated its stability.	
Surface tension	OECD Guideline 115 (Surface Tension of Aqueous Solutions)	Glutaraldehyde 50% aq. solution	Surface tension *ca*. 69 mN/m at 20 °C The product is not surface active	-	BASF 04L00165 (2004) BPD ID A3.13_01 key study
Viscosity	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Viscosity (63-18)	Glutaraldehyde 50% aq. solution	Kinematic viscosity 12.75 mm^2/s (static) at 25 °C	-	BASF 4217-F(02) (1999) BPD ID A3.01.2_01 key study
	Measured with an Ubbelohde viscosimeter (RL2, Study performed under conditions comparable to GLP)	Glutaraldehyde 50% aq. solution	Viscosity 4.79 mm^2/s (static) at 40 °C	-	BASF 04L00165 (2004) BPD ID A3.13_01 supporting study

Conclusion on the physical, chemical and technical properties of the product

The physico-chemical properties of Protectol GA 50 have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
Explosives	OECD Guideline 113 92/69/EC, annex A.14	Glutaraldehyde 50% aq. solution	non-explosive	-	BASF SIK 04/2080 (2004) key study
	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Explodability (63-16)	Glutaraldehyde 50% aq. solution	non-explosive	-	BASF 4217-F(02) (1999) BPD ID A3.01.2_01 supporting study
	-	-	-	The substance is an organic substance with exothermic decomposition energy lower than 300J/g (250J/g)	BASF SIK-Nr. 15/2089 (2015) Justification for waiving
Flammable gases	-	-	-	Since the biocidal product is not a gas, this test does not need to be performed.	-
Flammable aerosols	-	-	-	Since the biocidal product is not an aerosol, this test does not need to be performed.	-
Oxidising gases	-	-	-	Since the biocidal product is not a gas, this test	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				does not need to be performed.	
Gases under pressure	-	-	-	Since the biocidal product is not a gas, this test does not need to be performed.	-
Flammable liquids	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Flammability (63-15)	Glutaraldehyde 50% aq. solution	No flash point was observed at temperatures up to 95 °C.	-	BASF 4217-F(02) (1999) key study
Flammable solids	-	-	-	Since the biocidal product is liquid, this test does not need to be performed.	-
Self-reactive substances and mixtures	-	-	-	There are no ingredients with explosive or self-reactive properties present in the product. Hence, the formulation is not self-reactive. The available data on self-reactive properties of the test substance do not meet the	BASF SIK-Nr. 15/2089 (2015) Justification for waiving

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				criteria for classification according to Regulation (EC) 1272/2008 and are therefore conclusive but not sufficient for classification: The exothermic decomposition energy is less than 300 J/g. Hence, the substance is not self-reactive.	
Pyrophoric liquids	-	-	-	The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	-
Pyrophoric solids	-	-	-	Test for pyrophoric properties of solid substances does need to be performed,	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
				because the biocidal product is liquid.	
Self-heating substances and mixtures	-	-	-	The study does not need to be conducted as the biocidal product is liquid with a water content of 50 %. A liquid doesn’t show self-heating behaviour if it is not absorbed on a large surface.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	-	The biocidal product contains water. Hence, an emission of flammable gases is not expected when the formulation comes in contact with water.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
Oxidising liquids	-	-	-	Glutaraldehyde has no chemical groups indicating oxidising properties. This statement agrees with the recommendations of appendix 6 in the Manual of Tests and criteria of the United Nations.	-
	Pesticide Assessment Guidelines, Subdivision D, "Series 63", Oxidizing/reducing Action (63-14)	Glutaraldehyde 50% aq. solution	No oxidising properties	-	BASF 4217-F(02) (1999) supporting study
Oxidising solids	-	-	-	Since the biocidal product is liquid, this test does not need to be performed.	-
Organic peroxides	-	-	-	Since the biocidal product contains no organic peroxide, the test does not need to be performed.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Remarks/ Justification	Reference
Corrosive to metals	Annex A of ADR/Class 8; IATA-DGR 3.8.2.4; IMDG-Code, Class 8, 2.1.4.3; 49 CFR § 173; CLP-Regulation (EU)1272/2008 and UN Recommendations on the Transport of Dangerous Goods;	Glutaraldehyde 50% aq. solution	Non-corrosive	-	BASF 215.1153 TB01 (2015) key study
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15 (Auto-Ignition Temperature (Liquids and Gases)	Glutaraldehyde 50% aq. solution	Auto-ignition temperature 395 °C at 1002-1006 hPa	-	BASF SIK 04/2080 (2004) key study
Relative self-ignition temperature for solids	-	-	-	Since the biocidal product is liquid, this test does not need to be performed.	-
Dust explosion hazard	-	-	-	Since the biocidal product is a liquid formulation this test does not need to be performed. Furthermore, upon evaporation of water from the biocidal product	-

Property	**Guideline and Method**	**Purity of the test substance % (w/w)**	**Results**	**Remarks/ Justification**	**Reference**
				no dust can be formed. The resulting solid is a glassy-solid and not a fine powder, thus dust formation is not expected.	

Conclusion on the physical hazards and respective characteristics of the product
The safety relevant physico-chemical properties of the biocidal product have been evaluated. Protectol GA 50 is non-hazardous provided for its appropriate use, storage and transportation.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Glutaraldehyde	Potentio-metric titration	Absolute amount of active substance glutaraldehyde in the titration vessel: 90.330 mg/3 Meas.	> 0.999	No interference	At 90.330mg: 99.4-100.0 At 180.401mg: 98.9 At 361.320mg: 101.3 At 721.601mg: 99.0-101.1	At 90.330mg: 99.6 At 180.401mg: 98.9 At 361.320mg: 101.3 At 721.60mg: 99.9	≤ 1.0		BASF A4.01_01 BASF 4217-F(01)

Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
		180.401 mg/1 Meas. 361.320 mg/1 Meas. 721.601 mg/3 Meas.							
Glutaraldehyde	HPLC-UV-MSD scan (365 nm)	0.0288 – 0.0767 mg/L (0.00000288-0.00000767 wt.%) 2 samples at 5 levels	R^2= 0.99999 y=0.00001 x-0.0002	No interference	99.5-100.2 (at LOQ 98.3-100.6)	99.9 (at LOQ 99.3)	0.03	LOQ (1.0%)	BASF A4.01_02 or BASF OA01323 (2005) key study
Glutaraldehyde in 50% aq. solution	HPLC/UV-Vis/ LC-MS (365 nm)	0.43–56.5 wt.% glutaraldehyde in an actual formulation sample 4 samples at 6 levels	R^2= 0.9999 b=6.4923e +003 m=3.926e +004	No interference	98.09 – 110.2 (LOQ recovery 100±5%)	-	≤ 1.4	LOQ (S/N=10) 0.02% wt. LOD (S/N=3) 0.01% wt.	Dow/BASF R150228 (2015) Key study
Impurity in Protectol GA50	Capillary GC	-	0.9995	No interference	107.5-110.5	108.8	1.1	LOD for detection of the impurity – see IUCLID Chapter 5	BASF BPD ID A4.01_03
Water	Karl Fischer titration	-	0.99986	No interference	97.76-100.16	98.9-99.9	0.2-1.2	LOQ 1.0 g/kg	BPD ID A4.01_03

Analytical methods for monitoring

See details given for the detection of the active substance in air and water.

Analytical methods for soil

The eCA has accepted the justification considering the method requirement as scientifically unjustified because persistence or accumulation of glutaraldehyde or its metabolites in soil is not expected (Justification in BASF A4.2a, see AR glutaraldehyde 2014).

Analytical methods for air

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Glutaraldehyde (active substance)	HPLC-UV (363 nm)	10-400 µg/m³ 6 samples at 4 levels	Range 10-400 µg/m^3, 6 samples at 4 levels, For range 10-25 µg/m^3 $y=12.693x+7.7087$ $R^2=0.9992$ For range 10-500 µg/m^3 $y=15.555x+15.798$ $r^2 = 1$	no interference	68 - 96	77 for the range of 20-400 µg/m³ 92 for the range of 10-20 µg/m³	2.6 for the range of 20-400 µg/m³ 2.7 for the range of 10-20 µg/m³	LOQ: 1.3 µg/m³ (for 120 l of air/2ml desorption/10µl injection)	BASF ESE/MA - Z 570 (2015) key study

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Glutaraldehyde (active substance)	GC/MS	0.048 µg/L, and 0.505 µg/L (for drinking water and surface water) 6 per concentration	0.01 µg/L – 5.05 µg/L $r^2 > 0.9994$ (drinking water) 0.01 µg/L – 5.25 µg/L $r^2 > 0.9991$ (surface water)	No interference m/z = 450, m/z = 470, m/z = 178 retention time 20.4 min.	Drinking water:			LOQ 0.05 µg/L LOD 0,015 µg/L	BASF 06L00277 (2007) key study or BASF A4.02c_01
					104 - 115 (0.048 µg/L)	109	4		
					93 - 99 (0.505 µg/L)	97	2		
					Surface water:				
					98 - 123 (0.048 µg/L)	111	10		
					101 - 107 (0.505 µg/L)	103	2		

Analytical methods for animal and human body fluids and tissues
It is technically impossible at the moment to analyse glutaraldehyde in animal tissues as glutaraldehyde will react with the biological material, followed by rapid metabolisation.

Analytical methods for monitoring of active substances and residues in food and feeding stuff

The biocidal product is not intended to be added to food and feedstuffs or be used in facilities during food processing. Furthermore, due to evaporation, photodegradation and rapid reactions with proteins, only trace amounts would be expected even in the case of accident. In addition, it is technically impossible at the moment to analyse glutaraldehyde in animal tissues as the substance will react with the biological material, followed by rapid metabolisation.

Conclusion on the methods for detection and identification of the product

The active substance and the product are identical, therefore the methods for analysis of the active substance can be applied to the analysis of the product.

A new analytical method (HPLC/UV-Vis, LC-MS) has been provided for the determination of glutaraldehyde in glutaraldehyde biocide products (Dow/BASF study, 2015). The LOQ of this method is 0.02% wt. and the LOD 0.01% wt.

A new analytical method (HLPC/UV, BASF/Dow 2015) has been provided for the determination of glutaraldehyde in air.

The eCA has accepted the justification considering a method requirement for the detection of glutaraldehyde in soil as scientifically unjustified because persistence or accumulation of the substance or its metabolites in soil is not expected.

Furthermore, it is technically impossible at the moment to analyse glutaraldehyde in animal tissues as glutaraldehyde reacts with any biological material by rapid metabolic process.

The biocidal product is not intended to be added to food or feedstuffs or be used in facilities during food processing. Therefore, no method is required for these matrices.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Biocidal product Protectol® GA 50 is used as a preservative and slimicide in product types 6, 11 and 12.
The product demonstrated efficacy against a variety of Gram-positive and Gram-negative bacteria as well as yeasts and fungi.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The products are used to control microorganisms including Gram-positive and Gram-negative bacteria, yeasts and fungi as well as biofilm producing bacteria.

For the application in PT6, bacteria, yeasts and fungi should be controlled. In PT11 applications biocorrosion inducing sulphate reducing bacteria and bacteria causing microbially induced deterioration of auxiliaries should be controlled.
For PT12 applications, Protectol® GA 50 is used as a slimicide. Thus, biofilm forming bacteria and fungi should be controlled.

<u>Examples of typical microbes to be controlled:</u>

Gram-negative bacteria: *Pseudomonas aeruginosa, Alcaligenis faecalis, Klebsiella pneumoniae, Escherichia coli, Enterobacter aerogenes*

Gram-positive bacteria: *Staphylococcus aureus, Bacillus subtilis*

Sulfate reducing bacteria (associated with microbial induced corrosion): *Desulfovibrio alaskensis G20, Desulfovibrio vulgaris*

Fungi: *Candida albicans (yeasts)*

Aspergillus brasiliensis

<u>The following uses of Protectol® GA 50 and objects to be protected are intended as follows:</u>

As preservative for manufactured products during storage (PT06), Protectol® GA 50 is intended for the use in (i) preservation of detergents and cleaning fluids and any water based raw materials thereof (ii) preservation of wax and polymer emulsions and raw materials thereof, (iii) preservation of water based products used in the paper industry, (iv) preservation of paints/inks and raw materials thereof and (v) preservation of auxiliaries used in leather and textile industry.

As a preservative for liquid-cooling and processing systems (PT11) Protectol® GA 50 is used for vi) preservation of hydrotesting fluids in oil field applications (prevent corrosion on pipelines) and vii) preservation of production and injection water in oilfield applications such as seawater injection system (prevent corrosion in equipment upstream of injection wellhead), produced water re-injection (prevent corrosion in water treatment units before produced water is re-injected), produced water disposal (prevent corrosion in hydrocyclones, gas floatation unit and filters), gas/crude production and transmission pipelines and systems (prevent corrosion in transmission lines or systems where low amounts of water that could be present), crude and gas storage wells and systems (prevent corrosion in storage systems), pipeline pigging and scraping operation (prevent corrosion in pipelines by water in the pipelines during the cleaning process).

As a slimicide (PT12), Protectol® GA 50 is effective against biofilm and is used as viii) slimicide for hydrotesting fluids in oilfield applications (prevent biofilm formation on pipelines), ix) slimicide for production and injection water in oilfield applications (prevent biofilm formation in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations), x) slimicide in paper industry, wet-end (slime prevention) and xi) slimicide for paper industry, de-inking (slime prevention).

2.2.5.3 Effects on target organisms, including unacceptable suffering

Glutaraldehyde kills actively growing microbial cells if the concentration and time period are suitable. The microorganisms are killed faster at higher concentrations, higher temperatures and higher pH. Because glutaraldehyde reacts easily with primary amines of amino acids, activity is influenced by soilents.

For PT6, 11 and 12 no product type specific guidance for the efficacy testing of biocidal products was available when the application was prepared and submitted. There was only a guidance giving general principles: "Transitional Guidance on Efficacy Assessment for Preservatives" which was published in May 2014 after a public consultation. The performed tests have been selected to provide convincing data to confirm the efficacy of Protectol® GA for various applications.
For PT6 and PT12 papermill uses, the matrix used for the efficacy test is the corresponding soiling, therefore no separate tests were done. The testing was performed on relevant representatives of potential formulations because the variety of the potentially to be preserved formulations doesn't allow individual testing.

According to BPC-opinion, efficacy tests have to be performed in comparison to non-preserved samples. These tests have been performed (please refer to confidential part).
For field trials of PT11/12 paper mill applications please refer to the comment/justification in the confidential part. Corresponding semi-field trials are available in oilfield water for PT11 applications.

The submitted studies are summarised in table under 2.2.5.5 (Efficacy data). Microbiological tests to prove adequacy of preservation should be undertaken by the user of Protectol® GA 50 in order to determine the effective dose of the preservative for the specific matrix/location/system. Responsibility of sufficient storage stability is with the producer of the respective product preserved with Protectol GA 50. If needed, the manufacturer of the preservative product shall be consulted.

2.2.5.4 Mode of action, including time delay

Glutaraldehyde readily kills actively growing cells, while killing of viruses and bacterial spores requires longer exposure times and/or higher glutaraldehyde concentrations. The mode of action of glutaraldehyde is thought to differ according to the target organism. Bacterial cells are killed by cross-linking with primary amines located in the cell wall of the microorganisms, sealing the outer layer of the bacterial cell surface and inactivating cell enzymes. In fungi, inhibition of germination, spore swelling, mycelial growth and sporulation has been demonstrated.

The kinetics of the cross-linking mechanism is influenced by pH, glutaraldehyde concentration and temperature.

Kill rate of glutaraldehyde is rapid and ranges from 1 minute contact time for bacteria up to several hours for bacterial spores.

There is no time delay. The killing rate is faster at alkaline conditions, high temperatures and at higher glutaraldehyde concentrations. Under acidic conditions the free amino groups react more with H^+ ions (eq.1) and are less susceptible to react with glutaraldehyde (eq.2).

pH <6: $R\text{-}NH_2 + H^+ \Rightarrow RNH_3^+$ eq.1
pH >7: $R\text{-}NH_2 + GA \Rightarrow$ cross-linking eq.2

Further details on the mode of actions (study data) were already provided for the active substance approval.

2.2.5.5 Efficacy data

PT06 APPLICATIONS

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	PT06, Preservation of organic solutes in water (liquid formulations used for cleaning (hand dish washing, laundry detergent, hard surface cleaner) (Use #1)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Alcaligenis faecalis, Klebsiella pneumoniae* Gram-positive bacteria: *Bacillus subtilis* Initial cell numbers in test system: 2.02 x 10^6 cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Bacteria inoculum (mixed inoculum) Test item: organic solutes (liquid cleaner formulation) with 20, 50 and 100 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicate that the mixed bacterial inoculum exhibited a clear growth in the absence of Protectol® GA 50 over the time of the experiment.	Protectol® GA 50 was efficacious in the preservation of organic solutes against bacteria. 100 mg/kg Protectol® GA 50 (50 mg/kg a.s.) reduced the bacteria efficiently already by day 7 and until day 28.	BASF Grenzach GmbH BIO16-28 (2016a)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide, fungicide	PT06, preservation of organic solutes in water (liquid formulations used for cleaning (hand dish washing, laundry detergent, hard surface cleaner) (Use #1)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa* *Escherichia coli* Gram-positive bacteria: *Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - 10^6 cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Test item: organic solutes (liquid cleaner formulation) with 125, 250, 500 and 1000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 2, 7, 14 and 28. Results of the unpreserved control indicated that the Gram-positive bacteria *Staphylococcus aureus* was reduced over the time of the experiment and the yeast *Candida albicans* maintained at its initial cell number level only until day 7. The germ numbers of the fungi *Aspergillus brasiliensis* decreased	Protectol® GA 50 was efficacious in the preservation of organic solutes against bacteria. 125 mg/kg Protectol® GA 50 (62.5 mg/kg a.s.) efficiently reduced bacteria (Gram-negative and Gram-positive) and yeast. For the fungi *Aspergillus brasiliensis* preservation with 250 mg/kg product (125 mg/kg a.s.) was sufficient. At an appropriate concentration (125 mg/L against bacteria and yeast or 250 mg/L against bacteria, yeast and fungi) the product was efficacious from day 7 throughout day 28. The reduction of *Staphylococcus aureus* and *Candida albicans* in the unpreserved control suggests that these species might	Labor L+S AG BP11/056_c1 (2016a)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					and the Gram-negative bacteria *Escherichia coli* and *Pseudomonas aeruginosa* exhibited growth in the absence of Protectol® GA 50 over the time of the experiment.	not be representative species of those deteriorating such a product used in the test. After consultation with cMSs it was decided that the claim against yeasts and fungi cannot be accepted because no growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.	
Bactericide, fungicide	PT06, preservation of polymer emulsion (surface treatment or cleaning products)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa* Gram-positive bacteria:	Preservation challenge test under aerobic conditions (in-use test, Tier 2)	Single inoculum Test item: car polish as polymer emulsion with 50, 180, 500 and 2000 mg/kg Protectol® GA 50 No replicates	Protectol® GA 50 was efficacious in the preservation of polymer emulsion against bacteria, yeast and fungi.	Labor L+S AG EX15/028 (2016b)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
	(Use #2)		*Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - 10^6 cfu/g	(internal method)	Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that the Gram-positive bacteria *Staphylococcus aureus* was reduced over the time of the experiment and the yeast *Candida albicans* maintained at its initial cell number level only until day 14. In the absence of Protectol® GA 50 the Gram-negative bacteria *Pseudomonas aeruginosa* also decreased during the experiment but more slightly. The viable cell numbers of the fungi *Aspergillus brasiliensis* maintained at the level of inoculation in the	50 mg/kg Protectol GA 50 (25 mg/kg a.s.) efficiently reduced bacteria (Gram - and Gram-positive) and yeast. For the fungi *Aspergillus brasiliensis* preservation with 180 mg/kg product (90 mg/kg a.s.) was sufficient. At an appropriate concentration (50 mg/L against bacteria and yeast or 180 mg/L against bacteria, yeast and fungi) the product was efficacious from day 7 throughout day 28. The reduction of *Staphylococcus aureus* and *Candida albicans* in the unpreserved control suggests that these species might not be reprentative species of those deteriorating such a product used in the test.	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					absence of Protectol® GA 50 over the time of the experiment.	After consultation with cMSs it was decided that none of the claims on target organisms (against bacteria, yeasts and fungi) can be accepted because no growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.	
Bactericide, fungicide	PT06, preservation of inorganic dispersion as used in paper, paint and plastic industry, $CaCO_3$ slurry (Use #3)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenis faecalis* Gram-positive bacteria:	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Mixed inoculum for *Klebsiella pneumoniae, Alcaligenes faecalis, Bacillus subtilis* Test item: $CaCO_3$ slurry with 5, 20, 50, 180 and 2000 mg/kg Protectol® GA 50	Protectol® GA 50 was efficacious in the preservation of inorganic dispersion against bacteria and fungi. Protectol® GA 50 at 20 mg/L (10 mg/L a.s.) efficiently reduced bacteria (single and	BAV Institut GmbH EXBIO16_003 (2016)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Staphylococcus aureus *Bacillus subtilis* Fungi: *Candida albicans* (yeast) *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - 10^6 cfu/g		No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that the Gram-positive bacteria *Staphylococcus aureus* was reduced over the time of the experiment. *Pseudomonas aeruginosa* exhibited growth and the viable cell counts of other species maintaind at the level of inoculation in the absence of Protectol® GA 50 over the time of the experiment.	mixed inoculum) and yeast. For the fungi *Aspergillus brasiliensis* preservation with 180 mg/L product (90 mg/kg a.s.) was sufficiently active from day 14. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated. The slurries furnished with 2000 mg/L Protectol GA 50 (1000 mg/kg g a.s.) reduced bacteria, yeast and fungi efficiently already by day 7. The reduction of *Staphylococcus aureus* in the unpreserved control suggests that this species might not	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						be a reprentative species of those deteriorating such a product used in the test.	
Bactericide, fungicide	PT06, preservation of inorganic dispersion as used in paper, paint and plastic industry, $CaCO_3$ slurry (Use #3)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa* Gram-positive bacteria: *Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - 10^6 cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Test item: $CaCO_3$ slurry with 180, 300, 400, 1000 and 2000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control showed that the viable count maintained at least at the level of the inoculation except for *Pseudomonas aeruginosa* and *Staphylococcus aureus* at day 7 and *Candida albicans* from day 14	Protectol® GA 50 was efficacious in the preservation of inorganic dispersion against bacteria and fungi. 180 mg/kg Protectol® GA 50 (90 mg/kg a.s.) efficiently reduced bacteria (Gram-negative and Gram-positive) and yeast. For the fungi *Aspergillus brasiliensis* preservation with 400 mg/kg product (200 mg/kg a.s.) was moderate and sufficient at 1000 mg/kg product (500 mg/kg a.s.). However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it	Labor L+S AG EX15/023 (2016c)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					on. *Aspergillus brasiliensis* decreased slightly in the absence of Protectol® GA 50 during the experiment.	is considered that efficacy against filamentous fungi was not demonstrated. At an appropriate concentration (180 mg/kg against bacteria and yeast or 400 mg/kg against bacteria, yeast and fungi) the product was efficacious from day 7 throughout day 28.	
Bactericide	PT06, preservation of inorganic dispersion as used in paper, paint and plastic industry, Kaolin slurry (Use #3)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria *Pseudomonas aeruginosa* (single inoculum) Gram-negative bacteria *Alcaligenis faecalis, Klebsiella pneumoniae,* Gram-positive bacteria *Bacillus subtilis* (mixed inoculum)	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Bacteria inoculum (single and mixed inoculum) Test item: inorganic dispersion (Kaolin) with 10, 100, 250, 500 and 1000 mg/kg Protectol GA 50 No replicates The test formulations were inoculated at time point zero and after 14 d Incubation of inoculated test products: 20 - 25°C for 28 days	Protectol® GA 50 was efficacious in the preservation of inorganic dispersions against bacteria. 100 mg/kg Protectol® GA 50 (50 mg/kg a.s.) reduced the bacteria efficiently already by day 7, even after re-inoculation, and until day 28.	BASF Grenzach GmbH BIO16-018b (2016b)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Initial cell numbers in test system: 10^5 - 10^6 cfu/g		Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control showed that the mixed bacterial inoculum as well as the *Pseudomonas aeruginosa* inoculum exhibited a clear growth in the absence of Protectol GA 50 over the time of the experiment.		
Bactericide, fungicide	PT06, Preservation of organic polymer dispersion as used in pulp and paper industry. (Use #3)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis* Gram-positive bacteria: *Staphylococcus, aureus, Bacillus subtilis* Fungi:	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum for yeast, fungi, *Pseudomonas aeruginosa* and *Staphylococcus, aureus,* mixed inoculum for *Klebsiella pneumoniae, Alcaligenes faecalis* and *Bacillus subtilis* Test item: organic polymer dispersion (cellulose) with 10, 100, 200, 500, 1000 and 2000 mg/kg Protectol® GA 50 No replicates	Protectol® GA 50 was efficacious in the preservation of polymer dispersions against bacteria, yeast and fungi. Addition of 100 mg/kg Protectol® GA 50 was sufficient to effectively preserve against the inoculated bacteria mix and *Staphylococcus aureus*. At a concentration of 200 mg/kg Protectol® GA 50 the bacteria	BASF Grenzach GmbH BIO16-049 (2016c)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Candida albicans (yeast) *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - 10^6 cfu/g		Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that all tested germs exhibited a clear growth or maintaind at least at the level of the inoculation (yeast *Candida albicans*) in the absence of Protectol® GA 50 during the experiment.	*Pseudomonas aeruginosa* and at 500 mg/kg Protectol® GA 50 the yeast were reduced sufficiently. At 1000 mg/kg biocidal product the cellulose dispersion was also protected against fungis. At the appropriate concentrations (200 mg/kg against bacteria, 500 mg/kg bacteria and yeast or 1000 mg/kg against bacteria, yeast and fungi) the product was efficacious from day 7 throughout day 28. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide, yeasticide	PT06, Preservation of organic solutes in water used in wet end paper processes and wall paper paste (Use #3)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis* Gram-positive bacteria: *Bacillus subtilis* Yeast: *Candida albicans* Initial cell numbers in test system: 10^5 - 10^6 cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum for yeast, mixed inoculum for bacteria Test item: Starch solution in water with 100, 200, 300, 500 and 2000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 6, 14, 21 and 28. Results of the unpreserved control indicated that the mixed bacterial inoculum as well as yeast *Candida albicans* exhibited a clear growth in the absence of Protectol GA 50.	Protectol® GA 50 was efficacious in the preservation of organic solutes (starch solution) against bacteria and yeast. Protectol® GA 50 at 200 mg/kg (100 mg/kg a.s.) was sufficiently effective against the mixed bacterial inoculum. Addition of 500 mg/kg product (250 mg/kg a.s.) was required to efficiently reduce yeast. At the active concentrations, the product was effective already by day 6.	BASF Grenzach GmbH BIO16-026a (2016d)
Bactericide, fungicide	PT06, preservation of organic dispersions	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa*	Preservation challenge test under aerobic	Single inoculum Test item: pigment slurry with 180, 400,	Protectol® GA 50 was efficacious in the preservation of organic	Labor L+S AG EX15/024 (2016d)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
	used as pigment or filler in paper, paint and plastic industry, here pigment slurry (Use #4)		Gram-positive bacteria: *Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - $<10^6$ cfu/g	conditions (in-use test, Tier 2) (internal method)	800 and 2000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicate that the germ numbers of the fungi and the yeast remained unchanged over 28 d. The Gram-negative bacteria *Pseudomonas aeruginosa* exhibited significant growth in the non-preserved formulation. Germ numbers of Gram-positive bacteria *Staphylococcus aureus* decreased during the experiment.	dispersion against bacteria and fungi. 180 mg/kg Protectol GA 50 (90 mg/kg a.s.) efficiently reduced bacteria and yeast. For the fungi *Aspergillus brasiliensis* preservation with 400 mg/kg product (200 mg/kg a.s.) was sufficiently active after 14 days. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated. At 800 mg/kg the product was efficacious from day 7 throughout day 28 for all tested germs.	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						The reduction of *Staphylococcus aureus* in the unpreserved control suggests that this species might not be a reprentative species of those deteriorating such a product used in the test.	
Bactericide, yeasticide	PT06, preservation of organic dispersions used as pigment or filler in paper, paint and plastic industry, here pigment slurry (Use #4)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa* Gram-positive bacteria: *Staphylococcus aureus* Yeast: *Candida albicans* Initial cell numbers in test system: 10^5 - <10^6 cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Test item: pigment slurry with 20, 60 and 100 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that the Gram-negative *Pseudomonas aeruginosa* exhibited a clear growth (except	Protectol® GA 50 was efficacious in the preservation of organic dispersion against bacteria and yeast. 20 mg/kg Protectol® GA 50 (10 mg/kg a.s.) efficiently reduced *S. aureus* from day 7 on and yeast starting on day 21. Full efficacy for yeast starting on day 7 was observed at 60 mg/kg Protectol GA 50. At 100 mg/kg product (50 mg/kg a.s.) the product was efficacious from day 7 throughout day 28 for all tested bacteria strains and yeast. The reduction of	Labor L+S AG BIO16_002 (2016e)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					for day 21) and viable numbers of Gram-positive bacteria *Staphylococcus aureus* decreased in the absence of Protectol® GA 50 during the experiment. In the absence of Protectol® GA 50 *Candida albicans* showed a reduction to the 10^4 level (days 14 and 21) and further down to the 10^3 level on the last quarter of the experiment.	*Staphylococcus aureus* and *Candida albicans* in the unpreserved control suggests that these species might not be reprentative species of those deteriorating such a product used in the test.	
Bactericide, fungicide	PT06, preservation of water based formulations with multiple ingredients (Use #4)	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis* Gram-positive bacteria: *Staphylococcus aureus* *Bacillus subtilis* Fungi:	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Mixed inoculum for *Klebsiella pneumoniae, Alcaligenes faecalis, Bacillus subtilis* Test item: water based wall paint with 5, 20, 50, 180, 500 and 2000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test	Protectol® GA 50 was efficacious in the preservation of water based formulations with different ingredients against bacteria and fungi. Protectol® GA 50 at 5 mg/kg (2.5 mg/kg a.s.) efficiently reduced bacteria (single inoculum) and yeast. The fungi and mixed bacterial inoculum preservation with 50	BASF Grenzach GmbH BIO16-004 (2016e)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Candida albicans (yeast,) *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - <10^6 cfu/g, except for the mixed bacteria inoculum *B. subtilis, A. faecalis* and *K. pneumoniae*) for which the total initial cell number was 1.52*10^4		products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that all tested germs exhibited a clear growth or maintaind at least at the level of the inoculation in the absence of Protectol® GA 50 during the experiment, except for Gram-positive bacteria *Staphylococcus aureus,* which decreased to < 100 cfu/g from 14 days on, and *Candida albicans*, the cell count of which was at the level of 10^4 at day 7.	mg/kg product (25 mg/kg a.s.) was sufficiently active. At the active concentrations (5 mg/kg against single inoculum bacteria and yeast or 50 mg/kg against bacteria, yeast and fungi), the product was effective already by day 7. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated. The reduction of *Staphylococcus aureus* in the unpreserved control suggest that this species might not be a reprentative species of those deteriorating such a	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						product used in the test.	
Bactericide, fungicide	PT06, Preservation of polymer dispersion as used in production for sealants, glues and adhesive formulations Use #3, 4	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Escherichia coli, Pseudomonas aeruginosa* Gram-positive bacteria: *Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - $<10^6$ cfu/g	Preservation challenge test under aerobic conditions (in-use test, Tier 2) (internal method)	Single inoculum Test item: aqueous polymer dispersion with 125 and 500 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14 and 28. No activity against any of the five test strains was observed in the unpreserved control. Instead, the total viable counts increased over the 28 d of the test compared to the inocululation.	Protectol® GA 50 was efficacious in the preservation of aqueous polymer dispersion against bacteria and fungi. Protectol® GA 50 at 500 mg/kg (250 mg/kg a.s.) was capable to control the growth of the bacteria and the yeast from day 7. The fungi was controlled at the same concentration from day 14. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.	Labor L+S AG EX13/006A (2016f)
Bactericide, fungicide	PT06, Preservation of liquid	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria:	Preservation challenge test under	Single inoculum	Protectol® GA 50 was efficacious in the preservation of organic	Labor L+S AG

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
	formulations used in leather, textile or paper industry (Use #5)		*Pseudomonas aeruginosa* Gram-positive bacteria: *Staphylococcus aureus* Fungi: *Candida albicans* (yeast), *Aspergillus brasiliensis* Initial cell numbers in test system: 10^5 - $<10^6$ cfu/g	aerobic conditions (in-use test, Tier 2) (internal method)	Test item: re-fatting agent (organic emulsion) with 50, 180, 400 and 2000 mg/kg Protectol® GA 50 No replicates Incubation of inoculated test products: 20 - 25°C for 28 days Assessment: Reduction in total viable counts ($\log_{10}$) compared to time 0 was recorded on day 7, 14, 21 and 28. Results of the unpreserved control indicated that *Staphylococcus aureus* was reduced to the level of 10^2 over the time of the experiment. The germ numbers of *Candida albicans* and *Aspergillus brasiliensis* exhibited a not significant reduction until day 14, while the number of the surviving germs of *Pseudomonas aeruginosa* was	emulsions against bacteria and fungi. Protectol® GA 50 at 50 mg/kg (25 mg/kg a.s.) efficiently reduced bacteria and yeast already by day 7. For the fungi *Aspergillus brasiliensis* preservation with 400 mg/kg product (200 mg/kg a.s.) was sufficiently active efficiently already by day 7. The reduction of *Staphylococcus aureus, Candida albicans* and *Aspergillus brasiliensis* in the unpreserved control suggests that these species might not be reprentative species of those deteriorating such a product used in the test. After consultation with cMSs it was decided that the claim against yeasts cannot be accepted because no	EX15/015 (2016g)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					increased or maintained at least at the level of inoculation except for day 7.	growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.	

PT11 (PT12) APPLICATIONS

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	PT11, 12 Preservation of and slimicide in hydrotesting fluids as well as production and injection water in oil field applications (Use #6, 7, 8, 9)	Protectol® GA 50 (50% glutaraldehyde)	Sulfate reducing bacteria: *Desulfovibrio alaskensis G20, Desulfovibrio vulgaris*	Planktonic test method: NACE TM0194-2004 Biofilm test method: ASTM E2799	<u>Planktonic method</u> Initial density of bacteria: 2.2 x 10^7 cfu/mL (*Desulfovibrio alaskensis G20), 1* x 10^7 cfu/mL (*Desulfovibrio vulgaris)* Test item concentration: 1.56 – 250 mg/kg as Protectol® GA 50 (50% glutaraldehyde), blank (bacteria without biocide) and control (only media without bacteria and biocide) Incubation of test samples: 25°C for 4 and 24 h in 96-well plates (anaerobic cabinet) Replicates: 3 Assessment: The effective	Protectol® GA 50 was efficacious in the inhibition of sulfate reducing bacteria under test conditions of the given standards, NACE TM0194-2004 and ASTM E2799 <u>Planktonic results</u> 96 well plates: After 4 and 24 h effective at 25 mg/kg for both bacteria Spot plating: After 4 h: effective at 25 mg/kg for both bacteria After 24 h: effective at 25 mg/kg (for *Desulfovibrio vulgaris*) and 15.6 mg/kg (for *Desulfovibrio alaskensis G20)* <u>Biofilm results</u> After 4 h: effective at 312.5 mg/kg	BiSN 2016-119 (2016)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					concentration was recorded as the lowest concentration to prevent bacterial growth (> 3 log reduction compared with the untreated blank). Growth was assessed on both agar plates (spot plating analysis) and in 96 well plates (serial dilutions). Biofilm method Initial density of bacteria: 3.25 x 10^7 cfu/mL (*Desulfovibrio alaskensis G20)* Test item concentration: 15.6 – 2500 mg/kg as Protectol® GA 50 (50% glutaraldehyde), blank (bacteria without biocide) and control (only media without bacteria and biocide)	After 24 h: effective at 20 mg/kg	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Incubation of test samples: 25°C for 4 and 24 h in 96 well plates (anaerobic cabinet) Replicates: 3 Assessment: The MIC was recorded as the lowest concentration to prevent bacterial growth (> 3 log reduction compared with the untreated blank)		
Bactericide	PT11 Preservation of oilfield reservoir water (Use #6, 7, 8, 9)	Acticide GDA24 (24 % glutaraldehyde)	Microorganisms isolated from oilfield water (anaerobic, salt loving microbes with fermentative metabolism)	Challenge test under anaerobic conditions (in-use test, Tier 2) (internal method)	Test system: sterilized reservoir water (corresponding to re-injected production water) from a German on-shore oilfield supplemented 350 mg/kg with poly-carbohydrate rheology modifier polymer (Salt content: approximately 190 g/L Ions: Na^+, Ca^{2+}, Mg^{2+}, Fe^{2+}, Cl^-, pH: 6.1-6.8)	The unpreserved sample (0 mg/kg) showed a degradation of the carbohydrate polymer in presence of the inoculated microbes. The carbohydrate polymer as a rheology modifier was preserved against anaerobic microbes at a concentration of 10 and 100 mg/kg Protectol® GA 50	BASF SE supporting study

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Inoculum: 50 mL sterilized reservoir water with 2.5 mL microbial inoculum No replicates Test substance concentration: 0, 1, 10, 100 mg/kg Incubation temperature: 30°C (anaerobic conditions (nitrogen)) Soiling: 0.5 g/L yeast extract Samples were collected at day 0, 4, 14, 16 and 86 for measurements of viscosity and at day 4 and 11 for ATP measurements Sub-culturing to investigate irreversible damage: Aliquot of 300 µL was taken after 24 h contact time out and transferred to a test-tubes containing 6 mL		

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					350 mg/kg poly-carbohydrate, 0.5 g/L yeast extract in sterile reservoir water followed by incubation at 30°C for 3 days.		

PT12 APPLICATIONS

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	PT12, slimicide in paper industry Use #10, 11	Protectol® GA 50 (50% glutaraldehyde)	Gram-negative bacteria: *Pseudomonas aeruginosa, Enterobacter aerogenes* Initial cell numbers in test system: $2.3*10^6$ $-1.0*10^7$ cfu/g	ASTM 1839-13	Test system: acidic (pH 5.0-5.5) and alkaline (pH 8.0-8.5) pulp sterilized prior to the test No replicates Test item concentration: 1, 10, 50, 100, 150 and 500 mg/kg Protectol® GA 50 30 mg/kg value was added to the experiment for better differentiation of the active concentrations to *P. aeruginosa* in acid pulp. 1 mg/kg was not tested with *E. aerogenes* as this concentration proved to be not effective for *P. aeruginosa.* Incubation of inoculated pulp slurry: 36°C for 3 h Assessment: Reduction in total viable counts (log10) compared to time 0 (threshold ≥ 99% (≥ 2	Protectol® GA 50 was efficacious in the preservation of paper pulp against bacteria. Protectol® GA 50 was active against bacterial slime at a concentration of 10 mg/kg at alkaline conditions and of 30 mg/kg at acidic conditions. According to ASTM 1839-13 the control should either remain unchanged or increase over time. In this test the reduction in the control after 3h was 85.8 and 83.7 % for *E. aerogenes* in acidic and alkaline conditions respectively and for *P. aeruginosa* 43.9 and 17.5 % in acidic and alkaline conditions respectively. After consultation with cMSs it was decided that this study is not accepted as valid due to lack of	Hygiene Nord GmbH EX15/025 (2016)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					$\log_{10}$ steps)). The unpreserved control included in the test.	growth in the untreated control.	
Fungicide	PT12, slimicide in paper industry Use #10, 11	[Tradename] same product as Protectol GA 50 (50% glutaraldehyde)	authentic fungal colonies in paper mill	ASTM 1839-96 (reapproved 2002)			See 3.6 Confidential annex
Bactericide, Fungicide	PT12, slimicide in paper industry Use #10, 11	[Tradename] same product as Protectol GA 50 (50% glutaraldehyde)	Authentic population of natural microorganisms growing in the warm recirculating process water system of board machine	Demonstration of biocidal efficacy in real use conditions (field study)			See 3.6 Confidential annex

Although efficacy studies should always contain at least three replicates the presented tests without replicates can be accepted because the requirement for replicates was not explicitly mentioned in the transistional guidance that was applicable at the time of submission of the dossier. The presented tests all prove highly significant effects with CFU log reductions >>1. For the majority of the studies dose responses were recorded with at least one dose being not sufficiently active. The following effects were observed by testing Protectol® GA 50 in preservation of use specific products:

Use #1 – Preservation of detergents and cleaning fluids and raw materials thereof (PT06)

For the use of Protectol® GA 50 as preservative in **detergents and cleaning fluids** and raw materials thereof Protectol® GA 50 efficacy was demonstrated in Tier 2 challenge tests. In these tests, organic solutes were used as representative for liquid formulations used for cleaning (hand dish washing, laundry detergent, hard surface cleaner, etc.).
The product was sufficiently protected against Gram-negative bacteria (*Pseudomonas aeruginosa, Alcaligenis faecalis, Klebsiella pneumoniae, Escherichia coli),* Gram-positive bacteria (*Bacillus subtilis*, *Staphylococcus aureus)* and fungi *(Aspergillus brasiliensis)* and *yeast (Candida albicans)* .
Protectol® GA 50 at concentrations of 100 mg/kg and 125 mg/kg were required to control bacteria and yeasts. Fungi were controlled at a concentration of 250 mg/kg Protectol® GA 50. After consultation with cMSs it was decided that the claim against yeasts cannot be accepted because no growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.

Use #2 – Preservation of wax and polymer emulsions and raw materials thereof (PT06)

To test the activity of Protectol® GA 50 as a preservative for **water-based polymer emulsions** (e.g. but not limited to polishes, car polishes, waxes, etc.), a challenge test was performed in car polish using Gram-negative bacteria (*Pseudomonas aeruginosa),* Gram-positive bacteria (*Staphylococcus aureus),* as well as the fungi *(Candida albicans* and *Aspergillus brasiliensis).*
Protectol® GA 50 at a concentration of 50 mg/kg was sufficient to control bacteria and yeast. To reduce fungi, 180 mg/kg product is required. After consultation with cMSs it was decided that none of the claims on target organisms (against bacteria, yeasts and fungi) can be accepted because no growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated.

Use #3 – Preservation of water based products used in the paper industry (PT06)

In use #3, preservation of chemicals (including but not limited to inorganic slurries, organic dispersions, polymers, pigments, cellulose, starch, glues, pulp etc.) used in the production of paper is addressed.

Preservation of **inorganic dispersions** as used as raw material (filler) in paper, paint and plastic industry were tested with different representative products such as $CaCO_3$ slurry or Kaolin slurry in preservation challenge tests.

There are two different studies in $CaCO_3$ slurries treated with Protectol® GA 50. In one of them Protectol® GA 50 was effective against bacteria (Gram-negative, represented as *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenis faecalis* as well as *Staphylococcus aureus* and *Bacillus subtilis* representing Gram-positive bacteria) and yeast (*Candida albicans)* at a concentration of 20 mg/kg*.* Overall, at least 180 mg/kg product is required to control fungi (*Aspergillus brasiliensis).* Based on the other study on slightly different $CaCO_3$ slurry composition for example 400 mg/kg may be needed to control fungi (*Aspergillus brasiliensis)*. Therefore, appropriate required concentrations need to be defined from the final product (slurry) manufacturer.
In Kaolin slurries, bacteria (*Pseudomonas aeruginosa, Alcaligenis faecalis, Klebsiella pneumoniae, Bacillus subtilis)* can be controlled at a Protectol® GA 50 concentration of 100 mg/kg.

Organic dispersions (cellulose) as used in pulp and paper industry were effectively preserved against bacteria (Gram-negative: *Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis* and Gram-positive: *Staphylococcus aureus, Bacillus subtilis*) at a Protectol® GA 50 concentration of 200 mg/kg and against yeast (*Candida albicans)* at a concentration of 500 mg/kg. Against fungi (*Aspergillus brasiliensis*) Protectol® GA 50 was active at a concentration of 1000 mg/kg.

Starch solution (organic solutes in water), representative for liquid formulations used in wet end paper processes and/or wall paper paste are sufficiently preserved at Protectol® GA 50 concentrations of 200 mg/kg and 500 mg/kg against bacteria (*Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis, Bacillus subtilis)* and yeast (*Candida albicans)*, respectively.

Preservation of **aqueous polymer dispersion** as used in paper production for **sealants, glues and adhesive formulations** are also protected against Gram-negative bacteria (*Escherichia coli, Pseudomonas aeruginosa),* Gram-positive bacteria (*Staphylococcus aureus),* yeast (*Candida albicans)* and fungi (*Aspergillus brasiliensis*) by the addition of Protectol® GA 50. A concentration of 500 mg/kg is required to control respective test organisms.

After consultation with cMSs it was concluded that as the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), efficacy against filamentous fungi was not demonstrated for Use #3.

To demonstrate the efficacy of Protectol® GA 50 for preservation of **pigment dispersions** used in paper industry the two challenge tests in pigment slurry (see use #4) are applied.

Efficacy of Protectol® GA 50 was also demonstrated in **organic emulsions** used in paper industry. Similar products are used in leather and textile industry. Thus, please refer to use #5.

Use #4 – Preservation of paints and raw materials thereof (PT06)

In use #4, preservation of paints and raw materials for the production of paints, plastic and glues such as (but not limited to) pigments, polymer and pigment dispersions, inorganic slurries used as fillers etc. are covered.

Organic dispersions (pigment slurry) as used as pigment or filler in paper, paint and plastic industry Protectol® GA 50 is able to control bacteria (Gram-negative: *Pseudomonas aeruginosa* and Gram-positive: *Staphylococcus aureus*), yeast (*Candida albicans)* and fungi (*Aspergillus brasiliensis*).
Based on two challenge preservation studies, the overall efficacious concentration of Protectol® GA 50 in pigment slurry was observed at 100 mg/kg for bacteria and yeast. To control also fungi, a concentration of 400 mg/kg is required.

These tests are also used to demonstrate the efficacy of Protectol® GA 50 for preservation of **pigment dispersions** used in **paper industry** (use #3) as well as in **plastic and textile industry** (use #5).

To demonstrate the efficacy of Protectol® GA 50 in **water based formulations with multiple ingredients**, a challenge test in **water based wall paint** was performed. Test organisms included Gram-negative bacteria *(Pseudomonas aeruginosa, Klebsiella pneumoniae, Alcaligenes faecalis),* Gram-positive bacteria *(Staphylococcus aureus, Bacillus subtilis)* and fungi *(Candida albicans, Aspergillus brasiliensis)*. The product was sufficiently protected against all tested organisms at a Protectol® GA 50 concentration of 50 mg/kg.

After consultation with cMSs it was concluded that as the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), efficacy against filamentous fungi was not demonstrated for Use #4.

Preservation of **aqueous polymer dispersions** as used in paints are protected against Gram-negative and Gram-positive bacteria, yeast and fungi using Protectol® GA 50. Similar products are used in the production of glues. Thus, please refer to use #3.
<u>Use #5 – Preservation of auxiliaries used in leather and textile industry (PT06)</u>

Preservation of **organic emulsions used in leather and textile industry** was tested in a re-fatting agent in a preservation challenge test.
Protectol® GA 50 concentrations of 50 mg/kg were effective against bacteria (Gram-negative bacteria: *Pseudomonas aeruginosa* and Gram-positive bacteria: *Staphylococcus aureus*) and yeast (*Candida albicans).* To control fungi (*Aspergillus brasiliensis)* 400 mg/kg product is required*.* After consultation with cMSs it was decided that the claim against yeasts cannot be accepted because no growth in the untreated control was demonstrated in this study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated. In addition, the growth in the untreated control of the Gram-positive bacteria was not shown in the submitted study. Despite, it was concluded with cMSs that efficacy proof on Gram-negative bacteria is sufficient in this case because both types of bacteria are not required in the transitional guidance (May 2014) and based on expert judgement it is considered that Gram-negative bacteria are the main target of PT6 products. The applicant shall generate additional data in accordance with the new guidance at the time of the application for renewal.

To demonstrate the efficacy of Protectol® GA 50 for preservation of **pigment dispersions** used in **and textile industry** two challenge tests in pigment slurry (see use #4) are applied.

Use #6 – Preservation of hydrotesting fluids in oil field applications (PT11)

Use #7 – Preservation of production and injection water in oilfield applications (PT11)

Biocorrosion is recognized as a costly problem in oil production operations. Sulfate reducing bacteria (SRB) are commonly associated with biocorrosion. Therefore, the activity of Protectol® GA 50 to control SRB was studied against *Desulfovibrio alaskensis G20* and *Desulfovibrio vulgaris* for PT11.

The activity of Protectol® GA 50 to control planktonic SRB was studied and demonstrated against *Desulfovibrio alaskensis G20* and *Desulfovibrio vulgaris* after 4 hours and 24 hours contact time. The effective concentration was 25 mg/kg Protectol® GA 50 in all cases – see BiSN Study.

In a test with real oilfield injection/reservoir water and unspecified anaerobe microbes from an oilfield the effective Protectol® GA 50 concentration was 10 mg/kg after 4, 11, 16 and 86 days – see "Report Rheology Modifier".

Use #8 – Slimicide for hydrotesting fluids in oilfield applications (PT12)

Use #9 – Slimicide for production and injection water in oilfield applications (PT12)

Biocorrosion is recognized as a costly problem in oil production operations. Sulfate reducing bacteria (SRB) are commonly associated with biocorrosion. Therefore, the activity of Protectol® GA 50 to control sessile SRB was studied against *Desulfovibrio alaskensis G20* for PT12.

The activity of Protectol® GA 50 to control sessile SRB was studied and demonstrated against *Desulfovibrio vulgaris* after 4 hours and 24 hours contact time. The effective concentration was 312.5 mg/kg Protectol® GA 50 after 4 hours and 20 mg/kg after 24 hours. – see **BiSN Study.**

Note: It may be that the effective concentration for planktonic SRB is in the range of 20 mg/kg as well. 20 mg/kg was not tested in the planktonic test, only 15.6 mg/kg which proved to be not sufficient. In real-life applications soiling varies from oilfield to oilfield. It is recommended on the label to run preliminary tests to define the required glutaraldehyde amount and the amount of glutaraldehyde degradation during use. This is especially relevant for hydrotesting.

Use #10 – Slimicide for paper industry, wet end (PT12)

Use #11 – Slimicide for paper industry, de-inking (PT12)

Papermaking is a process very much prone to microbial spoilage. Formation of biofilms causes a bunch of processing problems ranging from odor formation, quality problems, functional loss of paper making additives and breaking of the paper web resulting in costly production stops. The activity of Protectol GA 50 to control microbes was demonstrated against *Pseudomonas aeruginosa* ATCC 15442 and *Enterobacter aerogenes* ATCC 13048.

The activity of Protectol GA 50 to control biofilms in paper making processes was demonstrated (ASTM 1839-13) against *Pseudomonas aeruginosa* ATCC 15442 and *Enterobacter aerogenes* ATCC 13048 after 3 hours contact time. The effective concentration was 30 mg/kg at acidic (pH 5.0-5.5) conditions and 10 mg/kg at alkaline (pH 8.0-8.5) conditions However, after consultation with cMSs it was decided that this study is not accepted as valid due to lack of growth in the untreated control.

In a field test in a paper mill (see study in confidential part) the concentrations necessary to obtain complete bacterial slime control were 79 mg/kg and 92 mg/kg Protectol GA 50. Fungicidal efficacy was sufficient according to ASTM 1839 with an authentic fungi population from a paper mill clear filtrate and a biofilm sample. Activity was proven for 24 hours contact time at acidic conditions (pH 5.4) and for 4 hours contact time at neutral conditions (pH 7.1) for 200 mg/kg Protectol GA 50 (see study in confidential part). After consultation with cMSs it was decided that the claim against fungi cannot be accepted because the initial cell counts were too low compared with the used standard (for pH 7.1) and growth in the untreated control could not be reliably shown in the submitted study (data at t0 not available for pH 5.4).

Data to demonstrate general bactericidal and fungicidal efficacy, as well as additional efficacy studies were already provided for the active substance approval.

Conclusion on the efficacy of the product

Protectol® GA 50 containing the active substance glutaraldehyde (50%) is intended to be used as a preservative for products during storage (PT06), for liquid cooling and processing systems (PT11) and as a slimicide (PT12) in oilfield-related uses or in paper production.

For PT06 applications the Protectol® GA 50 effect was evaluated in various products representative for the intended uses. Thus, the efficacy was demonstrated against Gram-positive and Gram-negative bacteria and fungi for 28 days. After consultation with cMSs it was decided that for PT6 it is not important to include the contact time in the SPC.

Effective concentrations are various, depending on the product and the target organism to be controlled. Overall, the minimal effective Protectol® GA 50 concentrations were in the range of 20 to 500 mg/kg. Higher concentrations in this range are required to control fungi. For use in detergents/cleaning fluids and auxillaries in leather and textile industry the claim against yeasts could not be accepted because growth in the untreated control was not achieved. For use in detergents/cleaning fluids the claim against fungi could not be accepted because growth in the untreated control was not achieved. Use in water-based polymer emulsions (waxes, polishes) could not be accepted at all because growth in the untreated control was not achieved for any target species in the submitted efficacy study. Furthermore, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated for any of the uses in PT6.

PT11:
Protectol® GA 50 was tested for its activity to prevent biofilm development in oilfield related uses. Biofilm is commonly associated with the growth of sulfate reducing bacteria (SRB). Planktonic SRB were controlled at a Protectol® GA 50 concentration of 25 mg/kg (4 h and 24 h exposure).

PT12:
As a slimicide for paper industry, Protectol® GA 50 was tested according to laboratory ASTM standard test. At concentrations of ≥ 30 mg/kg efficacy was shown against bacteria in 3 h contact time. However, this study was not accepted as valid due to lack

of growth in the untreated control. Against authentic fungi populations, the product was active at a concentration of 200 mg/kg in 24 h contact time at pH 5.4. However, the claim against fungi could not be accepted because the initial cell counts were too low compared with the used standard (pH 7.1) and growth in the untreated control could not be reliably shown (data at t0 not available for pH 5.4). In a field trial, the biocidal product was active against biofilm/slime formation at concentrations of 79 - 92 mg/kg. With regards to the efficacious concentration in oilfield related uses, the results of tests performed for PT11 uses can be used. Planktonic SRB were controlled at a Protectol® GA 50 concentration of 25 mg/kg (4 h and 24 h exposure). Biofilm SRB required concentrations of 312.5 mg/kg (4 h exposure) or of 20 mg/kg (24 h exposure).

2.2.5.6 Occurrence of resistance and resistance management

In the area of medical instrument (esp. endoscopes) disinfection in hospitals, various reports have been published on findings with atypical mycobacteria strains showing increased tolerance to glutaraldehyde and other aldehydes such as o-phthalaldehyde (OPA).

The mechanism of the resistance has been studied and it appeared that the cell surface of the resistant mycobacteria strains has been modified. Especially protein structures on the cell wall surface are preferred targets for the glutaraldehyde molecule. The special membrane composition of mycobacteria is discussed as the reason for their generally lower susceptibility to glutaraldehyde in comparison to other microorganisms. Mutants of mycobacteria with defects in porin expression and thus reduced level of reactive proteins on the cell surface might result in missing targets for glutaraldehyde (Svetlikova et al., 2009; McDonnell & Burke, 2011).

Findings on the occurrence of increased glutaraldehyde tolerance with other bacteria than Mycobacteria are seldomly reported. Findings of Vikram et al. (2015) in an in-vitro biofilm model (1-5 days old biofilms) with *Pseudomonas* species show that the glutaraldehyde tolerance of the bacteria increased with the age of the biofilm. The finding that surface-attached microorganisms and biofilms are less susceptible to biocides compared to planktonic microorganisms is a phenomenon well known for many diverse biocides and not specific for glutaraldehyde (Otter et al., 2015).

Various measures are available for resistance management for avoiding problems with glutaraldehyde-containing disinfectants:

- proper use of disinfectants and cleaning of the instruments prior to disinfection (Deva et al., 1998, Griffiths et al., 1997; Tschudin-Sutter et al., 2011)
- microbiological investigations in hospitals to check the effectiveness of cleaning & disinfection measures (Duarte et al., 2009) and monitor the occurrence of strains with increased biocide tolerance
- use combinations of glutaraldehyde with other biocides in disinfecting products to provide products with a broader antimicrobial spectrum (many products on the market are combinations of glutaraldehyde with other biocides such as glyoxal and quaternary ammonium compounds)
- alternate treatment regimens (e.g. change type of disinfectants regularly)
- use of biocides with different mode of action such as per acetic acid or other oxidizing biocides instead of aldehydes in cases of aldehyde-tolerant atypical Mycobacteria (deOliveira Lorena et al., 2010; Fisher et al., 2012).

In industrial applications (in-can preservation, paper and oil industries), resistance to glutaraldehyde is not a significant problem. Vikram et al. (2014) investigated the effect of the special composition of produced water typical in the oil and gas exploration on the efficacy of glutaraldehyde and other biocides (Vikram et al., 2014). The authors found that the special conditions in such water samples (high salt concentrations, presence of additional excipients typical for produced water such as oxygen scavengers, corrosion and scale inhibitors etc.) have a negative impact on glutaraldehyde activity. The reasons for that are not fully explored but the reduced sensitivity might be caused by special gene induction and metabolism of bacteria under the high salt conditions.

2.2.5.7 Known limitations

No undesirable or unintended side effects were observed.
Bacteria in biofilms are less susceptible to glutaraldehyde since bacteria form agglomerates. Thus, glutaraldehyde is hindered in targeting individual microorganisms and higher concentration of glutaraldehyde or a longer contact time is needed.

2.2.5.8 Evaluation of the label claims

The product Protectol® GA 50 was tested in representative reference products for the different intended uses claimed. The tested organisms were also in line with organisms to be controlled. In addition, the claimed concentrations reflect the efficacious concentrations tested in respective reference products (please also refer to the following table). The table was amended by the eCA to show the effective concentration covering both bacteria and fungi in each use. These concentrations are given in % to facilitate the comparison of the effective concentrations with the risk assessment parts of the PAR. Note that usually higher concentrations are required against fungi than bacteria to achieve efficacy. However, the CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated for any of uses in PT6.

PT	Uses/ objects to be protected/ labeled claim	Effective concentrations tested	Claimed concentration [mg/kg]
06	Preservatives for detergents (e.g. laundry softeners, liquid detergent, raw materials thereof)- **Use #1** After consultation with cMSs it was decided that the claim against yeasts and fungi cannot be accepted because no growth in the untreated control was demonstrated in this study. *)	Bacteria: 100 mg/kg [Fungi:] 125 mg/kg (yeast) [and 250 mg/kg] *max. of which corresponding to 0.025%*	100 - 1958
06	Preservation of wax and polymer emulsions and raw materials thereof (e.g. car polish) - **Use #2** After consultation with cMSs it was decided that use in water-based polymer emulsions (waxes, polishes) cannot be accepted at all because growth in the	[Bacteria: 50 mg/kg Fungi: 50 mg/kg (yeast) and 180 mg/kg] *max. of which corresponding to 0.018%*	50 - 1958

PT	Uses/ objects to be protected/ labeled claim	Effective concentrations tested	Claimed concentration [mg/kg]
	untreated control was not achieved for any target species in the submitted efficacy study. *)		
06	Preservation of water based products used in the paper industry- **Use #3** *(in inorganic particle dispersions - $CaCO_3$ slurries) **	Bacteria: 20 mg/kg [Fungi:] 20 mg/kg (yeast) [and 180 or 400 mg/kg] for different slurry compositions *max. of which corresponding to 0.040%*	20 - 1958
06	Preservation of water based products used in the paper industry - **Use #3** *(in inorganic particle dispersions – kaolin slurries)*	Bacteria: 100 mg/kg *corresponding to 0.010%*	
06	Preservation of water based products used in the paper industry - **Use #3** *(in organic dispersions – cellulose) *)*	Bacteria: 200 mg/kg [Fungi:] 500 mg/kg (yeast) [and 1000 mg/kg] *max. of which corresponding to 0.10%*	
06	Preservation of water based products used in the paper industry - **Use #3** *(in organic solutes – Starch)*	Bacteria: 200 mg/kg Yeast: 500 mg/kg *max. of which corresponding to 0.050%*	
06	Preservation of water based products used in the paper industry - **Use #3** *(in aqueous polymer dispersion) *)*	Bacteria: 500 mg/kg [Fungi:] 500 mg/kg (incl. yeast*)* *max. of which corresponding to 0.050%*	
06	Preservation of water based products used in the paper industry - **Use #3** *(In pigment dispersions used in paper) *)*	Bacteria: 100 mg/kg [Fungi:] 100 mg/kg (yeast) [and 400 mg/kg] *max. of which corresponding to 0.040%*	
06	Preservation of paints and raw materials thereof - **Use #4** *(wall paint) *)*	Bacteria: 50 mg/kg [Fungi:] 5 mg/kg (yeast) [and 50 mg/kg] *max. of which corresponding to 0.005%*	50-1958
06	Preservation of paints and raw materials thereof - **Use #4** *(in pigment dispersions) *)*	Bacteria: 100 mg/kg [Fungi:] 100 mg/kg (yeast) [and 400 mg/kg] *max. of which corresponding to 0.040%*	
06	Preservation of paints and raw materials thereof - **Use #4** (polymer dispersions used for paints) *)	Bacteria: 500 mg/kg [Fungi:] 500 mg/kg (incl. yeast) *max. of which corresponding to 0.050%*	

PT	Uses/ objects to be protected/ labeled claim	Effective concentrations tested	Claimed concentration [mg/kg]
06	Preservation of auxiliaries used in leather and textile - **use #5** *(pigment dispersions used in plastic, textile etc.) *)*	Bacteria: 100 mg/kg [Fungi:] 100 mg/kg (yeast) [and 400 mg/kg] *max. of which corresponding to 0.040%*	50 - 1958
06	Preservation of auxiliaries used in leather and textile - **use #5** *(auxiliaries used in leather and textile industry)* After consultation with cMSs it was decided that the claim against yeasts cannot be accepted because no growth in the untreated control was demonstrated in this study. *)	Bacteria: 50 mg/kg [Fungi: 50 mg/kg (yeast) and 400 mg/kg] *max. of which corresponding to 0.040%*	
11	Preservation of hydrotesting fluids in oil field applications - **use #6**	Sulfate reducing bacteria Planktonic: 25 mg/kg Biofilm: 312.5 mg/kg (after 4 h) or 20 mg/kg (after 24 h) *max. of which corresponding to 0.031%*	25 - 4000
11	Preservation of production and injection water in oilfield applications - **use #7**	Sulfate reducing bacteria Planktonic: 25 mg/kg Biofilm: 312.5 mg/kg (after 4 h) or 20 mg/kg (after 24 h) *max. of which corresponding to 0.031%*	25 - 1500
12	Slimicide for hydrotesting fluids in oilfield applications- **use #8**	Sulfate reducing bacteria Planktonic: 25 mg/kg Biofilm: 312.5 mg/kg (after 4 h) or 20 mg/kg (after 24 h) *max. of which corresponding to 0.031%*	25 - 4000
12	Slimicide for production and injection water in oilfield applications - **use #9**	Sulfate reducing bacteria Planktonic: 25 mg/kg Biofilm: 312.5 mg/kg (after 4 h) or 20 mg/kg (after 24 h) *max. of which corresponding to 0.031%*	25 – 1500
12	Slimicide for paper industry, wet end - **use #10** After consultation with cMSs it was decided that the claim against fungi cannot be accepted because the initial	[Bacteria: 30 mg/kg (acidic, pH 5.0-5.5), 10 mg/kg (alkaline, pH 8.0-8.5) Fungi: 200 mg/kg]	10/30 - 400

PT	Uses/ objects to be protected/ labeled claim	Effective concentrations tested	Claimed concentration [mg/kg]
	cell counts were too low compared with the used standard (for pH 7.1) and growth in the untreated control could not be reliably shown in the submitted study (data at t0 not available for pH 5.4). In addition, the bacterial study giving the results of 10/30 mg/L was considered invalid due to failure in the growth of the untreated control.	Bacterial biofilm/slime: ~ 79 - 92 mg/L *max. of which corresponding to 0.020%*	
12	Slimicide for paper industry, de-inking - **use #11** After consultation with cMSs it was decided that the claim against fungi cannot be accepted because the initial cell counts were too low compared with the used standard (for pH 7.1) and growth in the untreated control could not be reliably shown in the submitted study (data at t0 not available for pH 5.4). In addition, the bacterial study giving the results of 10/30 mg/L was considered invalid due to failure in the growth of the untreated control.	[Bacteria: 30 mg/kg (acidic, pH 5.0-5.5), 10 mg/kg (alkaline, pH 8.0-8.5) Fungi: 200 mg/kg] Bacterial biofilm/slime: ~ 79 - 92 mg/L *max. of which corresponding to 0.020%*	10/30 – 250

*) The CFU method for filamentous fungi is not acceptable according to The Transitional Guidance on Efficacy Assessment of Preservatives (May 2014), and therefore, it is considered that efficacy against filamentous fungi was not demonstrated for any of uses in PT6.

Microbiological tests to prove adequacy of preservation should be undertaken by the user of Protectol® GA 50 in order to determine the effective dose of the preservative for the specific matrix/location/system. Responsibility of sufficient storage stability is with the producer of the respective product preserved with Protectol® GA 50. If needed, the manufacturer of the preservative product shall be consulted.

Users can also prepare pre-dilutions of Protectol® GA 50 (e.g. to 25% Glutaraldehyde by 1:1 dilution of Protectol®GA 50 with water). Pre-dilutions are then added to the final product in an automated manner. Re-calculation of the dilution volume applied is required in order to reach appropriate glutaraldehyde concentration for final preservation.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The biocidal product is not intended to be used with other products including other biocidal products.

2.2.6 Risk assessment for human health

As the biocidal product (b.p.) Protectol® GA 50 is identical to the active substance as well as to the representative biocidal product in the Competent Authority (CA) report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, the toxicological properties are summarised in the CA report and briefly discussed below. The classification is in accordance to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP).

Glutaraldehyde is acutely toxic by the oral route and very toxic by inhalation. Classification as Acute Tox. 3; H301 Toxic if swallowed and Acute Tox. 2; H330 Fatal if inhaled are therefore warranted. The effects are considered to result mainly from corrosivity as glutaraldehyde also causes severe irritation to skin and eyes. Glutaraldehyde is therefore classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde in concentrations > 5% has to be labelled with EUH071, Corrosive to respiratory tract.

Skin sensitisation has been clearly demonstrated and human data indicates that glutaraldehyde must be considered as a respiratory sensitizer as well (Skin Sens. 1A; H317 May cause an allergic skin reaction and Resp. Sens. 1; H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled).

Considering the available data and mixture rules laid down in Regulation (EC) No, 1272/2008 the classification of glutaraldehyde is also applicable to the b.p. Protectol® GA 50 (50% solution (w/w) of glutaraldehyde in water). In addition, Protectol® GA 50 has to be classified as Eye Damage Cat 1 but not additionally labelled as labelling for Skin Corr 1B already covers serious eye damage.

None of the studies available for glutaraldehyde can be considered to give sufficient information for establishing a value for dermal absorption. It was concluded in the glutaraldehyde AR that most of the glutaraldehyde will react immediately in the skin leaving little free glutaraldehyde for absorption and it was agreed that a conservative value of 10% for dermal absorption should be used unless further information is provided.

2.2.6.1 Assessment of effects on Human Health

In this section, relevant information for hazard identification and classification of Protectol® GA 50 are provided. For additional data it is referred to the CA report on glutaraldehyde (RMS Finland, 2014) as Protectol® GA 50 is identical to the active substance as well as to the example product in the CA report.

Skin corrosion and irritation
(*cf.* IUCLID Section 8.1)

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Similar to OECD 404 GLP RL1	Rabbit, New Zealand White Female 5 (4% 3 animals, 15% 1 animal, 24% 1 animal)	Glutaraldehyde, 4, 15 and 24% aqueous solution, 4 h (additionally: 3 min / 1 h), With rinsing Semiocclusive	Erythema (24/48/72h after 4h patch removal): 4%: 2.0, 3.3, 3.3 (no corrosion) 15%: 3.0, 4.0, 4.0 24%: 4.0, n.a. [9],, n.a. Edema (24/48/72h after 4h patch removal): 4%: 3.0, 3.0, 3.0 15%: 4.0, 4.0, 4.0 24%: 4.0, n.a., n.a. 4%: No corrosion was observed. 15%: corrosion was observed at 4 h exposure 24%: corrosion was observed at 1 and 4 h exposure Not reversible	/	Dow, BASF 110192 (2012) **Key study**
Similar to OECD 404 No GLP RL2	Rabbit, White Vienna 3 males and 1 female	Glutaraldehyde, Solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water, 4 h, With rinsing	Erythema: 2.0, 2.0, n.a. Edema (mean 24-48 h): 2.5, 1.75, n. a. Not reversible	Not performed according to OECD 404: The observation period was only 8 days, the scaling system	BASF 80/265 (1994)

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[9] n.a. not assessed

Summary table of animal studies on skin corrosion /irritation

Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
		Occlusive	necrosis, erythema and edema were present at day 8 (necrosis confirmed by gross pathology)	was different and observations were not performed at 72h, However, the results are in line with 110192 (2012).	
Similar to OECD 404 No GLP RL2	Rabbit, White Vienna 2 females	Glutaraldehyde, Solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water, 3 min / 1 h, With rinsing Occlusive	3 min exposure: minor effects, 1 h exposure: slight erythema and edema, not reversible, with scaling		BASF 80/265 (1994)
Similar to OECD 404 No GLP RL3	Rabbit, White Vienna 2 animals	Regulan GT/M, Solution of 25% glutaraldehyde, 8% methanol, 67% water, 1 min, 5 min, 15 min, 20 h (dorsal skin and ear), With rinsing Occlusive	Slight erythema already present at 1 min exposure, accompanied by slight necrosis (5 minutes and higher exposure duration) and slight / severe edema (20 h) Not reversible There was marked scaling on the ear at 8 days.	Not performed according to OECD 404. pH 3 due to low content of sulfuric acid. Supportive study to 110192 (2012).	BASF XX/117 (1970)
Similar to OECD 404 No GLP RL3	Rabbit, White Vienna 2 animals	Regulan GT/M, Solution of 25% glutaraldehyde, 8% methanol, 67% water, 1 min, 5 min, 15 min, 20 h (dorsal skin and ear), With rinsing Occlusive	Questionable erythema already present at 1 min exposure, accompanied by slight necrosis (20 h) and slight / marked edema (20 h)	Not performed according to OECD 404. pH 3 due to low content of sulfuric acid The test substance was post-treated	BASF XX/118 (1970)

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
			Not reversible There was marked scaling on the ear at 8 days.	with charcoal and by filtration. Supportive study to 110192 (2012).	

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Protectol GA 50 is to be classified concerning Skin corrosion.
Justification for the value/conclusion	Several *in vivo* studies and human data show that active substance glutaraldehyde is corrosive to the skin. Since the generic concentration limit for classification for skin corrosion is 5%, the product Protectol GA 50 is classified as Skin Corr. 1B, H314.
Classification of the product according to CLP	Protectol GA 50 is to be classified Skin Corr. 1B; H314 "Causes severe skin burns and eye damage" according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	IUCLID, Section 8.1.
Justification	No dermal irritation study with Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available dermal irritation studies conducted with different aqueous glutaraldehyde solutions classification of the biocidal product Protectol® GA 50 with respect to skin corrosion (Skin Corr. 1B; H314) is warranted in accordance with Regulation (EC) No. 1272/2008. For details on the studies please refer to the endpoint study records.

Eye irritation

(*cf*. IUCLID Section 8.2)

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Fed. Reg. 38, No. 187, § 1500.42, p. 27019 of Sept. 27, 1973 No GLP RL1	Rabbit, White Vienna, Males and females 3/sex/group	Glutaraldehyde, Solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water, 0.1 mL, eyes not rinsed	Cornea: 1.2, 2, 3; Opacity, scattered/ diffuse (24 h) to nearly complete (8 d), affected area: 75 to 100% Iris: 1, 1, 1; Folds above normal, swelling and circum-corneal injection Conjunctival redness: 2, 2, 2.5 Chemosis: 2, 2.2, 2.8 Redness, swelling with partial eversion of the eyelids, swelling with half-closed lids (seen until day 8), eye discharge Not reversible	Observation period 8 days	BASF 80/265 (1994) **Key study**
Similar to OECD 405 No GLP RL3	Rabbit, White Vienna 2 animals	Regulan GT/M, Solution of 25% glutaraldehyde, 8% methanol, 67% water, 0.05 mL, eyes not rinsed	After 1 h: corrosion of the mucosa with redness (score: 1), marked chemosis (score: 2) and corneal opacity (score: 2). After 24 h: corrosion of the ocular bulb and mucosa as well as severe chemosis (score 3-4) and corneal opacity (score: 2) After 8 days: the findings were similar as above and in addition, staphyloma and suppuration also were seen. Not reversible	Not performed according to OECD 405. Observation period 8 days. pH 3 due to low content of sulfuric acid. Supportive study to 80/265 (1994).	BASF XX/117 (1970)

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Similar to OECD 405 No GLP RL3	Rabbit, White Vienna 2 animals	Regulan GT/M, Solution of 25% glutaraldehyde, 8% methanol, 67% water, 0.05 mL, eyes not rinsed	After 1 h: corrosion of the mucosa with redness (score: 1), marked chemosis (score: 2) and corneal opacity (score: 1). After 24 h: corrosion of the ocular bulb and mucosa as well as severe chemosis (score 3-4) and corneal opacity (score: 2) After 8 days: the findings were similar as above and in addition, in addition bulging of the cornea with suppuration and alopecia around the eye. Not reversible	Not performed according to OECD 405. Observation period 8 days. pH 3 due to low content of sulfuric acid The test substance was post-treated with charcoal and by filtration. Supportive study to 80/265 (1994).	BASF XX/118 (1970)

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Protectol GA 50 is severely irritating to the eyes
Justification for the value/conclusion	Several *in vivo* studies show that active substance glutaraldehyde is severely irritating to the eyes. Since the generic concentration limit for classification for eye irritation is 3%, the product Protectol GA 50 is classified as Eye Dam. 1, H318.
Classification of the product according to CLP	Protectol GA 50 is to be classified as Eye Dam. 1; H318 "Causes serious eye damage" according to Regulation (EC) 1272/2008. According to CLP Guideline the b.p. is classified as Eye Dam. Cat 1, but not additionally labelled, because labelling for Skin Corr. 1B already covers serious eye damage.

Data waiving	
Information requirement	IUCLID, section 8.2. Study scientifically unjustified.
Justification	No eye irritation study with Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available eye irritation studies conducted with different aqueous glutaraldehyde solutions classification of the biocidal product Protectol® GA 50 with respect to eye irritation (Eye Dam. 1; H318) is warranted in accordance with Regulation (EC) No. 1272/2008. For details on the studies please refer to the endpoint study records.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Protectol GA 50 is to be labelled as corrosive to respiratory tract.
Justification for the conclusion	Data and the resulting classification for respiratory tract irritation are derived from the CA report on active substance glutaraldehyde (RMS Finland, 2014). Since the specific concentration limit for classification as STOT SE 3; H335 is 0.5%≤ C <5%), Protectol GA 50 is not to be classified concerning respiratory tract irritation. However, it should be labelled with EUH071.
Classification of the product according to CLP	Protectol GA 50 is not to be classified as STOT SE 3; H335 "May cause respiratory irritation" because specific concentration limits have been derived according to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) (STOT SE3; H335 0.5%≤ C <5%). However, as active substance glutardehyde is concerned as peripheral sensory irritant and this is supported by human data, Protectol GA 50 is to be labelled with EUH071 "Corrosive to the respiratory tract".

Data waiving	
Information requirement	Not an information requirement for biocidal products according to "Guidance on the BRP: Volume III. Part A.
Justification	No data regarding respiratory tract irritation of Protectol® GA 50 is available. However, as the b.p. Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data for respiratory irritation is available in the CA report (RMS Finland, 2014). Glutaraldehyde was described as a moderately potent peripheral sensory irritant. Together with human data, the results indicate that glutaraldehyde in concentrations > 5% should be labelled as EUH071 corrosive to respiratory tract according to Regulation (EC) No. 1272/2008.

Skin sensitization
(*cf.* IUCLID Section 8.3)

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Open epicutaneous test with guinea pig No guideline No GLP, RL2	Guinea pig, Pirbright White, Females, 10 (treatment), 3 (control)	Relugan GT, 25% glutaraldehyde, 67% water, 8% methanol, Induction: 10 applications in 2 weeks, Challenge: single application for 12 h, epicutaneous, open	10/10 Induction: thick bloody scabs (10/10) Challenge: distinct spotted erythema (10/10) Negative control: no reactions	/	BASF XXIII/115 **Key study**
LLNA No guideline No GLP, RL2	Mouse, Balb/c, Females 6/group	Glutaraldehyde dissolved in DAE433 (40% (v/v) N,N-dimethylacetamide, 30% acetone, 30% ethanol) Induction 1% on 3 consecutive days, Challenge (12 days after the last induction): 0.5% on 3 consecutive days	Significant increase in ear weight, Significant increase in lymph node weight Upon challenge: marked up-regulation of the IL-4 gene expression and an increased synthesis of interleukin IL-4	/	Ulrich et al. (1998)

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Protectol GA 50 is to be classified concerning Skin sensitisation.
Justification for the value/conclusion	All available studies (including human data) indicate that active substance glutaraldehyde is a potential skin sensitiser. Since the generic concentration limit for classification for skin sensitisation is 0.1%, the product Protectol GA 50 is classified as Skin Sens. 1A, H317.
Classification of the product according to CLP	Protectol GA 50 is to be classified as Skin Sens. 1A; H317 “May cause an allergic skin reaction” according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	IUCLID, section 8.3.
Justification	No skin sensitisation study with the biocidal product Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available skin sensitisation studies the biocidal product Protectol® GA 50 is classified with respect to skin sensitisation (Skin Sens. 1A; H317). For details on the studies please refer to the endpoint study records.

Respiratory sensitization (ADS)
(*cf.* IUCLID Section 8.4)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Protectol GA 50 is to be classified concerning respiratory sensitisation.
Justification for the value/conclusion	Data and the resulting classification for respiratory tract sensitisation are taken from the Assessment Report (RMS Finland, 2014). Since the active substance glutaraldehyde is classified for respiratory sensitisation based on the human data and the generic concentration limit for respiratory sensitisation for liquid substances is 1%, the biocidal product Protectol GA 50 is classified as Resp Sens. 1, H334.
Classification of the product according to CLP	Protectol GA 50 is to be classified as Resp. Sens. 1; H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled" according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	IUCLIC, section 8.4.
Justification	The respiratory sensitisation data reported in the CA report on active substance glutaraldehyde (Finland, 2014) have been used to assess the respiratory sensitisation potential of biocidal product Protectol® GA 50. The potential for respiratory sensitisation has not been directly demonstrated but based on the overall evidence on skin sensitisation and human data showing asthma in relation to glutaraldehyde exposure, the evidence is sufficient for classification for respiratory sensitization, Resp Sens. 1; H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled", according to Regulation (EC) No. 1272/2008. For details on the studies please refer to the CA report on glutaraldehyde (RMS Finland, 2014).

Acute toxicity
Acute toxicity by oral route (cf. IUCLID Section 8.5.1)

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Similar to OECD 401 No GLP RL1	Rat Sprague-Dawley Males and females 5 / sex / group	Glutaraldehyde, Solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water: 215, 316, 464 and 1470 mg/kg bw (test substance). Gavage 14-day post exposure period	All treated animals showed symptoms indicative of general toxicity, e.g. dysphonia, apathy, piloerection and trembling.	LD50 ♂ 158 mg GA/kg bw LD50 ♀ 143 mg GA/kg bw LD50 ♂ + ♀ 151 mg GA/kg bw Respective values for 50 % test substance: 316, 285, 301 mg/kg bw	**Spontaneously dying animals:** - Acute congestion; the stomach of these animals was dilated and the wall of the glandular stomach was thickened - In forestomach and glandular stomach, there were leathery bloody ulcerations, purulent abscesses and purulent fibrinous coatings - The mucosa of the small intestines partly appeared reddened and the intestinal contents were tinged with blood **Survivors:** no abnormalities	BASF 80/265 (1994) **Key study**

Similar to OECD 401 No GLP RL2	Rat Sprague-Dawley Males and females 10 / sex / group	Regulan GT/M, Solution of 25% glutaraldehyde, 8% methanol, 67% water 200, 400, 500, 640, 800 and 1600 mg/kg bw. 14-day post exposure period	Treated animals showed signs indicative of general toxicity, e.g. calmness, quietness and unkept fur.	LD50 ♂ / ♀ 132.5 mg GA/kg bw Respective value for 25 % test substance: 530 mg/kg bw	The pH was 3 (due to low content of sulfuric acid). High concentration of methanol (8%) compared to glutardehyde (25%). **Spontaneously dying animals:** Serous smeared snouts in several cases; in almost all animals that died, erosive and inflammatory lesions of the gastro-intestinal tract (thickening of the glandular stomach with edema and spotted bleeding, and /or distention of the stomach due to fluid content), muscular cyanosis, stenosis. **Survivors**: some cases of lesions affecting the glandular stomach	BASF XX/117

Similar to OECD 401 No GLP RL2	Rat Sprague-Dawley Males and females 10 / sex / group	Relugan GT/M Solution of 25% glutaraldehyde, 8% methanol, 67% water 200, 400, 500, 640, 800, 1000, 1250 and 1600 mg/kg bw. 14-day post exposure period	Treated animals showed signs indicative of general toxicity, e.g. calmness, staggering, unkept fur and irregular respiration.	LD50 ♂ / ♀ 185 mg GA/kg bw Respective value for 25 % test substance: 742 mg/kg bw	The pH was 3 (due to low content of sulfuric acid). The test substance was post-treated with charcoal and by filtration. High concentration of methanol (8%) compared to glutardehyde (25%). **Spontaneously dying animals:** increased incidence of hydrothorax, erosive and inflammatory lesions of the glandular stomach and adhesive-phlogistic processes of the stomach Survivors: signs of bleeding within the lining of the stomach resulting in grey discolouration, a case of severe ulceration in the glandular stomach with thickening and adhesive-phlogistic processes of the stomach lining; one case of liver hypertrophy	BASF XX/118

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 285 mg/kg bw (143 mg/kg bw for pure glutaraldehyde). Protectol GA 50 is to be classified concerning Acute oral toxicity.
Justification for the selected value	The lowest observed LD50 value from a key study following guidelines with a 50% solution of glutaraldehyde has been chosen to be used in the classification of Protectol GA 50 in accordance to Regulation 1272/2008. This evaluation leads to classification of Acute toxicity, Cat. 3; H301.

Classification of the product according to CLP	Protectol GA is to be classified as Acute Tox, 3; H301 "Toxic if swallowed" according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	IUCLID, section 8.5.1
Justification	No study regarding acute oral toxicity with the biocidal product Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available acute oral toxicity studies conducted with different aqueous glutaraldehyde solutions, Protectol® GA 50 is classified with respect to acute oral toxicity (Acute Tox. 3; H301 Toxic if swallowed). For details on the studies please refer to the endpoint study records.

Acute toxicity by inhalation
(cf. IUCLID Section 8.5.2)

Summary table of animal studies on acute inhalation toxicity

Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
Similar to OECD 403 No GLP RL1	Rat Sprague-Dawley Male and female, 10/sex/ group	Glutaraldehyde, solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water, Aerosol, Nominal concentrations: 0.23, 0.41, 0.53, 0.68, 0.9 mg/L	Mortality: 0.10 mg/L: 0/20; 0.18 mg/L: 4/20; 0.28 mg/L: 4/20; 0.39 mg/L: 14/20; 0.44 mg/L: 19/20	LC50 ♂ 0.35 mg/L LC50 ♀ 0.28 mg/L ♂ + ♀: 0.28 mg/L < LC50 < 0.39 mg/l	Necropsy of the animals that died during the experiment: acute congestion, pronounced emphysema of the lungs, edematization	BASF, 80/265 (1994) **Key study**

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
		Analytical concentrations: 0.10, 0.18, 0.28, 0.39 and 0.44 mg/L Exposure: 4 h, nose only Post-exposure observation period: 14 days	Clinical signs: lid closure, snout wiping, aqueous or red discharge from eyes and noses, whooping or gasping respiration, poor general state.	Values are based on analytical GA concentrations and need not be corrected for 50 % GA used	and infarctoid hyperemia. Surviving animals: no pathological abnormalities reported	
Similar to OECD 403 (IHT) No GLP RL1	Rat Sprague-Dawley Male and female, 3-6/sex/ group	Glutaraldehyde, solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water, Vapour, After 1 hour: ca. 16 mg/L (ca. 3800 ppm) After 3 hours: ca. 17 mg/L (ca. 4100 ppm) After 7 hours: ca. 13 mg/L (ca. 3300 ppm) Thus, the mean test concentration was about 15	Mortality: - after 1 h: no mortality - after 3 h: 1/12 - after 7 h:6/6 Clinical signs: lid closure, snout wiping, salivation, lacrimation, aqueous to reddish discharge from the nose, sticky eyes and dyspnea.	LC100 ♂ and ♀ > 15 mg/L	Necropsy of the rats that died during the experiment: acute dilation of the heart (atrium) and acute congestion, slight to moderate acute emphysema, often accompanied by edema, in the lungs.	BASF, IHT 80/265 (1994)

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
		mg/L air Exposure: 1-7 h h, whole body Post-exposure observation period: 14 days			- Necropsy of the survivors: no abnormalities.	
Similar to OECD 403 No GLP RL1	Rat Sprague-Dawley Male and female, 10/sex/ group	Glutaraldehyde, 50% aqueous solution, Aerosol, Nominal concentrations: 0.35, 0.58, 0.72 mg/L Analytical concentrations: 0.22, 0.31, 0.63 mg/L Exposure: 4 h, nose only Post-exposure observation period: 14 days	Mortality: 0.22 mg/L: no mortality; 0.31 mg/L: 3/20; 0.63 mg/L: 15/20. Clinical signs: a slight nasal discharge, snout wiping, flank respiration, irregular to intermittent respiration, bloody nasal discharge, whooping or gasping respiration and tremulous gait.	LC50 ♂ 0.52 mg/L LC50 ♀ 0.45 mg/L ♂ + ♀: 0.48 mg/L Values are based on analytical GA concentrations and need not be corrected for 50 % GA used	Necropsy of the rats that died during the experiment: general congestion, slightly increased blood content small emphysema-areas in the lung; in three cases pronounced emphysema of the lungs - Necropsy of the survivors: no abnormalities.	BASF, 83/59 (2001)

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
Similar to OECD 403 (IHT) No GLP RL2	Rat Sprague-Dawley Male and female, 6/sex	Regulan GT/M, solution of 25% glutaraldehyde, 8% methanol, 67% water, Vapour, 12 mg/L air Exposure: 8 h, whole body	Mortality: No mortality Clinical signs: moderate irritation of the mucosa Necropsy: A conspicuous enlargement of the liver in the male rats.	LC50 ♂ and ♀ > 12 mg/L	Not performed according to OECD 403. pH 3 due to low content of sulfuric acid. High concentration of methanol (8%) compared to glutardehyde (25%).	BASF, XX/117 (1970)
Similar to OECD 403 (IHT) No GLP RL2	Rat Sprague-Dawley Male and female, 6/sex	Regulan GT/M, solution of 25% glutaraldehyde, 8% methanol, 67% water, Vapour, 40 mg/L air Exposure: 8 h, whole body	Mortality: No mortality Clinical signs: moderate irritation of the mucosa Necropsy: No mortalities	LC50 ♂ and ♀ > 12 mg/L	Not performed according to OECD 403. The pH was 3 (due to low content of sulfuric acid). The test substance was post-treated with charcoal and by filtration. High concentration of methanol (8%) compared to glutardehyde (25%).	BASF, XX/118 (1970)

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC50 280 mg/m^3 Protectol GA 50 is to be classified concerning Acute inhalation toxicity.
Justification for the selected value	Based on the available data it can be assumed that mortality after inhalation is predominantly caused by aerosol and not by vapour: the different inhalation hazard tests show that glutaraldehyde vapour is not the toxic component in glutaraldehyde atmosphere. Therefore, the study with the lowest observed LC50 value after aerosol exposure has been selected to be used in the classification of Protectol GA 50 in accordance to Regulation 1272/2008. This evaluation leads to classification of Acute toxicity, Cat. 2; H330.
Classification of the product according to CLP	Protectol GA 50 is to be classified as Acute Tox. 2; H330 "Fatal if inhaled" according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	IUCLID, Section 8.5.2
Justification	No study regarding acute inhalation toxicity with the biocidal product Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available acute inhalation toxicity studies conducted with different aqueous glutaraldehyde solutions Protectol® GA 50 is classified with respect to acute inhalation toxicity (Acute Tox. 2; H330 Fatal if inhaled). For details on the studies please refer to the endpoint study records.

Acute toxicity by dermal route
(cf. IUCLID Section 8.5.3)

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPP 81-2 (Acute Dermal Toxicity) GLP	Rabbit, New Zealand White Male / female, 5/sex/group	Glutaraldehyde, 50.2% aqueous solution, 2000 mg/kg bw, intact	Mortalities: none. Clinical signs: mucoid faeces (days	LD50♂ / ♀ > 1000 mg GA/kg bw Respective value for 50% test	Local skin effects: Severe erythema, moderate to severe edema	WIL Research Laboratories Inc., 234002 (1994)

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
RL1		clipped skin on the back of the animals (semiocclusive, 24 h) Post-exposure observation period 14 days.	1 and 2), wet brown urogenital staining (4 h after application).	substance: > 2000 mg/kg bw	and eschar with subsequent exfoliation (all animals). In addition, there were signs of corrosion, fissuring and desquamation. Signs of severe skin irritation persisted in all animals over the complete observation period.	**Key study**
Similar to OECD 402, No GLP RL2	Rat Sprague-Dawley Male and female 5/sex/group	Glutaraldehyde, solution of 50% glutaraldehyde, 0.5% methanol, 49.5% water 400, 1000 and 2000 mg/kg bw, intact clipped skin on the back or flank of the animals (occlusive, 24 h) Post-exposure observation period 14 days.	Mortalities: 1 female animal (2000 mg/kg bw group) Clinical signs: poor general state, dyspnea, apathy, excitation, staggering, atony, trembling, ruffled fur and diarrhea.	LD50♂ / ♀ > 1000 mg GA/kg bw Respective value for 50% test substance: > 2000 mg/kg bw	Spontaneously dying animal: diarrheal contents in the intestines Local skin changes at all dose levels over the whole observation period, including necrosis and oedema of different levels of severity.	BASF, 80/265 (1994)

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>2000 mg/kg bw Protectol GA 50 is not to be classified concerning Acute dermal toxicity.
Justification for the selected value	Both available studies revealed an LD50 value of >2000 mg/kg bw for male and female animals both for rabbits and for rats.
Classification of the product according to CLP and DSD	Protectol GA 50 is not to be classified concerning acute dermal toxicity according to Regulation 1272/2008.

Data waiving	
Information requirement	IUCLIC, section 8.5.3
Justification	No study regarding acute dermal toxicity with the biocidal product Protectol® GA 50 was conducted as performing a new study is scientifically unjustified. However, as the biocidal product Protectol® GA 50 is identical to the active substance as well as to the representative product in the CA report on glutaraldehyde (RMS Finland, 2014), ca. 50% solution (w/w) of glutaraldehyde in water, data is taken from the CA report. Considering the obtained results of the available acute dermal toxicity studies conducted with different aqueous glutaraldehyde solutions, Protectol® GA 50 is not classified with respect to acute dermal toxicity. For details on the studies please refer to the endpoint study records.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Glutaraldehyde, 50% aqueous solution (w/w)
Value(s)	100% / 10%
Justification for the selected value(s)	As the Protectol GA 50 is classified concerning skin corrosion, a 100% dermal absorption has been used as agreed in the BPC-WG-III meeting in 2016 for corrosive substances. Dermal absorption value 10% was discussed and agreed during the active substance gluatardehyde evaluation (RMS Finland, 2014) and this value is taken forward for the risk assessment for the Protectol GA 50 treated products (containing max. 0.0979% glutaraldehyde)

Data waiving	
Information requirement	IUCLID, section 8.6
Justification	In the BPC-WG-III meeting in 2016 it was agreed that 100% dermal absorption is to be used in the risk assessment of corrosive substances. The dermal absorption data reported in the AR on glutaraldehyde (Finland, 2014) has been used in to assess the dermal absorption of active substance glutaraldehyde from biocidal product Protectol® GA 50, however, the highest concentration tested during the active substance evaluation was 7.5% and therefore these agreements are valid only for the products treated with Protectol GA 50 (containing max. 0.0979% glutaraldehyde).

	Glutaraldehyde was systemically available in the blood of dermally treated rats but it was also rapidly removed from there, either by macromolecular binding or by metabolism (Dow 021134, 2004). In an *in vitro* skin penetration test (Reifenrath 1985), glutaraldehyde did not penetrate thick stratum corneum, while 2.8% - 4.4% of the applied dose penetrated the isolated epidermis and 3.3% - 13.8% of the applied dose penetrated thin stratum corneum. In the AR on glutaraldehyde it is concluded that none of the available studies can be considered to give sufficient information for establishing a value for dermal absorption. It can be considered that most of the glutaraldehyde that was found to absorb in the skin will react immediately, leaving little free glutaraldehyde for absorption. Nevertheless, the absorption of metabolites needs to be considered as well and furthermore it was shown that small amounts of free glutaraldehyde can also be detected from the blood after dermal dosing. The RMS concluded that a conservative value of 10 % for dermal absorption should be used unless further information is provided. For these reasons, it is justified to consider a dermal absorption value of 100% or 10% in the relevant scenarios of the human health exposure and risk assessment.

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

As the biocidal product Protectol® GA 50 consists only of a ca. 50% solution (w/w) of glutaraldehyde in water, there are no substances other than the active substance contained in the product that are classified in relation to their potential to cause adverse effects to human health once formulated into the intended product. Therefore, there is no substance of concern available in the biocidal product.

Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance(s) of concern is a component of are not required.

Other

Germ Cell Mutagenicity, Carcinogenicity and Reproductive Toxicity

Under *in vitro* conditions, glutaraldehyde is mutagenic to bacteria and to mammalian cells in culture with and without metabolic activation, and is clastogenic in mammalian cells. However, under *in vivo* conditions, glutaraldehyde was neither mutagenic nor clastogenic, and furthermore there were no indications of a mutagenic potential in germ cells. Therefore, no classification for genetic toxicity is warranted for active substance glutaraldehyde and biocidal product Protectol GA 50 according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

No carcinogenic potential was evident from oral and inhalative long-term animal studies conducted with glutaraldehyde. A carcinogenic effect resulting from long-term dermal exposure to glutaraldehyde is not expected, as severe skin reactions come to the fore. Therefore, no classification for carcinogenicity is warranted for active substance glutaraldehyde and biocidal product Protectol GA 50 according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

Glutaraldehyde does not affect the reproductive performance and fertility, and neither possesses an embryo/fetotoxic nor a teratogenic potential. Therefore, no classification for reproductive toxicity is warranted for active substance glutaraldehyde and biocidal product Protectol GA 50 according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.
For details on the studies please refer to the CA report on glutaraldehyde (RMS Finland, 2014).

Aspiration hazard

Active substance glutaraldehyde and the biocidal product Protectol GA 50 are not classified for aspiration hazard.

Specific Target Organ Toxicity – Repeated Exposure (STOT-RE)

Systemic toxicity of glutaraldehyde under repeated oral exposure conditions is not expected, possible effects would be related to the corrosive potential of this substance. No systemic toxicity of glutaraldehyde under repeated dermal exposure conditions is expected. Under repeated inhalation exposure conditions, the upper respiratory tract was identified as target for the toxicity of glutaraldehyde vapours. Therefore, according to Annex VI of EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 glutaraldehyde is classified corrosive to respiratory tract (EUH071) as well for specific target organ toxicity after single exposure (STOT SE 3). Based on the available data, or biocidal product Protectol GA 50 do not have to be classified with respect to STOT-RE 1 or STOT-RE 2 effects, respectively.
For details on the studies please refer to the CA report on glutaraldehyde (RMS Finland, 2014).

Neurotoxicity

Glutaraldehyde had no neurotoxic potential when tested in rats for 90 days. Therefore, there is no neurotoxic potential expected for the Protectol GA 50.
For details on the study please refer to the CA report on glutaraldehyde (RMS Finland, 2014).

Food and feedingstuffs studies and effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Human exposure to the biocidal product *via* food is not considered to be relevant because it is not intended to be used in areas where food is produced, stored, transported or processed. This is also the case for feeding stuffs.

2.2.6.2 Exposure assessment

The biocidal product (b.p.) Protectol® GA 50 is a 50% solution of glutaraldehyde in water. It has many uses including short- and medium-term preservation of aqueous solutions during storage or for liquid-cooling and processing systems and as slimicide in the paper-making process or in oilfield applications, and has therefore been notified for National authorisation in the following Product Types (PT): 6, 11, and 12. Protectol® GA 50 is identical

to the active substance as well as to therepresentative product in the CA report on glutaraldehyde (RMS Finland, 2014). Most of the following uses are identical to the scenarios assessed in the CA Report with adaptions to the currently recommended models and new efficacy results.
Exposure to professionals could occur during application of the 50% aqueous solution of glutaraldehyde for preservation or during handling of articles/formulations preserved with Protectol® GA 50. Exposure to non-professionals is limited to the handling of the articles/formulations preserved with Protectol® GA 50.

The effects of exposure reduction due to PPE, described within this dossier, are generic and considered acceptable for risk assessment in professional settings.

The assessments used a relative dermal absorption of 10% of the applied dose for all scenarios as in the CA report on glutaraldehyde (RMS Finland, 2014) the RMS proposed 10% as a conservative value. Acute and chronic exposure values are calculated.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	***Via* food**
Inhalation	Yes	Yes	No	n.a.	n.a.	n.a.	no
Dermal	Yes	Yes	No	n.a.	Yes	Yes	no
Oral	n.a.	n.a.	n.a.	Yes	No	Yes	no

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
PT 6			
Industrial/Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs))			
[1a]**	PT 6 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)	Primary exposure; Exposure during connecting/disconnecting drums (maximum glutaraldehyde content 50%)	Industrials Professionals
[1b]**	PT 6 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs))	Primary exposure; Exposure during connecting/disconnecting IBCs (maximum glutaraldehyde content 50%)	Industrials Professionals
Industrial/Professional users applying detergents preserved with Protectol® GA 50			
[2]**	PT 6 – Professional users mixing and loading liquid dish washing detergent	Primary exposure*; Exposure during mixing and loading of liquid hand dish washing detergent (maximum glutaraldehyde content in liquid hand dish washing detergent 0.0979%)	Industrials Professionals
[3]**	PT 6 – Professional users applying liquid dish washing detergent	Primary exposure*; Exposure during hand dish washing (maximum glutaraldehyde content in liquid hand dish washing detergent 0.0979%)	Industrials Professionals
[4]	PT 6 – Professional users loading liquid detergent for hand washing	Primary exposure*; Exposure during loading of liquid detergent for hand washing of clothes (maximum glutaraldehyde content in liquid detergent for hand washing 0.0979%)	Industrials Professionals
[5]	PT 6 – Professional users applying liquid hand washing detergent	Primary exposure*; Exposure during hand washing of clothes (maximum glutaraldehyde content in liquid detergent for hand washing 0.0979%)	Industrials Professionals
[6]**	PT 6 – Professional users loading laundry softener	Primary exposure*; Exposure during loading of laundry softener (maximum glutaraldehyde content in laundry softener 0.0979%)	Industrials Professionals
[7a]**	PT 6 – Professional users applying undiluted wax emulsion	Primary exposure*; Exposure during application of undiluted wax emulsion (maximum glutaraldehyde content in wax	Industrials Professionals

		emulsion 0.0979%)	
[7b]	PT 6 – Professional users applying diluted wax emulsion	Primary exposure*; Exposure during application of diluted wax emulsion (maximum glutaraldehyde content in wax emulsion 0.0979%)	Industrials Professionals
[8]**	PT 6 – Professional users applying car polish	Primary exposure*; Exposure during application of car polish (maximum glutaraldehyde content in car polish 0.0979%)	Industrials Professionals
Industrial/Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals			
[9]	PT 6 – Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals	Primary exposure*; The b.p. is applied to auxiliaries used in the leather and textile industry. Worst-case exposure during leather treatment is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals
Industrial/Professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics			
[10a]	PT 6 – Professional users spraying paints	Primary exposure*; The b.p is used for the preservation of pigment and polymer dispersions used for plastic and paints and for the preservation of water-based paints. Worst-case exposure during spraying the paint preserved with glutaraldehyde is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals
[10b]	PT 6 – Professional users rolling/brushing paints	Primary exposure*; The b.p is used for the preservation of pigment and polymer dispersions used for plastic and paints and for the preservation of water-based paints. Worst-case exposure during rolling/brushing the paint preserved with glutaraldehyde is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals
Industrial/Professional use as preservative for paper wet-end additives and paper coatings			
[11a]**	PT 6 – Professional use as preservative for paper wet-end additives and paper coatings preservation – fully preserved pulp (cellulose and additives)	Primary exposure*; The b.p. is used for preservation in the paper-making process. Exposure during loading / unloading of slurry tanks including glutaraldehyde as preservative is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals

[11b]	PT 6 – Professional use as preservative for paper wet-end additives and paper coatings preservation – preserved paper additive(s) only	Primary exposure*; The b.p. is used for preservation in the paper-making process. Exposure during loading / unloading of slurry tanks including glutaraldehyde as preservative is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals
Industrial/Professional use as preservative for polymer dispersions e.g. glues and raw material thereof			
[12]	PT 6 – Professional use as preservative for polymer dispersions e.g. glues and raw material thereof	Primary exposure*; The b.p. is used for the preservation of glues and raw material thereof. Worst-case exposure during using a glutaraldehyde preserved glue is calculated (maximum glutaraldehyde content 0.0979%).	Industrials Professionals
Non-professional users applying detergents preserved with Protectol® GA 50			
[13]**	PT 6 – Non-professional users mixing and loading liquid dish washing detergent	Primary exposure*; Exposure during mixing and loading of liquid hand dish washing detergent (maximum glutaraldehyde content in liquid hand dish washing detergent 0.0979%)	Non-professionals
[14]**	PT 6 – Non-professional users applying liquid dish washing detergent	Primary exposure*; Exposure during hand dish washing (maximum glutaraldehyde content in liquid hand dish washing detergent 0.0979%)	Non-professionals
[15]	PT 6 – Non-professional users loading liquid detergent for hand washing	Primary exposure*; Exposure during loading of liquid detergent for hand washing of clothes (maximum glutaraldehyde content in liquid detergent for hand washing 0.0979%)	Non-professionals
[16]	PT 6 – Non-professional users applying liquid hand washing detergent	Primary exposure*; Exposure during hand washing of clothes (maximum glutaraldehyde content in liquid hand washing detergent 0.0979%)	Non-professionals
[17]**	PT 6 – Non-professional users loading laundry softener	Primary exposure*; Exposure during loading of laundry softener (maximum glutaraldehyde content in laundry softener 0.0979%)	Non-professionals
[18a]**	PT 6 – Non-professional users applying undiluted wax emulsion	Primary exposure*; Exposure during application of undiluted wax emulsion (maximum glutaraldehyde content in wax emulsion 0.0979%)	Non-professionals
[18b]	PT 6 – Non-professional users applying diluted wax emulsion	Primary exposure*; Exposure during application of diluted wax emulsion (maximum glutaraldehyde content in wax	Non-professionals

		emulsion 0.0979%)	
[19]**	PT 6 – Non-professional users applying car polish	Primary exposure*; Exposure during application of car polish (maximum glutaraldehyde content in car polish 0.0979%)	Non-professionals
Non-professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics			
[20]	PT 6 – Non-professional users applying spray paints	Primary exposure* Exposure during application of spray paint (maximum glutaraldehyde content 0.0979%)	Non-professional
Secondary (indirect) exposure of the general public			
[21]**	PT 6 – Secondary (Indirect) exposure of the general public from detergent or fabric softener residues from textiles/clothes	Secondary exposure; Exposure from detergent or fabric softener residues from textiles/clothes (maximum glutaraldehyde content in the detergent/softener 0.0979%)	General public
[22]**	PT 6 – Secondary (Indirect) exposure of the general public to liquid dish washing detergent	Secondary exposure; Exposure from dish washing detergent on crockery was calculated (maximum glutaraldehyde content in the liquid dish washing detergent 0.0979%)	General public
[23]	PT 6 - Toddler -dermal contact with wet paint and mouthing	Secondary exposure: Toddler touches wet surface and mouthes contaminated hands (maximum glutaraldehyde content in the paint 0.0979%)	General public
PT12			
Slimicides for paper pulp: wet-end slimicides			
Industrial/Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Wet end slimicides			
[24a]**	PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Wet end slimicides	Primary exposure Exposure during connecting/disconnecting drums (maximum glutaraldehyde content 50%)	Industrial/ Professional
[24b]**	PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Wet end slimicides	Primary exposure Exposure during connecting/disconnecting IBCs (maximum glutaraldehyde content 50%)	Industrial/ Professional
Exposure of industrial/professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water			
[25]**	PT 12 - Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water	Primary exposure Exposure during cleaning/maintenance of tanks (maximum glutaraldehyde content 0.013%)	Industrial/ Professional

Secondary (Indirect) exposure of industrial/professional users			
[26]**	PT 12 - Secondary (Indirect) exposure of professional users to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry	Secondary exposure Exposure to vapours and aerosols in the paper mill (maximum glutaraldehyde content 0.01%)	Industrial/ Professional
Slimicides for paper pulp: paper de-inking slimicides			
Industrial/Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Paper de-inking			
[27a]**	PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Paper de-inking	Primary exposure Exposure during connecting/disconnecting drums (maximum glutaraldehyde content 50%)	Industrial/ Professional
[27b]**	PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Paper de-inking	Primary exposure Exposure during connecting/disconnecting intermediate bulk containers, IBCs (maximum glutaraldehyde content 50%)	Industrial/ Professional
Exposure of industrial/professional users during cleaning/maintaining of pulp tanks - paper de-inking			
[28]**	PT 12 - Exposure during Cleaning/Maintenance of Pulp Tanks – Paper Deinking	Primary exposure Exposure during cleaning/maintenance of tanks (maximum glutaraldehyde content 0.013%)	Industrial/ Professional
Oilfield applications			
PT 11/PT 12 Product types were merged according to the CA report on glutaraldehyde (RMS Finland, 2014), as the activities for the workers during hydrotesting or mineral oil extraction and therefore the risk assessment is identical for both PTs. The difference is only based on the purpose of the treatment with the biocidal product (prevention of corrosion (PT 11) or biofilm formation (PT 12))			
Prevention of corrosion and biofilm formation in liquid cooling and processing systems (hydrotesting fluid)			
[29]**	PT 11/PT12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)	Primary exposure Exposure during connecting/disconnecting drums (maximum glutaraldehyde content 50%)	Industrial/ Professional
[30]**	PT 11/PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers, IBCs)	Primary exposure Exposure during connecting/disconnecting intermediate bulk containers, IBCs (maximum glutaraldehyde content 50%)	Industrial/ Professional
Prevention of corrosion and biofilm formation during mineral oil extraction (production and oil injection water)			

[31]**	PT 11/PT12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)	Primary exposure Exposure during connecting/disconnecting drums (maximum glutaraldehyde content 50%)	Industrial/ Professional
[32]**	PT 11/PT 12 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers, IBCs)	Primary exposure Exposure during connecting/disconnecting intermediate bulk containers, IBCs (maximum glutaraldehyde content 50%)	Industrial/ Professional

*Primary exposure to the end-use product treated with Protectol® GA 50
**Scenarios assessed in the active substance authorisation, please refer to CA Report on glutaraldehyde (RMS Finland, 2014); adaption to the currently recommended models and new efficacy results

2.2.6.2.1 Product Type 6

Aqueous products intended for professional and consumer use are prone to microbial spoilage (bacteria, fungi and yeasts). For this reason, a preservative is added to these aqueous systems during their production; the added preservative is intended to prevent the bio-deterioration of these systems until they are used within a few weeks/months after production. Protectol® GA 50 is used as an in-can preservative for different types of water-based products like washing and cleaning fluids, products used in paper production, for paints, paper or plastic and as auxiliaries in the production of leather and textile. During manufacture of these products and/or of their raw materials, the formulation is spiked with the respective amount of Protectol® GA 50 to obtain concentrations between 10 and 979 mg/kg (0.001 - 0.0979 % w/w) of glutaraldehyde. Subsequently, the preserved formulation, the treated article, remains in a closed container for a minimum period of 14 days until the formulation is available at the customer sites (usually between 2 and 8 weeks) and is used in the respective applications described under PT6. This period of 14 days is at least required (selling and transport process) after filling until the customer receives and potentially opens the container (e.g. drums, buckets, etc.). In general, the exposure calculations are perfomed with the highest concentration on the formulation (0.0979%) where no degradation of the active substance is considered, therefore representing a worst-case scenario for the treated articles. If 50% degradation derived from Rowher 2016a is considered, it is represented as an individual Tier in the exposure assessment calculations [Tier 4, Scenario 10a] and [Tier 3, Scenario 12].

The worst-case scenario for exposure assessment for PT6 products is conservative, as in-house data show that the degradation process of glutaraldehyde (Protectol® GA 50) starts directly after filling of the formulation and can be described as exponential degradation process[10]. A typical PT6 organic particle formulation (pH 8.5), a wall paint, was doped with 500 mg/L glutaraldehyde (corresponds 1,000 mg/L Protectol® GA 50, as representative in-use concentration) directly before filling. The glutaraldehyde content in the stored paint was monitored using HPLC over a period of 4 weeks after filling. The half-life time of glutaraldehyde is approx. two weeks, i.e. when a container for PT6 application is opened at

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[10] Rohwer, H., BASF SE (2016) Decomposition in wall paints. Analysis Report 15N01611 (*cf.* IUCLID Section 10.2)

customer sites after a storage and transport period of two weeks (which is regarded as lowest duration of storage and transport) only 50% (approx. 250 mg/L) of the preservative is still available in the organic particle formulation. The concentration of glutaraldehyde further decreased (factor 2) after application and removal of the solvent by e.g. drying of the formulation. After a typical storage and transport period of at least two weeks only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration, Rowher 2016b) of evaporated glutaraldehyde are available when opening the container at customer sites, i.e. exposure with Protectol® GA 50 by inhalation during e.g. 'PT6 mixing and loading' and 'PT6 application' is very low[11]. The applied wall paint contains substantial amounts of caolin, calcium carbonate and acrylate. Therefore, these results are also regarded as representative for additives in the paper production and for glues.

The risk assessment is conducted in first instance by using recommended models and indicative values. However, GA-specific and PT6-representative results are included in a tiered-approach human risk assessment.

Regarding the use as preservative of detergents several representative scenarios have been assessed to cover a wide spectrum of detergents, therefore providing data to for the evaluation of the worst-case scenarios in the PT6 use of Protectol GA 50.

The primary dermal and inhalation exposure of the following user groups to glutaraldehyde is assessed.

- professional users adding Protectol® GA 50 by transfer/pumping as an in-can preservative to different types of products and/or raw materials
- professional and non-professional users using treated articles (i.e. detergents, fabric softener, paints, textiles) containing glutaraldehyde.

Secondary oral exposure to Protectol® GA 50 can arise *via* residues on dishes and cutlery (= post-application) or toddler touching and mouthing wet paint. Secondary dermal exposure of adults and children might occur *via* residues in clothes or toddler touching wet paint.

Industrial exposure

Please refer to professional exposure

Professional exposure

Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs))

Potential primary exposures have been assessed for professional workers handling and connecting/disconnecting drums (*via* opening caps / manually inserting drums, Scenario [1a]) or for professional workers handling intermediate bulk containers (IBCs; pumping *via* valve connection, automated process, Scenario [1b])) containing Protectol® GA 50 during product formulation.

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[11] Rohwer, H., BASF SE (2016) Determination of Glutaraldehyde concentration in vapor phase over paint. Analysis Report 16N00791 (*cf.* IUCLID Section 10.2)

Scenario [1a] PT 6 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)

The professional worker is connecting / disconnecting drums *via* opening caps / manually inserting drums. The task is carried out for 10 minutes per shift and the estimated frequency is twice per year. As the systemic effects are considered minor compared to the local effects of the corrosive product due to the dermal exposure, for the dermal exposure no systemic risk assessment but a qualitative local risk assessment is performed with consideration of minimising exposure with appropriate PPE and RMM (TAB, 08/2017, TOX 14; Chapter 2.2.6.3). The systemic exposure *via* the inhalation is evaluated.

Description of Scenario [1a]

The potential worker exposure (assumed body weight: 60 kg) for handling drums and pumping the b.p. (maximum 50% glutaraldehyde) into the formulation system in dedicated filling lines was assessed according to *Model 7 – Mixing and loading*, provided in the Human Health TNsG (2002 version) Part 2 page 141-143 using the 'pump liquid' data and the corrected indicative values agreed in the HEEG Opinion at TMI08 for a (semi) automated liquid transfer/pumping scenario. **Dermal** exposure will be mainly on the hands, resulting from accidentally touching the contaminated hose or pump. The systemic effects are considered minor compared to local effects of the corrosive product and no systemic risk assessment is performed as stated in the TAB entry TOX 14 (Technical Agreements for Biocides, 08/2017: B.5 Human health/Corrosive substances). According to the local risk characterisation, suitable PPE to prevent exposure (gloves, coated coveralls, eye protection) with other operational RMM cover the systemic risks (See 2.2.6.3). The Tier 1 indicative value for **inhalation** exposure is 22 mg/m^3 (no RPE), Tier 2 indicative value is 2.2 mg/m^3 (RPE with 10% penetration; APF 10) and Tier 3 indicative value is 0.55 mg/m^3 (RPE with 2.5% penetration; APF 40). The TNsG (2007) Use pattern (Excel database) informs that processes involving the loading of biocides are typically carried out for 10 minutes per shift. The estimated frequency is twice per year.

This scenario also covers the filling of liquids preserved with Protectol® GA 50 in/from drums in dedicated filling lines usually operated with local exhaust ventilation. However, in the preserved products glutaraldehyde is only present in concentrations up to 0.0979% which is a factor 500 lower than the worst-case assumption used in this calculation. For drumming of preserved products, the inhalation exposure is therefore negligible and no RPE is required.

This scenario represents also a worst-case assumption for the professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Wet end slimicides (Scenario [24a]), professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Paper de-inking (Scenario [27a]), professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – hydrotesting fluid (Scenario [29a] and professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) -mineral oil extraction (Scenario [31a].

	Parameters[1]	Value
Tier 1	Glutaraldehyde max. concentration [%]	50
	Exposure duration [min/shift]	10 (twice a year)[2]
	Indicative value inhalation exposure [mg/m^3]	22[1]
	A.s. concentration [mg/m^3]	11
	Dermal absorption [%]	100[4]
	Inhalation rate [m^3/h]	1.25[3]
Tier 2	Indicative value inhalation exposure [mg/m^3]	2.2
	PPE	Gloves and clothes (10% penetration)[5] RPE (10%)[6]

Tier 3	Indicative value inhalation exposure [mg/m^3]	0.55
	PPE	Gloves and clothes (10% penetration)[5] RPE (2.5% penetration)[6]

[1] Indicative value, TM108 TNsG model recommendation. Model 7-Mixing and Loading (pump liquid), TNsG 2002, Part 2, from Ad Hoc WG Recommendations on Methods and Models.

[2] Biocides guidance database for human exposure and Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015)

[3] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

[4] BPC-WG-III agreement for corrosive substances, 2016

[5] HEEG Opinion 9 on default protection factors for protective clothing and gloves, TM I 2010

[6] TNsG on human exposure (2007)

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [1a]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1a] PT 6 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)	1/-	$3.82E^{-2}$	n.a.	n.a.	$3.82E^{-2}$
	2/coated coverall, gloves, eye protection and RPE (10% penetration)	$3.82E^{-3}$	n.a.	n.a.	$3.82E^{-3}$
	3/ coated coverall, gloves, eye protection and RPE (2.5% penetration)	$9.6E^{-4}$	n.a.	n.a.	$9.6E^{-4}$

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [1a] PT 6 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)	1/-	11	n.a.[1]
	2/coated coverall, gloves, eye protection and RPE (10% penetration)	1.1	n.a.[1]
	3/ coated coverall, gloves, eye protection and RPE (2.5% penetration)	0.275	n.a[1]

[1] n.a. = not applicable; only 10 min exposure

Scenario [1b] PT 6 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs))

The professional worker is connecting a pump on the tap of the IBC by means of a hose which resembles closed system conditions. After discharge of the IBC the tap is flushed and closed and the hose will be connected to the next IBC. During this work, the professional is wearing gloves. Dermal and inhalation exposure are regarded as negligible, because there is in principle a continuous closed system and no further exposure assessment is conducted. This is in agreement with HEEG Opinion 1 (TM I 08).

This scenario represents also a worst-case assumption for the professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Wet end slimicides (Scenario [24b]) and professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Paper de-inking (Scenario [27b]).

Professional users applying detergents preserved with Protectol® GA 50

Protectol® GA 50 is used as preservative for different types of detergents and raw material thereof. Several representative scenarios have been assessed to cover a wide spectrum of detergents and are reported below.

Scenario [2]: PT 6 – Professional users mixing and loading liquid dish washing detergent

Description of Scenario [2]

Human exposure during mixing and loading liquid dish washing detergent has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Dishwashing products - Hand dishwashing liquid - mixing & loading* and are adapted for professional users (the frequency of use was increased). As described, this scenario comprises mixing and loading. For the professional user dealing with liquid dish washing detergents preserved with Protectol® GA 50 only the loading task is relevant. Therefore, this scenario is regarded as worst-case estimate. The maximum concentration of glutaraldehyde present in the product is 0.0979% where no decomposition of glutardehyde during storage period is considered. This task was estimated to be carried out 10 times/day (3,650 times/year).

For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The applied amount to skin (splashes) is 0.01 g and the exposed area 215 cm^2 (one palm). A dermal penetration rate of 10% was applied for glutaraldehyde.

For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction): exposure duration is 0.75 min and application duration 0.3 min. The product amount is 500 g, the room volume into which the glutaraldehyde vapour evaporates is a personal breathing zone of 1 m^3. Ventilation rate is 2.5/h. The inhalation rate of the applicant is 1.25 m^3/h. The release area is 20 cm^2. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation.

This scenario represents also a worst-case assumption for the use of preserved raw material for liquid dish washing detergents and non-professional users mixing and loading liquid dish washing detergents (Scenario [13]).

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	0.75[1] (10 times/day)
	Exposed dermal area [cm^2]	205[4]
	Applied amount (dermal) [g]	0.01[1]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	1[1]
	Ventilation rate [1/h]	2.5[1]
	Applied amount (inhalation) [g]	500[1]
	Release area [cm^2]	20[1]
	Application duration [min]	0.3[1] (10 times/day)
	Molecular weight matrix [g/mol]	36[1]
	Mass transfer rate [m/min]	0.052[3]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[4]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Dishwashing products - Hand dishwashing liquid - mixing & loading / Cleaning Products Fact Sheet)
[2] CA Report on glutaraldehyde (RMS Finland, 2014)
[3] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)
[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [2] PT 6 – Professional users mixing and loading liquid dish washing detergent	1/-	4.1E^{-8*}	1.6E^{-4*}	n.a.	1.6E^{-4*}

*Daily exposure based on the 10 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [2] PT 6 – Professional users mixing and loading liquid dish washing detergent	1/-	1.6E^{-5}	2.5E^{-7}

Scenario [3]: PT 6 – Professional users applying liquid dish washing detergent

Description of Scenario [3]		
Human exposure to liquid dish washing detergent during application has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Dishwashing products - Hand dishwashing liquid - Application*. The maximum concentration of glutaraldehyde present in the liquid dish washing detergent is 0.0979% where no decomposition of glutaraldehyde during storage period is considered. Considering also the 714-fold dilution of the detergent in water (ConsExpo default) an in-use concentration of 1.34E^{-4}% of detergent is calculated. This task was estimated to be carried out 10 times/day (3,650 times/year). For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The applied amount is 8.2 g and the exposed area 820 cm^2. A dermal penetration rate of 10% was applied for glutaraldehyde. For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction): exposure duration is 60 min and application duration 16 min. The product amount is 15,000 g, the room volume into which the glutaraldehyde vapour evaporates is 15 m^3. Ventilation is assumed to be high with 2.5/h. The inhalation rate for the person is 1.25 m^3/h. The release area is 1,500 cm^2. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. This scenario represents also a worst-case assumption for the application of preserved raw material for liquid dish washing detergents and for the non-professional users applying liquid dish washing detergents (Scenario [14]).		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	60[1] (10 times/day)
	Exposed dermal area [cm^2]	820[2]
	Applied amount (dermal) [g]	8.2[3]
	Dermal absorption [%]	10[4]
	Room volume [m^3]	15[1]
	Ventilation rate [1/h]	2.5[1]
	Applied amount (inhalation) [g]	15,000[1]
	Release area [cm^2]	1,500[1]
	Application duration [min]	16[1] (10 times/day)
	Molecular weight matrix [g/mol]	18[1]
	Mass transfer rate [m/min]	0.052[5]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[2]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Dishwashing products - Hand dishwashing liquid - mixing & loading / Cleaning Products Fact Sheet)

[2] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

[3] modified by value given in HEEG Opinion 17 and a dermal layer thickness of 0.01 cm

[4] CA Report on glutaraldehyde (RMS Finland, 2014)

[5] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [3]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [3]: PT 6 – Professional users applying liquid dish washing detergent	1/-	2.7E^{-7*}	1.9E^{-4*}	n.a.	1.9E^{-4*}

* Daily exposure based on the 10 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (10 h TWA)**
		[mg/m³]	
Scenario [3]: PT 6 – Professional users applying liquid dish washing detergent	1/-	1.3E^{-6}	1.3E^{-6} [1]

[1] As the overall duration is 600 min (10 × 60 min) which correlates to a 10 h working shift, no 8 h TWA but rather a 10 h TWA (which is similar to the estimated acute dose) was calculated.

Scenario [4]: PT 6 – Professional users loading liquid detergent for hand washing

Description of Scenario [4]		
Human exposure during loading liquid hand washing detergent has been estimated using ConsExpo Web. The calculations are based on the default model *for Cleaning & Washing - Laundry products - Detergent liquid - Loading* and are adapted for professional users (the frequency of use was increased to 10 times/day). The maximum concentration of glutaraldehyde present in the liquid detergent for hand washing is 0.0979%. This task was estimated to be carried out 10 times/day (3,650 times/year). For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The applied amount to skin is 0.01 g (splashes) and the exposed area 215 cm^2 (one palm). A dermal penetration rate of 10% was applied for glutaraldehyde. For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction): exposure duration is 0.75 min and application duration 0.3 min. The product amount is 500 g, the room volume into which the glutaraldehyde vapour evaporates is a personal volume of 1 m^3 around the user. Ventilation rate is 2/h. The inhalation rate for the person is 1.25 m^3/h. The release area is 20 cm^2 (ConsExpo defaults). Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. This scenario represents also a worst-case assumption for the use of preserved raw material for liquid detergents for hand washing and non-professional users loading liquid detergent for hand washing (Scenario [15]).		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	0.75[1] (10 times/day)
	Exposed dermal area [cm^2]	215[1]
	Applied amount (dermal) [g]	0.01[1]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	1[1]
	Ventilation rate [1/h]	2[1]
	Applied amount (inhalation) [g]	500[1]
	Release area [cm^2]	20[1]
	Application duration [min]	0.3[1] (10 times/day)
	Molecular weight matrix [g/mol]	90[1]
	Mass transfer rate [m/min]	0.052[3]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[4]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Laundry products - Detergent liquid - Loading / Cleaning Products Fact Sheet)

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

[3] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [4]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [4]: PT 6 – Professional users loading liquid detergent for hand washing	1/-	$1.0E^{-7*}$	$1.6E^{-4*}$	n.a.	$1.6E^{-4}$

*Daily exposure based on the 10 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [4]: PT 6 – Professional users loading liquid detergent for hand washing	1/-	$3.9E^{-5}$	$6.09E^{-7}$

Scenario [5]: PT 6 – Professional users applying liquid hand washing detergent

Description of Scenario [5]

Human dermal exposure to liquid hand washing detergent during application has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing – Laundry products - Detergent liquid - Application*. The maximum concentration of glutaraldehyde present in the product is 0.0979%. Considering also the dilution in water and therefore a dilution factor of 100 (ConsExpo default) an in-use concentration of 0.000979% is calculated. This task was estimated to be carried out 10 times/day (3,650 times/year).

For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. During hand-wash, the diluted product comes in direct contact with the skin of hands and potentially of forearms. Thus, the exposed area is the skin surface area of forearms and hands, i.e. 1948.8 cm^2 (HEEG Opinion 17, TM II 2013). The estimated thickness of an aqueous product layer on the skin is 0.01 cm (RIVM/ConsExpo default), i.e. by multiplying the exposed area (cm^2) with 0.01 cm the amount of diluted product to which the dermal barrier is exposed is 19.5 cm^3 or 19.5 g (density 1 g/cm^3). A dermal penetration rate of 10% was applied for glutaraldehyde.

For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction): exposure duration is 60 min and application duration 16 min. The product amount is 15,000 g and the room volume into which the glutaraldehyde vapour evaporates is 15 m^3. Ventilation rate is 2.5/h. The inhalation rate for the person is 1.25 m^3/h. The release area is 1,500 cm^2. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation.

This scenario represents also a worst-case assumption for the application of preserved raw material for liquid detergents for hand washing and non-professional users applying liquid hand washing detergent (Scenario [16]).

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.000979
	Exposed dermal area [cm^2]	1948.8[1]
	Applied amount (dermal) [g]	19.5[2]
	Dermal absorption [%]	10[3]
	Exposure duration [min]	60[2]
	Room volume [m^3]	15[2]
	Ventilation rate [1/h]	2.5[2]
	Applied amount (inhalation) [g]	15,000[2]
	Release area [cm2]	1,500[2]
	Application duration [min]	16[2]
	Molecular weight matrix [g/mol]	22[3]
	Mass transfer rate [m/min]	0.052[4]
	Uptake fraction (inhalation) [%]	100[3]
	Inhalation rate [m^3/h]	1.25[1]

[1] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013
[2] ConsExpo Web default value (Default model: Cleaning & Washing - – Laundry products - Detergent liquid - Application / Cleaning Products Fact Sheet)
[3] CA Report on glutaraldehyde (RMS Finland, 2014)
[4] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [5]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [5]: PT 6 – Professional users applying liquid hand washing detergent	1/-	0.0002	0.0032*	n.a.	0.0034

* Daily exposure based on the 10 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m^3]	
Scenario [5]: P PT 6 – Professional users applying liquid hand washing detergent	1/-	9.4E^{-4}	1.2E^{-3}

Scenario [6]: PT 6 – Professional users loading laundry softener

Description of Scenario [6]		
The human exposure to laundry softeners has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Laundry products - Fabric conditioner - Loading* and are adapted for professional users (the frequency of use was increased). The maximum concentration of glutaraldehyde present in the fabric conditioner is 0.0979%. This task was estimated to be carried out 10 times/day. For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The applied amount to skin is 0.01 g and the exposed area 215 cm^2. A dermal penetration rate of 10% was applied for glutaraldehyde. For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction): exposure duration is 0.75 min and application duration 0.3 min. The product amount is 500 g, the room volume into which the glutaraldehyde vapour evaporates is a personal breathing zone of 1 m^3. Ventilation rate is 2/h. The inhalation rate of the applicant is 1.25 m^3/h. The release area is 20 cm^2. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. This scenario represents also a worst-case assumption for the use of preserved raw material for laundry softener and non-professional users loading laundry softener (Scenario [17]).		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	0.75[1] (10 times/day)
	Exposed dermal area [cm^2]	205[4]
	Applied amount (dermal) [g]	0.01[1]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	1[1]
	Ventilation rate [1/h]	2[1]
	Applied amount (inhalation) [g]	500[1]
	Release area [cm^2]	20[1]
	Application duration [min]	0.3[1] (10 times/day)
	Molecular weight matrix [g/mol]	90[1]
	Mass transfer rate [m/min]	0.052[3]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[4]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Laundry products - Fabric conditioner - Loading / Cleaning Products Fact Sheet)
[2] CA Report on glutaraldehyde (RMS Finland, 2014)
[3] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)
[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [6]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [6]: PT 6 – Professional users loading laundry softener	1/-	$1.0E^{-7*}$	$1.6E^{-4*}$	n.a.	$1.6E^{-4}$

* Daily exposure based on the 10 applications / day

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [6]: PT 6 – Professional users loading laundry softener	1/-	$3.9E^{-5}$	$6.09E^{-7}$

Professional users applying wax emulsion

To cover both the professional users applying undiluted and diluted wax emulsion two different exposure calculations are conducted.

Scenario [7a]: PT 6 – Professional users applying undiluted wax emulsion

Description of Scenario [7a]

The human exposure to undiluted wax emulsions has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Floor, Carpet and Furniture Products - Floor polish - Application*. The maximum concentration of glutaraldehyde present in the product is 0.0979 %. This task was estimated to be carried out 1 time/day.

For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. According to the glutaraldehyde CAR Scenario 15 the applied amount is 5.5 g and the exposed area 430 cm^2. A dermal penetration rate of 10% was applied for glutaraldehyde.

For the assessment of **inhalation** exposure, the ConsExpo evaporation model is used (uptake: fraction). The default values for the manual application and exposure durations are 90 minutes; this scenario assumed a floor polishing machine was used so the application and exposure durations were reduced to 60 minutes. The product amount, room volume and release area are adapted for professional use in theglutaraldehyde CAR Scenario 15. The product amount is 550 g, the room volume into which the glutaraldehyde vapour evaporates is 58 m^3 and the release area is 60 m^2, the release area increases over time. Ventilation rate is 0.5/h. The inhalation rate for the applicant is 1.25 m^3/h. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. The calculated exposure value is regarded as worst-case estimate. As described at the beginning of the PT6 chapter and in the Section 'Monitoring data', the preserved products are usually stored before using. After a storage and transport period of at least two weeks only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration (500 mg/L glutaraldehyde)) of evaporated glutaraldehyde are available when opening the container at customer sites, i.e. exposure with Protectol® GA 50 by inhalation during application of wax emulsion is very low and therefore overestimated in this scenario (for details on evaporation of glutaraldehyde in the matrix please refer to IUCLID Section 10.2). Considering this aspect, a glutaraldehyde concentration in the air of 0.009 µg/m^3 (550 g product contains 0.54 g glutaraldehyde, 5.38 µg glutaraldehyde will evaporate in a room volume of 58 m^3) and an inhalation uptake of 0.001 µg/kg bw/day (considering an inhalation rate of 1.25 m^3/h and a body weight of 60 kg) is estimated. The worst-case assumptions are however used for risk characterisation.

This scenario represents also a worst-case assumption for non-professional users applying undiluted wax emulsion (Scenario [18a]) as non-professionals use 10-fold dilutions in water for cleaning / maintenance of floors.

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	60[1] (1 time/day)
	Exposed area [cm^2]	430[1]
	Applied amount (dermal) [g]	5.5[2]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	58[2]
	Ventilation rate [1/h]	0.5[2]

	Applied amount (inhalation) [g]	550[1]
	Release area [cm^2]	2.2E^{5}[1]
	Application duration [min]	60[1] (1 time/day)
	Molecular weight matrix [g/mol]	22[1]
	Mass transfer rate [m/min]	0.052[3]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[4]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Floor, Carpet and Furniture Products - Floor polish / Cleaning Products Fact Sheet); default values for manual application and exposure durations are 90 minutes; this scenario assumed a floor polishing machine was used so the application and exposure durations were reduced to 60 minutes; applied amount, release area and room volume are adapted for professional use

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

[3] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [7a]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [7a]: PT 6 – Professional users applying undiluted wax emulsion	1/-	1.2E^{-3*}	9.0E^{-3*}	n.a.	1.0E^{-2}

* Daily exposure based on the 1 application / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m^3]	
Scenario [7a]: PT 6 – Professional users applying undiluted wax emulsion	1/-	5.8E^{-2}	7.3E^{-3}

Scenario [7b]: PT 6 – Professional users applying diluted wax emulsion

Description of Scenario [7b]		
The human exposure to diluted wax emulsions has been estimated using in part ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Floor, Carpet and Furniture Products - Floor cleaning liquid - Application*. The maximum concentration of glutaraldehyde present in the product is 0.0979 %. In addition, a dilution factor of 20 is applied. This is the ConsExpo default dilution factor for floor cleaners and is therefore also applied for estimation of the dilution of wax emulsions. Thus, the concentration in the diluted wax polish is 0.00495%. This task was estimated to be carried out 4 times/day (1,460 times/year). For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. According to the glutaraldehyde CAR Scenario 15 the applied amount is 5.5 g and the exposed area 430 cm^2. A dermal penetration rate of 10% is applied for glutaraldehyde. For the assessment of **inhalation** exposure, the ConsExpo evaporation model is used (uptake: fraction). The default values for the manual application and exposure durations are adapted for professional users to 60 and 240 minutes. The product amount is 550 g, the room volume into which the glutaraldehyde vapour evaporates is 58 m^3. Ventilation rate is 0.5/h. The inhalation rate for the applicant is 1.25 m^3/h. The release area is 220,000 cm^2, the release area increases over time. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. This scenario represents also a worst-case assumption for non-professional users applying diluted wax emulsion non-professional users applying undiluted wax emulsion (Scenario [18b]).		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.00495
	Exposure duration [min]	240[1] (4 times/day)
	Exposed area [cm^2]	430
	Applied amount (dermal) [g]	5.5[2]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	58[1]
	Ventilation rate [1/h]	0.5[1]
	Applied amount (inhalation) [g]	550[1]
	Release area [cm^2]	220,000[1]
	Application duration [min]	60[1] (4 times/day)
	Molecular weight matrix [g/mol]	22[2]
	Mass transfer rate [m/min]	0.052[3]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[4]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Floor, Carpet and Furniture Products – Floor Cleaning Liquid - Application / Cleaning Products Fact Sheet)

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

[3] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [7b]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [7b]: PT 6 – Professional users applying diluted wax emulsion	1/-	$3.2E^{-3*}$	$1.8E^{-3*}$	n.a.	$5.0E^{-3}$

* Daily exposure based on the 4 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (n h TWA)**
		[mg/m³]	
Scenario [7b]: PT 6 – Professional users applying diluted wax emulsion	1/-	$9.7E^{-3}$	$9.7E^{-3}$ [1]

[1] As the overall exposure duration is > 480 min (4 × 240 min), the TWA is similar to the estimated acute dose.

Scenario [8]: PT 6 – Professional users applying car polish

Description of Scenario [8]		
The human exposure to car polish has been estimated in part using the default model for *Cleaning & Washing - Floor, Carpet and Furniture Products - Floor* polish using ConsExpo Web. The maximum concentration of glutaraldehyde present in the product is 0.0979%. This task was estimated to be carried out 2 times/day. For the estimation of **dermal** exposure, the instant application (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The mass of polish for a typical car was estimated as 59 g (or 2 ounces[12]). The Cleaning Products Fact Sheet (RIVM, 2006) stated "*For estimating dermal exposure during cleaning, there are no data found for the amount contacting the skin. It is assumed that 1 % of the product amount gives dermal exposure*" so the product amount on the skin was 0.6 g. The exposed area is 430 cm^2. A dermal penetration rate of 10% was applied for glutaraldehyde. For the assessment of **inhalation** exposure, the ConsExpo evaporation model is used (uptake: fraction). It is assumed that workers use a polishing machine so the application and exposure durations were reduced to 60 minutes. The product amount is 59 g. The worst-case garage room volume and ventilation rate have been derived from the default model for *Painting Products - Spray Painting - Spray Can – Application*. If the task is performed outdoors or in a large volume garage then the inhalation exposure would be much lower. The inhalation rate for the person is 1.25 m^3/h. The release area is 11 m^2 as the metal surface area of a typical car was estimated as 11 m^2, the release area increases over time. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	60[1] (2 times/day)
	Exposed area [cm^2]	410[7]
	Applied amount (dermal) [g]	0.6[2]
	Dermal absorption [%]	10[3]
	Room volume [m^3]	34[4]
	Ventilation rate [1/h]	1.5[4]
	Applied amount (inhalation) [g]	59[5]
	Release area [m^2]	11
	Application duration [min]	60[1]
	Molecular weight matrix [g/mol]	22[1]
	Mass transfer rate [m/min]	0.052[6]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[7]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Floor, Carpet and Furniture Products - Floor polish / Cleaning Products Fact Sheet); default values for manual application and exposure durations are 90 minutes; this scenario assumed a polishing machine was used so the application and exposure durations were reduced to 60 minutes

[2] Estimation based on the mass of polish for a typical car and the assumptions described in the Cleaning Products Fact Sheet
[3] CA Report on glutaraldehyde (RMS Finland, 2014)
[4] ConsExpo 4.1 default value (Default model: Painting Products - Spray Painting - Spray Can – Application)
[5] Reference: http://www.autogeekonline.net/forum/auto-detailing-101/39994-how-much-polish-sealant-per-car.html
[6] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)
[7] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [8]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [8]: PT 6 – Professional users applying car polish	1/-	$1.6E^{-3*}$	$2.0E^{-3*}$	n.a.	$3.6E^{-3}$

*Daily exposure based on the 2 applications / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [8]: PT 6 – Professional users applying car polish	1/-	$3.9E^{-2}$	$9.8E^{-3}$

Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals

Glutaraldehyde is used as preservative for auxiliaries (e.g. re-fattening agents, pigment preparations and optical brightener) used in the leather and textile industry. It is also used as tanning agent in the leather industry in concentrations up to 1.5% which is a factor 30 higher than the concentration in the auxiliaries. In the BREF document of the European

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12 http://www.autogeekonline.net/forum/auto-detailing-101/39994-how-much-polish-sealant-per-car.html (please refer also to the CA report on glutaraldehyde (RMS Finland, 2014))

Commission (2013)[13] it is stated that glutaraldehyde used as tanning agent reacts completely with the proteins found both in the hides and skins and in the effluents and is generally fully exhausted in the tanning process. Therefore, it is assumed that glutaraldehyde exposure when handling treated leathers is negligible. Glutaraldehyde used for the preservation of auxiliaries used in the leather and textile industry will also react with proteins and chemicals during the leather and textile treatment process and exposure to glutaraldehyde when handling the leather/textile is therefore also regarded as negligible. To confirm that the worker exposure during handling of the treated leather is safe exposure of workers handling leather after coating is estimated.

Scenario [9]: PT 6 – Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals

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[13] European Commission (2013), Best Available Techniques (BAT) Reference Document for the Tanning of Hides and Skins. JRC Reference reports.

Description of Scenario [9]		
Glutaraldehyde is used as preservative for auxiliaries (e.g. re-fattening agents, pigment preparations and optical brightener) used in the leather and textile industry. After a typical storage time for the preserved auxiliaries of 4 – 6 weeks they are applied automatically to the leather or textile by special technologies like roll coating or exhaustion processes. The maximum initial concentration of glutaraldehyde present in the formulation is 0.0979%. The exposure of workers handling touch dry leather after coating is estimated using the *BEAT scenario for solvent-based double vacuum timber pre-treatment.* Although glutaraldehyde is used for preservation of aqueous solutions this model is regarded as suitable as the proposed model according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015), BEAT scenario water-based vacuum timber pre-treatment, would lead to an overestimation of the worker exposure due to the described reactions of glutaraldehyde with proteins and chemicals. The relevant indicative values for potential **dermal** exposure are 4 µL/min for body exposure and 1.18 µL/min for actual hand exposure (worker wearing gloves). The indicative value regarding **inhalation** exposure is 0.55 µL/m^3. The estimations include a default duration time of 360 min. In the Tier 1 evaluation the worker is wearing gloves and in the tier 2 evaluation, the worker is wearing gloves and an impermeable coverall (5% penetration). Tier 2 is included as impermeable coveralls are usually recommended to be used when handling leather/textiles. A dermal penetration rate of 10% was applied for glutaraldehyde. The indicative value of 0.55 µL/m^3 potential inhalation exposure provided in the solvent-based double vacuum timber pre-treatment model is regarded to overestimate worker inhalation exposure during leather treatment. The indicative value of 0.55 µL product/m^3 is mainly based on measurements of aerosol formation in the industrial pre-treatment of timber at different industrial sites[14]. Due to the leather/textile treatment process aerosol formation is regarded negligible. Therefore, only a low amount of glutaraldehyde evaporates from matrices and exposure to Protectol® GA 50 by inhalation during leather treatment will be very low and is therefore overestimated in this scenario (for details on evaporation of glutaraldehyde in the matrix please refer to IUCLID Section 10.2). However, the worst-case assumptions are used for risk characterisation.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Potential body exposure [µL/min]	4[1]
	Actual hand exposure [µL/min] (worker wearing gloves)	1.18[1]
	Exposure duration [min]	360[1]
	Dermal absorption [%]	10[2]
	Potential inhalation exposure [µL/m^3]	0.55[1]
	Inhalation rate [m^3/h]	1.25[3]
Tier 2	Protective clothing	Impermeable coverall, 5% penetration; gloves

[1] BEAT scenario solvent-based double vacuum timber pre-treatment; 75th percentiles of fitted log normal distributions to solvent based timber pre-treatment data set is used
[2] CA Report on glutaraldehyde (RMS Finland, 2014)
[3] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [9]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [9]: PT 6 – Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals	1/ gloves	$6.73E^{-5}$	$3.0E^{-3}$	n.a.	$3.1E^{-3}$
	2/Impermeable coveralls, 5% penetration; gloves	$6.73E^{-5}$	$8.E^{-4}$	n.a.	$8.8E^{-4}$

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[14] Garrod, A.N.I., Martinez, J., Pearson, J., Proud, A. and Rimmer, D.A. (1999) Exposure to Preservatives Used in the Industrial Pre-treatment of Timber. Annals of Occupational Hygiene 43(8), 543-555. (publication cited in BEAT)

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [9]: PT 6 – Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals	1/ gloves	$5.4E^{-4}$	$4.1E^{-4}$
	2/Impermeable coveralls, 5% penetration; gloves	$5.4E^{-4}$	$4.1E^{-4}$

Professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics

Glutaraldehyde is used for the preservation of pigment and polymer dispersions used for plastic and paints and for the preservation of water-based paints. The majority of Protectol GA® 50 is used as preservative of dispersions used in plastic and paint production. For assessing the worst-case, the direct exposure of workers during the use of a preserved paint is calculated. Two scenarios are considered: professional workers using spray paints (Scenario [10a]) and rolling or brushing the paint (Scenario [10b]).

Scenario [10a]: PT 6 – Professional users spraying paints

Description of Scenario [10a]

For calculation of worker exposure during spraying of preserved paint the BEAT model "Spray application of masonry preservative" was used. This model was agreed to be the most appropriate model for this scenario in recently accepted PT7 active substance evaluation.
The maximum initial concentration of glutaraldehyde in the preserved formulations is 0.0979%. Calculations using glutaraldehyde concentration of 0.04895% after degradation has also been used. The indicative values are 261 µL/min for body exposure and 9.4 µL/min for potential hand exposure. The indicative value regarding inhalation exposure is 97.5 µL/m^3. The default exposure duration is 360 min. In the Tier 2 refinement the worker is wearing a coated coverall with 10% penetration. In the Tier 3 refinement, the worker is also wearing a coated coverall, gloves (10% penetration) and RPE (10% penetration). In the Tier 4 refinement, the degradation of glutaraldehyde during the storage period is considered and the worker is wearing a coated coverall, gloves (10% penetration) and RPE (10% penetration). A dermal penetration rate of 10% was applied for glutaraldehyde. The indicative value of 97.5 µL/m^3 for inhalation exposure is regarded to overestimate worker inhalation exposure during paint spraying. The amount of glutaraldehyde in the air space of a container containing a matrix preserved with 500 mg/L glutaraldehyde after a typical storage and transport period of at least two weeks was measured. Only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration (500 mg/L glutaraldehyde)) of glutaraldehyde were evaporated. Therefore, only a low amount of glutaraldehyde evaporates from matrices and is available in the vapour, which reduces the potential inhalation to Protectol® GA 50. Nevertheless, RPE is recommended for spraying processes and therefore this worst-case estimation is used for risk characterisation.
If paints are used containing pigments preserved with Protectol® GA 50 there is an additional dilution step when applying the preserved pigments in the paints. In this step, pigments are further diluted to paints to form 20-25 % dilution. Therefore, the worst-case estimation covers also the use of preserved pigments as for the 20-25% dilution there is no requirement for RPE based on the risk assessment. However, RPE is always recommended in the spraying process.

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Glutaraldehyde concentration after degradation [%]	0.04895 (Tier 3 and 4)
	Potential body exposure [µL/min]	261^1
	Potential hand exposure [µL/min]	238^1
	Actual hand exposure [µL/min]	9.4^1
	Exposure duration [min]	360^1
	Clothing type	Coated coveralls, 10% penetration^2
	Dermal absorption [%]	10^3
	Potential inhalation exposure [µL/m^3]	97.5^1

	Inhalation rate [m^3/h]	1.25[4]
Tier 2	Actual hand exposure [µL/min]	9.4[1]
	PPE	RPE (10% penetration)[2]

[1] BEAT model Masonry Preservatives.
[2] HEEG opinion 9 on default protection factors for protective clothing and gloves, TM I 2010
[3] CA Report on glutaraldehyde (RMS Finland, 2014)
[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [10a]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [10a]: PT 6 – Professional users spraying paints	1/ no PPE	0.0119	0.293	n.a.	0.305
	2/Gloves, Coated coveralls, 10% penetration, RPE, 10 % penetration	0.00119	0.0209	n.a.	0.0221
	3/Gloves, Coated coveralls, 10% penetration, glutaraldehyde degradation 50%	0.0.00597	0.0104	n.a.	0.0164
	4/Gloves, Coated coveralls, 10% penetration, and RPE, 10% penetration, glutaraldehyde degradation 50%	0.000597	0.0104	n.a.	0.0110

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [10a]: PT 6 – Professional users spraying paints	1/ -	0.095	0.071
	2/Gloves, Coated coveralls, 10% penetration, RPE, 10% penetration	0.0095	0.0071
	3/Gloves, Coated coveralls, 10% penetration, glutaraldehyde degradation 50%	0.048	0.036
	4/Gloves, Coated coveralls, 10% penetration, and RPE, 10% penetration, glutaraldehyde degradation 50%	0.0048	0.0036

Scenario [10b]: PT 6 – Professional users rolling/brushing paints

<table>
<tr><th colspan="3">**Description of Scenario [10b]**</th></tr>
<tr><td colspan="3">For calculation of worker exposure during rolling/brushing the preserved paint the *PT8 Professional brush treatment model* is used which is recommended for brush or combined brush/roller painting according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015). The maximum initial concentration of glutaraldehyde in the preserved formulations is 0.0979%. The default application time according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015) is 240 min.
The indicative values are 0.2382 mg/m^2 for potential body exposure and 0.5417 mg/m^2 for potential hand exposure and the application area is 31.6m^2. The indicative value regarding inhalation exposure is 0.0016 mg/m^2. A dermal penetration rate of 10% was applied for glutaraldehyde. The indicative values are considered to be sufficiently conservative, because e.g. evaporation of glutaraldehyde from preserved paint formulations was shown to be negligible (<0.001% of glutaraldehyde content in paint evaporates). The amount of inhalable aerosols during brush application of preserved paints is also considered to be negligible.</td></tr>
<tr><td></td><td>Parameters</td><td>Value</td></tr>
<tr><td rowspan="8">Tier 1</td><td>Glutaraldehyde max. concentration [%]</td><td>0.0979</td></tr>
<tr><td>Potential body exposure [mg/m^2]</td><td>0.2382[1]</td></tr>
<tr><td>Potential hand exposure [mg/m^2]</td><td>0.5417[1]</td></tr>
<tr><td>Application area [m^2]</td><td>31.6[1]</td></tr>
<tr><td>Exposure duration [min]</td><td>240[1]</td></tr>
<tr><td>Dermal absorption [%]</td><td>10[2]</td></tr>
<tr><td>Potential inhalation exposure [mg/m^2]</td><td>0.0016[1]</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>

CA Report on glutaraldehyde (RMS Finland, 2014)[1] Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015) (indicative values normalised to 1% active substance). McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

Output table with detailed dermal calculation is found in Annex 3.2.

Calculations for Scenario [10b]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [10b]: PT 6 – Professional users rolling/brushing paints	1/-	8.25^{-5}	$4.0E^{-3}$	n.a.	$4.10E^{-3}$

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
	1/ -	$1.60E^{-3}$	$7.98E^{-4}$
Scenario [10b]: PT 6 – Professional users rolling/brushing paints			

Professional use as preservative for paper wet-end additives and paper coatings

The exposure of professional users resulting from preservation of paper wet-end additives or paper coatings during the papermaking process is calculated. The first exposure estimation (scenario [11a]) is conducted according to the CA report on glutaraldehyde (RMS Finland, 2014)) and is regarded as worst-case estimation for pulps (cellulose and additives) that have been fully preserved with glutaraldehyde (semiautomated loading/use of preserved slurry). However, typically actual glutaraldehyde concentrations during preservation of paper wet-end additives or paper coatings are considerably lower, because of the dilution of preserved additives and coatings. Therefore, a second scenario for preserved additives/coatings is added (semiatomated loading / use of preserved additives in slurry, scenario [11b]).

Scenario [11a]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – fully preserved pulp (cellulose and additives)

Description of Scenario [11a]		
Additives containing glutaraldehyde as in-can preservative are used by professionals in the papermaking process (semiautomated loading/use of preserved slurry). These additives (e.g. kaolin slurry used in the wet-end stage of paper production) generally contain maximum 0.0979% of glutaraldehyde. Paper mill workers at the wet-end and drying stages of the paper mill normally work remotely from the paper machines, controlling the paper manufacturing operations *via* computers located in air-conditioned rooms away from the noise, elevated temperatures and odours of the paper machines. Periodic exposure to glutaraldehyde could potentially arise when (i) workers load and unload storage tanks containing preserved slurry (up to 0.0979% glutaraldehyde; (semi)automated process), (ii) from volatilisation of glutaraldehyde from the "white water" or (iii) from entering the paper machine areas to adjust and maintain the machines. The drying section of the paper mill is where the highest airborne concentrations of glutaraldehyde might be expected to occur. However, most of the glutaraldehyde was already removed together with about >90% of the water and due to the high temperature during the papermaking process the remaining glutaraldehyde will degrade even faster and the steam produced is extracted by means of powerful fans and any traces of volatilised glutaraldehyde are extracted at the same time. Due to the described processes, no aerosol formation is expected. Therefore, inhalation exposure of the professional user will be very low and the calculation below is regarded as worst-case estimation. Exposure duration is estimated to be 120 min. As described in the CA report on glutaraldehyde (RMS Finland, 2014) *RISKOFDERM (loading liquid, automated or semi-automated) and EASE model within EUSES version 2.0.3* could be used to assess the potential exposure to the operator loading and unloading slurry tanks. Measurements of atmospheric glutaraldehyde concentrations conducted in actual paper mills (Report Ref. GAWORKERSEXPOSLIMICIDE.DOC (2000); please refer to the CA report on glutaraldehyde (RMS Finland, 2014)) have been used to set the maximum airborne concentration (0.087 mg/m^3) of glutaraldehyde to which a worker may be exposed. Tier 1 assumes that the operator is not wearing personal protective equipment (PPE). Tier 2 assumes that gloves and coated coveralls with 10% penetration are used. In Tier 3, in addition RPE is assumed to be used with a penetration of 10%.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Potential body exposure [mg/min]	2.02[1]
	Potential hand exposure [mg/min]	101[1]
	Maximum airborne concentration [mg/m^3]	0.087
	Exposure duration [min]	120
	Dermal absorption [%]	10[2]
Tier 2	PPE	Gloves (10% penetration)[3]
	Clothing type	Coated coveralls (10% penetration)[3]
Tier 3	PPE	Gloves (10% penetration)[3] RPE (10%)[4]

	Clothing type	Coated coverall (10% penetration)[3]

1 HEEG Opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, TM I 2008; Table 3 RISKOFDERM (loading liquid)
2 CA Report on glutaraldehyde (RMS Finland, 2014)
3 HEEG opinion 9 on default protection factors for protective clothing and gloves, TM I 2010
4 TNsG on human exposure (2007)

Calculations for Scenario [11a]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [11a]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – fully preserved pulp (cellulose and additives)	1/-	0.003625	0.0202	n.a.	0.0238
	2/Coated coveralls, 10% penetration and gloves	0.003625	0.0020	n.a.	0.0056
	3/ Coated coveralls, 10% penetration, gloves and RPE, 10%	0.0003625	0.0020	n.a.	0.0024

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m^3]	
Scenario [11a]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings - fully preserved pulp (cellulose and additives)	1/-	0.087	0.022
	2/Coated coveralls, 10% penetration and gloves	0.087	0.022
	3/ Coated coveralls, 10% penetration, gloves and RPE, 10%	0.0087	0.0022

Scenario [11b]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – preserved paper additive(s) only

Description of Scenario [11b]

Additives containing glutaraldehyde as in-can preservative are used by professionals in the papermaking process (semiautomated loading / use of preserved additives in slurry). These additives (e.g. kaolin slurry used in the wet-end stage of paper production) generally contain maximum 0.0979%. These slurries are then further diluted during the papermaking process. The amount of the preserved slurries in the paper is approx. 20%, i.e. the glutaraldehyde content in the paper is further reduced to a maximum of 0.00196%. Paper mill workers at the wet-end and drying stages of the paper mill normally work remotely from the paper machines, controlling the paper manufacturing operations *via* computers located in air-conditioned rooms away from the noise, elevated temperatures and odours of the paper machines. Periodic exposure to glutaraldehyde could potentially arise when (i) workers load and unload storage tanks containing preserved additives in slurry (up to 0.0979% glutaraldehyde; (semi)automated process) (ii) from volatilisation of glutaraldehyde from the "white water" or (iii) from entering the paper machine areas to adjust and maintain the machines. The drying section of the paper mill is where the highest airborne concentrations of glutaraldehyde might be expected to occur. However, most of the glutaraldehyde was already removed together with about >90% of the water and due to the high temperature during the paper making process the remaining glutaraldehyde will degrade even faster and the steam produced is extracted by means of powerful fans and any traces of volatilised glutaraldehyde are extracted at the same time. Due to the described processes, which are generally fully automated, no aerosol formation is expected and the highest exposure is reached during loading/unloading of slurry tanks. Therefore, exposure to workers loading/unloading slurry tanks is calculated.

To assess the potential **dermal** exposure to the operator (assumed body weight: 60 kg) loading and unloading slurry tanks (maximum 0.0979% glutaraldehyde) *RISKOFDERM Toolkit (Connecting line)* was used. The indicative value for dermal exposure is 0.92 mg/min. Dermal exposure will be exclusively on the hands (820 cm^2), resulting from accidentally touching contaminated parts. Exposure duration is estimated to be 120 min.

For estimation of the **inhalation** exposure to glutaraldehyde the highest indicative value for manual loading/pouring procedures of liquids as provided in the HEEG Opinion 1 (TM I 08) has been considered (1.9 mg/m^3; mixing and loading model 6, TNsG part 2, p 138). As the described processes are highly automated these calculations are regarded as worst-case estimations.

This scenario also covers the further processing of the preserved slurries during the ongoing papermaking. As described, the additives/coatings are further diluted (1:5) and degradation processes are ongoing leading to lower glutaraldehyde concentrations in the paper.

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Actual hand exposure [mg/min]	0.92[1]
	Exposure duration [min]	120
	Dermal absorption [%]	10[2]
	Potential inhalation exposure [mg/m3]	1.91[3]

1 HEEG Opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, TM I 2008

2 CA Report on glutaraldehyde (RMS Finland, 2014)

3 Biocides guidance database for human exposure and Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015)

Output table with detailed dermal calculation is found in Annex 3.2.

Calculations for Scenario [11b]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [11b]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – preserved paper additive(s) only	1/-	7.79E^{-5}	1.8E^{-4}	n.a.	2.6E^{-4}

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m^3]	
Scenario [11b]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – preserved paper additive(s) only	1/-	1.87E^{-3}	4.68E^{-4}

Secondary (Indirect) Exposure during the paper making process

There should be no secondary (indirect) exposure as the glutaraldehyde present during the papermaking process will be degraded by the following routes and will not be present in the final article:

1. Loss of glutaraldehyde (~25%) by evaporation in the drying section and coating press (residues will be trapped in a scrubber).
2. Glutaraldehyde undergoes aldol condensation under alkaline conditions. The rate of this reaction depends mainly on the pH and the temperature of the water; high pH and warm conditions speed up the reaction. The temperature and pH conditions that prevail

in the paper machine are as follows: T ≥ 35° C and pH = 8. Under these conditions, a half-life T ≤ 61 days can be computed.

3. Reaction with micro-organisms renders the glutaraldehyde inactive.

Following tests (GAFATEPP.DOC (1998), please refer to the CA report on glutaraldehyde (RMS Finland, 2014) it has been shown that paper that is produced in paper mills that use 50% glutaraldehyde as a preservative for the additives do not contain detectable glutaraldehyde residues and can therefore be used to pack food. The US FDA clearance (FDA 21CFR 176.170/180), the German BfR 36 and the Dutch WarenWet confirm such paper to be safe for food wrapping.

Professional use as preservative for polymer dispersions e.g. glues and raw material thereof

The exposure of professional users resulting from preservation of polymer dispersions e.g. glues and raw material thereof is calculated.

Scenario [12]: PT 6 – Professional use as preservative for polymer dispersions e.g. glues and raw material thereof

Description of Scenario [12]

Glutaraldehyde is used for the preservation of glues and raw materials thereof. For assessing the worst-case, the exposure of workers during the use of preserved glue is calculated. The maximum concentration of glutaraldehyde in the formulation is 0.0979%. As described at the beginning of the PT6 chapter and in Section 'Monitoring data', the preserved formulation is usually stored before using and glutaraldehyde decomposes during this storage period. The half-life of glutaraldehyde in complex matrices (i.e. a wall paint containing > 10% acrylate and doped with 500 mg/L glutaraldehyde) is approximately 2 weeks and a period of 14 days after filling is at least needed (for selling and transport processes) until the preserved formulation can be used by a downstream user (for details on degradation of glutaraldehyde in the matrix please refer to IUCLID Section 10.2, Rohwer 2016a). As the polyacrylate dispersions, calcium carbonate fillers and pigments are present in the compositions of both wall paints and glues, the results could be assigned to glues and therefore it is assumed that the maximum concentration of glutaraldehyde present in the glue will be 0.04895% (Tier 3).

For calculation of worker exposure during the use of preserved glues the default model for *DIY products - Glues - Carpet glue – Application* of ConsExpo Web is used. This is also in agreement with Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015) in which the scenario "Use of glues and adhesives by professional and non-professional users" represents the worst-case for glues, adhesives, sealants.

For the estimation of **dermal** exposure, the constant rate (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The contact rate is 30 mg/min, the release duration 4,500 sec and the exposed area 110 cm^2. A dermal penetration rate of 10% was applied for glutaraldehyde. This is regarded as worst-case as it is assumed that glutaraldehyde will not be very mobile in the viscous matrix of glues compared to an aqueous solution.

For the assessment of **inhalation** exposure, the ConsExpo evaporation model from constant surface is used (uptake: fraction). The default values for the application and exposure durations are 75 minutes. The product amount is 9,000 g, the room volume into which the glutaraldehyde vapour evaporates is 58m^3. Ventilation is assumed to be 0.5/h. The inhalation rate for the person is 1.25 m^3/h. The release area is 40,000 cm^2. Sparks method as discussed in McCready and Fontaine (2010) was chosen for evaporation. This task was estimated to be carried out 1 times/day (260/year for a professional worker). As only water-based glues are intended for preservation with Protectol® GA 50 the default molecular weight matrix of 3,000 g/mol was reduced to 45 g/mol. According to the Painting Products Fact Sheet a molecular weight matrix of 45 g/mol is the default value for waterborn paints with 40% water. This is also regarded as representative for the water-based glues preserved with Protectol® GA 50. The calculated exposure value is regarded as worst-case estimate. As described at the beginning of the PT6 chapter and in the Section 'Monitoring data', the preserved formulation is usually stored before using. After a typical storage and transport period of at least two weeks only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration (500 mg/L glutaraldehyde)) of evaporated glutaraldehyde are available when opening the container at customer sites, i.e. exposure with Protectol® GA 50 by inhalation during application of glues is very low (for details on evaporation of glutaraldehyde in the matrix please refer to IUCLID Section 10.2, Rohwer 2016b). When degradation is taken into account, 9,000 g product contains 4,406 mg glutaraldehyde (9,000 g × 0.00049 × 1,000). Considering the described results of the evaporation test 0.044 mg glutaraldehyde will evaporate (4,406 mg × 0.00001) in a room volume of 53 m^3, which leads to a glutaraldehyde concentration in air of 0.8312 µg/m^3. Taken into account the application duration and the inhalation rate the estimated inhalation uptake is 0.0216 µg/kg bw. However, the ConsExpo-modelled worst-case assumptions are used for risk characterisation.

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure duration [min]	75[1] (260 times/year)
	Exposed area [cm^2]	110[1]
	Contact rate [mg/min]	30[1]
	Release duration [sec]	4,500[1]
	Dermal absorption [%]	10[2]
	Room volume [m^3]	58[1]
	Ventilation rate [1/h]	0.5[1]
	Applied amount (inhalation) [g]	9,000[1]
	Release area [cm^2]	40,000[1]
	Application duration [min]	75[1]
	Molecular weight matrix [g/mol]	45[3]
	Mass transfer rate [m/min]	0.052[4]
	Uptake fraction (inhalation) [%]	100[1]
	Inhalation rate [m^3/h]	1.25[5]
Tier 2	Respirary protective equipment	10%
Tier 3	Glutaraldehyde concentration after degradation [%]	0.04895

[1] ConsExpo Web default value (Default model: DIY products - Glues - Carpet glue – Application / DIY Products Fact Sheet)

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

[3] As only water-based glues are intended for preservation with Protectol® GA 50 the default molecular weight matrix of 3000 g/mol was reduced to 45 g/mol.

[4] McCready and Fontaine (2010) Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Hum Ecol Risk Assess 16(4)

[5] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [12]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [12]: PT 6 – Professional use as preservative for polymer dispersions e.g. glues and raw material thereof	1/-	$2.1E^{-3*}$	$3.7E^{-3*}$	n.a.	$5.8E^{-3}$
	2/RPE, 10%	$2.1E^{-4*}$	$3.7E^{-3*}$		$3.9E^{-3}$
	3/ Glutaraldehyde degradation 50%, no RPE	$1.1E^{-4}$	$1.8E^{-3}$		$1.9E^{-3}$

* Daily exposure based on the 1 application / day.

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [12]: PT 6 – Professional use as preservative for polymer dispersions e.g. glues and raw material thereof	1/-	$8.1E^{-2}$	$1.3E^{-2}$
	2/RPE, 10%	$8.1E^{-3}$	$1.3E^{-3}$
	3/ Glutaraldehyde degradation 50%, no RPE	$4.1E^{-2}$	$6.4E^{-3}$

Further information and considerations on scenarios [1-12]

According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) glutaraldehyde (100%) is classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde is labelled with EUH071, Corrosive to respiratory tract. Skin sensitisation has been clearly demonstrated, and human data indicates that glutaraldehyde has to be considered as a respiratory sensitizer as well (Skin Sens. 1A, H317 May cause an allergic skin reaction and Resp. Sens. 1, H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled). The critical effects are therefore characterised by irritation and tissue damage at the site of contact, and by respiratory and skin sensitization. According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) there is a specific concentration limit of $0.5\% \leq C < 5$ concerning respiratory irritation. For the other local effects, the generic concentration limits of the CLP legislation apply (i.e. 0.1% for skin sensitisation and 1% for respiratory sensitisation and 5% for skin corrosion). Therefore, there is a risk regarding the

described local effects when handling the pure biocidal product Protectol® GA 50, a 50% aqueous solution of glutaraldehyde. However, the risk can be controlled by using the respective PPE and there is no risk of irritation or sensitisation when handling the treated articles (glutaraldehyde concentrations < 0.1%).
A qualitative and / or a (semi-)quantitative risk assessment is performed regarding these local effects (see Risk characterisation). According to BPR: Volume III Part B (ECHA; Oct 2015) the substance has to be assigned to the hazard category 'very high'.

Combined scenarios

A professional could do the loading and also the application of liquid dish washing detergent or liquid detergent for hand washing on one day. Therefore, the scenarios for mixing and loading [2 or 4] and application [3 or 5] were combined.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
	mg/kg bw/day			
Scenario [2] & [3] PT6 - Professional users mixing and loading/applying liquid dish washing detergent; Tier 1	$3.1E^{-7}$	$3.5E^{-4}$	n.a.	$3.5E^{-4}$
Scenario [4] & [5] PT 6 – Professional users loading/applying liquid detergent for hand washing; Tier 1	$4.0E^{-4}$	$3.4E^{-3}$	n.a.	$3.8E^{-3}$

Non-professional exposure

Six different consumer products which contain glutaraldehyde as an in-can preservative have been assessed. These include laundry softener, liquid dish washing detergent, liquid detergent for hand washing, wax emulsion, car polish and paints. ConsExpo has been used

to perform the exposure assessment calculations. Because all non-professional scenarios except applying car polish and applying spray paint are identical with the professional scenarios they were not redrafted. The only difference is the frequency of use, which is higher with professionals and represents therefore a worst-case estimate for non-professionals.
Regarding the use of glutaraldehyde as preservative of auxiliaries used in leather and textile industry and polymer dispersions of glues no non-professional use is intended. Also, the preservation during the paper-making process is professional use only. Therefore, no non-professional exposure assessment for these uses is conducted.

Non-professional users applying detergents preserved with Protectol® GA 50

The exposure of non-professional users resulting from application of several representative detergents preserved with Protectol® GA 50 is calculated.

Scenario [13] PT 6 – Non-professional users mixing and loading liquid dish washing detergent

See Scenario [2]

Scenario [14]: PT 6 – Non-professional users applying liquid dish washing detergent

See Scenario [3]

Scenario [15]: PT 6 – Non-professional users loading liquid detergent for hand washing

See Scenario [4]

Scenario [16]: PT 6 – Non-professional users applying liquid hand washing detergent

See Scenario [5]

Scenario [17]: PT 6 – Non-professional users loading laundry softener

See Scenario [6]

Non-professional users applying wax emulsion

Scenario [18a]: PT 6 – Non-professional users applying undiluted wax emulsion

See Scenario [7a]

Scenario [18b]: PT 6 – Non-professional users applying diluted wax emulsion

See Scenario [7b]

Scenario [19]: PT 6 – Non-professional users applying car polish

Description of Scenario [19]		
The calculations are based on the U.S. Environmental Protection Agency (1986) standard scenarios for estimating exposure to chemical substances during use of consumer products. The maximum concentration of glutaraldehyde present in the product is 0.0979%. The following inputs have been used according to Ad hoc Working Group on Human Exposure Recommendation 14: the skin surface area exposed of 410 cm^2 is the palms and outstretched fingers of both hands for an average adult. The density of the product is 1.022 g/cm^3. The product film thickness on the skin is 0.00325 cm. It is assumed that the non-professional user polishes their car six times a year. The US EPA (1986) assumed this activity occurs outdoors in the open air so inhalation exposure will be negligible.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Product on the skin [mg]	1.362[1]
	Skin surface area [cm^2]	410[2]
	Active substance on skin [mg]	133.30
	External dermal loading (active substance) [mg/cm^2]	0.00325
	Internal active dose *via* skin [mg]	0.13
	Dermal absorption [%]	10[1]

[1] Calculated based on the HEEG Recommendation No 14 on the default values (410 cm x 0.00325 cm x density 1.022 g/cm).

[2] BPC Ad hoc Working Group on Human Exposure Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products.

Calculations for Scenario [19]

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [19] PT 6 – Non-professional users applying car polish	1/-	n.a.	0.0022	n.a.	0.0022

Non-professional users applying organic particle dispersions preserved with Protectol GA® 50 e.g. pigment and polymer dispersions used in paints and plastics

The exposure of non-professional users resulting from spraying a paint preserved with Protectol® GA 50 is calculated.

Scenario [20]: PT 6 – Non-professional users applying spray paints

Description of Scenario [20]

Glutaraldehyde is used for the preservation of pigment and polymer dispersions used for plastic and paints and for the preservation of water-based paints. Most of the application is as preservative of dispersions used in plastic and paint production, but for assessing the worst-case, the direct exposure of non-professionals during the use of a preserved paint is calculated. The theoretically maximum concentration of glutaraldehyde in preserved paints is 0.0979%.

For calculation of non-professional exposure during the use of a preserved paint ConsExpo Web is used. The calculations are based on the default model *for Painting Products – Spray painting – Pneumatic spraying - Application*. This task was estimated to be carried out by a non-professional 2 times/year.

For the estimation of **dermal** exposure, the constant rate (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The exposed area of 9,519 cm^2 is a worst-case estimation including hands, forearms, head, feet and legs. The contact rate is 110 mg/min and the release duration 798 sec. A dermal penetration rate of 10% was applied for glutaraldehyde.

For the assessment of **inhalation** exposure, the ConsExpo spray model is used (uptake: fraction). Spray duration is 13.3 min and exposure duration 25 min. The room volume is 34 m^3 and ventilation rate 1.5/h. This inhalation exposure is regarded as worst-case. This spray scenario considers aerosol and vapour formation during spraying. The amount of glutaraldehyde in the air space of a container containing a matrix preserved with 500 mg/L glutaraldehyde after a typical storage and transport period of at least two weeks was measured. Only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration (500 mg/L glutaraldehyde)) of glutaraldehyde were evaporated. Therefore, only a low amount of glutaraldehyde evaporates from complex matrices, such as paints, and is available in the vapour, which reduces the potential inhalation of Protectol® GA 50 (Rohwer, 2016b). However, the worst-case ConsExpo-estimation is taken for risk characterisation.

For the assessment of the non-respirable **oral** uptake the oral uptake fraction is 40%.

This estimation also covers non-professionals rolling/brushing paints as estimated inhalation uptake is markably higher in spraying applications than in brush/roller applications.

Tier 1	Parameters	Value
	Glutaraldehyde max. concentration [%]	0.0979
	Exposed area [cm^2]	9,519[1]
	Contact rate [mg/min]	110[1]
	Release duration [sec]	798[1]
	Dermal absorption [%]	10[2]
	Spray duration [min]	13.3[1]
	Exposure duration [min]	25[1]
	Room volume [m^3]	34[1]
	Room height [m]	2.25[1]
	Ventilation rate [1/h]	1.5[1]

	Mass generation rate [g/sec]	0.5[1]
	Airborne fraction [fraction]	0.20[1]
	Weight fraction non-volatile [fraction]	0.5[1]
	Density non-volatile [g/cm^3]	1.5[1]
	Inhalation cutoff diameter [µm]	15[1]
	Inhalation rate [m^3/h]	1.25[3]
	Oral absorption [%]	40[2]

[1] ConsExpo Web default value (Default model: Painting Products – Spray painting – Pneumatic spraying / Painting Products Fact Sheet)

[2] CA Report on glutaraldehyde (RMS Finland, 2014)

[3] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [20]

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [20]: PT 6 – Non-professional users applying spray paints	1/-	0.0024	0.0024	1.5E^{-4}	0.0050

Summary table: estimated acute and daily (24 h TWA) inhalation dose from non- professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (24 h TWA)**
		[mg/m^3]	
Scenario [20]: PT 6 – Non-professional users applying spray paints	1/-	0.28	4.9E^{-3}

Further information and considerations on scenarios [13-20]

According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) glutaraldehyde (100%) is classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde is labelled with EUH071, Corrosive to respiratory tract. Skin sensitisation has been clearly demonstrated, and human data indicates that glutaraldehyde has to be considered as a respiratory sensitizer as well (Skin Sens. 1A, H317 May cause an allergic skin reaction and Resp. Sens. 1, H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled). The critical effects are therefore characterised by irritation and tissue damage at the site of contact, and by respiratory and skin sensitization. According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) there is a specific concentration limit of $0.5\% \leq C < 5$ concerning respiratory irritation. For the other local effects, the generic concentration limits of the CLP legislation apply (i.e. 0.1% for skin sensitisation and 1% for respiratory sensitisation and 5% for skin corrosion). Therefore, there is no risk regarding the described local effects for non-professionals as they will only handle treated articles preserved with Protectol® GA 50 (glutaraldehyde concentrations < 0.1%).

Combined scenarios

For the non-professionals, the same combined scenarios are relevant as for the professionals (mixing and loading and application of liquid dish washing detergent or liquid detergent for hand washing). As these scenarios are identical to the professional scenarios they are not redrafted, please refer to the professional section for details (Combined scenarios [2] & [3] and [4] & [5]).

Exposure of the general public

Scenario [21] PT 6 – Secondary (Indirect) exposure of the general public from detergent or fabric softener residues from textiles/clothes

Description of Scenario [21]		
Secondary exposure from detergents and laundry softeners has been estimated using the ConsExpo Cleaning Product Fact Sheet and ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Laundry products - Fabric conditioner – Post application* as presumably the fraction of residues on clothes is higher when one is using fabric conditioner instead of liquid detergent. This is because fabric conditioner is added at the last rinsing cycle of the washing machine. The estimation of secondary exposure to residues in clothes using the ConsExpo Cleaning Product Fact Sheet is in agreement with Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure (agreed on 28th January 2015). Compared to the results based on the considerations of HERA Guidance Document Methodology (2005) the calculated exposure values are higher and therefore regarded as worst-case. The maximum concentration of glutaraldehyde present in the detergent is 0.0979%. This concentration is used for assessing the worst-case risk for the general public regarding secondary exposure from detergents and laundry softeners. For the estimation of **dermal** exposure, the migration (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. Exposed area is the clothing area in direct contact with the skin, which is about 50% of the mean surface area of an adult body surface area. According to Cleaning Product Fact Sheet a typical amount of laundry softener is 68 g/5 kg laundry. Worst case, it is assumed that 50% is deposited on the fabric. Further, it is assumed that 50% of the residues of the fabric conditioners are leachable. The leachable fraction is 3.33E^{-6} (0.0034 × 0.000979) and the skin contact factor 0.8. A dermal penetration rate of 10% was applied for glutaraldehyde. As no markable residues are not expected to be left to the fabric after washing due to the high reactivity of the glutaraldehyde, this worst-case scenario is considered to cover also the risk caused by toddler mouthing the fabric.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Exposure frequency [1/day]	365[1]
	Exposed area [cm^2]	9,550[1]
	Leachable fraction	3.33E^{-6} [1]
	Skin contact factor	0.8[1]
	Product amount [g]	1,000[1]
	Dermal absorption [%]	10[2]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Laundry products - Fabric conditioner – Post application / Cleaning Products Fact Sheet)
[2] CA Report on glutaraldehyde (RMS Finland, 2014)

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [21]

Summary table: systemic exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [21]: PT 6 – Secondary (Indirect) exposure of the general public from detergent or fabric softener residues from textiles/clothes	1/-	n.a.	$4.4E^{-3}$	n.a.	$4.4E^{-3}$

Scenario [22] PT 6 – Secondary (Indirect) exposure of the general public to liquid dishwashing detergent

Description of Scenario [22]		
Secondary exposure from consuming residues of liquid dish washing detergent present on crockery following washing has been estimated using ConsExpo Web. The calculations are based on the default model for *Cleaning & Washing - Dishwashing products - Hand dishwashing liquid– Post application*. The maximum concentration of glutaraldehyde present in the dishwashing detergent is 0.0979 %. This concentration is used for assessing the worst-case risk for the general public regarding secondary exposure from dish washing detergents. For the estimation of **oral** exposure, the direct intake (uptake: fraction) model of ConsExpo is used. A body weight of 60 kg is considered. The ingested amount is 0.00042 g and oral absorption 40%. The scenario 22 is seen as a worst-case scenario of dietary exposure food contact with Protectol GA 50 used as liquid diswashing detergent is likely, and as exposure is relatively high because of the large surface area containing residues that is in contact with food and because it occurs on a daily basis.		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Amount ingested [g]	0.00042[1]
	Oral absorption [%]	40[2]

[1] ConsExpo Web default value (Default model: Cleaning & Washing - Dishwashing products - Hand dishwashing liquid– Post application / Cleaning Products Fact Sheet)
[2] CA Report on glutaraldehyde (RMS Finland, 2014)

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [22]

Summary table: systemic exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [22]: PT 6 – Secondary (Indirect) exposure of the general public to liquid dish washing detergent	1/-	n.a.	n.a.	2.7E^{-6}	2.7E^{-6}

Scenario [23] PT 6 – Toddler -dermal contact with wet paint and mouthing

Description of Scenario [23]

Secondary exposure of a toddler touching a wet painted surface and mouthing is evaluated using Recommendation No. 5 of the BPC Ad hoc Working Group on Human Exposure: non-professional use of antifouling paints: exposure assessment for a toddler. This is relevant for other types of paint also. Dermal exposure to wet paint and oral exposure through hand-to-mouth transfer are calculated. Paint contains glutaraldehyde as an in-can preservative (PT6).
(See Scenario [20] - *Non-professional users applying spray paints.)*

	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.0979
	Total area of toddler hands (palms and backs of both hands) [cm^2]	230.4[1]
	Toddler body weight [kg]	10[1]
	Application rate for paint (non-professional) application [ml paint/cm^2]	0.01[2]
	Density of the wet paint [g/ml]	1
	Application rate for paint (non-professional) application [mg paint/cm^2]	10
	Transfer coefficient of wet paint from treated surface to hand [%]	50
	Amount of a.s. per unit treated surface area for wet paint [mg glutaraldehyde/cm^2]	**$9.8E^{-4}$**
	Total area of toddler hands in contact with the removed wet paint [cm^2]	115.2
	Amount of a.s. on palms of both hands from contact with removed wet paint [mg a.s.]	**$5.6E^{-2}$**
	DERMAL EXPOSURE TO WET PAINT	
	Amount of a.s. per unit treated surface area for wet paint – that is transferable from treated surface to the hand [mg a.s./cm^2]	0.00049
	SYSTEMIC DERMAL EXPOSURE TO WET PAINT [mg a.s./kg bw/event]	
	Dermal absorption [%]	10[3]
	Amount of a.s. absorbed through the skin [mg glutaraldehyde]	$5.6E^{-3}$
	Systemic DERMAL exposure to wet paint [mg glutaraldehyde/kg bw/event]	$5.6E^{-4}$

	ORAL EXPOSURE TO WET PAINT	
	Transfer coefficient of wet paint from hand to mouth (i.e. from two fingers only) [%]	10
	Amount of a.s. transferrable to the mouth [mg a.s.]	$5.6E^{-3}$
	Oral absorption [%]	40[3]
	Amount of a.s. ingested [mg glutaraldehyde]	$2.3E^{-3}$
	Systemic ORAL exposure to wet paint [mg a.s./kg bw/event]	2.3^{-4}

[1] Recommendation No. 12 of BPC Ad hoc Working group on Human Exposure – Default human factor values for use in exposure assessments for biocidal products

[2] Calculated from a general default of 10 m^2/l for paint coverage based on use instructions of paint products

[3] CA Report on glutaraldehyde (RMS Finland, 2014)

Summary table: systemic exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [23]: PT 6 – Toddler -dermal contact with wet paint and mouthing.	1/-	n.a.	$5.6E^{-4}$	$2.3E^{-4}$	$7.9E^{-4}$

Further information and considerations on scenario [21-23]

According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) glutaraldehyde (100%) is classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde is labelled with EUH071, Corrosive to respiratory tract. Skin sensitisation has been clearly demonstrated, and human data indicates that glutaraldehyde has to be considered as a respiratory sensitizer as well (Skin Sens. 1A, H317 May cause an allergic skin reaction and Resp. Sens. 1, H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled). The critical effects are therefore characterised by irritation and tissue damage at the site of contact, and by respiratory and skin sensitization. According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) there is a specific concentration limit of $0.5\% \le C < 5$ concerning respiratory irritation. For the other local effects, the generic concentration limits of the CLP legislation apply (i.e. 0.1% for skin sensitisation and 1% for respiratory sensitisation and 5% for skin corrosion). Therefore, there is no risk regarding the described local effects for the general public as the glutaraldehyde concentrations in the respective uses are < 0.1%.

2.2.6.2.2 Product Type 12

Protectol® GA 50 is used as slimicide for paper pulp and paper production water. It is applied in the wet-end of the paper production and during paper de-inking processes. The dosing into the paper pulp is performed either once or several times per day (maximum 3 - 4 times/day). The use of Protectol® GA 50 in PT12 is associated with the primary dermal and inhalation exposure of the following user groups:

- professional users handling containers of Protectol® GA 50
- professional users performing cleaning / maintenance work

In addition, the secondary exposure of professionals to aerosols and vapours of glutaraldehyde used as a slimicide in the paper industry is assessed, too.

Industrial exposure

Please refer to professional exposure

Professional exposure

Slimicides for paper pulp: wet-end slimicides

Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Wet end slimicides

Protectol® GA 50 is automatically dosed into the wet-end of the paper circuit. Exposure of the worker is therefore limited during connecting/disconnecting of drums or IBCs. Potential primary exposures have been assessed for professional workers handling and connecting/disconnecting drums or intermediate bulk containers (IBCs) containing Protectol® GA 50 during product formulation. The task is carried out approximately once per month.
These scenarios are identical with PT6-scenarios [1a] and [1b] and calculations are not repeated.

Scenario [24a] PT 12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Wet end slimicides

See Scenario [1a]

Scenario [24b] PT 12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Wet end slimicides

See Scenario [1b]

Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water

The possibility of exposure during cleaning and other daily maintenance tasks of the pulp tank is considered in the primary exposure assessment of professional workers. Most tank cleaning is done automatically (not requiring human intervention) with fixed rotary jet spraying equipment installed in the tank, or semi-automatically with static spray balls. A complete manual cleaning is mainly done with a spray gun using water. As worst-case assumption, exposure of workers during manual cleaning is calculated.

Scenario [25]: PT 12 - Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water

Description of Scenario [25]		
As worst-case assumption, exposure of workers (body weight: 60 kg) during manual cleaning is calculated using *spraying model 2 from the TNsG 2002*. The task is expected to last 4 h and glutaraldehyde concentration in the pulp tanks is estimated as 0.013% glutaraldehyde which is based on the recommended use concentrations for glutaraldehyde as slimicide for use in paper-wet end production and de-inking processes in paper production (max. 0.025% Protectol® GA 50, i.e. max. 0.013% glutaraldehyde). The indicative values for **body and hand** exposure are 222 mg/min and 273 mg/min. A dermal absorption of 10% is used for exposure assessment. The indicative value for **inhalation** exposure is 76 mg/m^3. Tier 1 estimation does not include a reduction factor for PPE. In the Tier 2 estimation it is assumed that the workers are wearing coated coveralls with 10% penetration and gloves. In addition, RPE is recommended to reduce inhalation exposure. The calculated exposure values overestimate the exposure of professional users during the cleaning task. Using *Spraying model 2* considering a concentration of 0.013% estimates the exposure for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. However, there is only residual glutaraldehyde in the tank and the spraying is done with neat water diluting the residual amounts of glutaraldehyde quickly. In addition, the estimated glutaraldehyde concentration is based on the recommended use concentrations for glutaraldehyde as slimicide for use in paper-wet end production and de-inking processes in paper production (max. 0.025% Protectol® GA 50, i.e. max. 0.013% glutaraldehyde). Therefore, the residual glutaraldehyde will be much lower during cleaning and maintenance-processes. However, these worst-case assumptions are used for risk-characterisation. This scenario represents also a worst-case assumption for exposure of professional users during cleaning/maintenance of pulp tanks – paper de-inking (Scenario [27]).		
	Parameters[1]	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.013
	Potential body exposure [mg/min]	222[1]
	Potential hand exposure [mg/min]	273[1]
	Exposure duration [min/shift]	240[2]
	Dermal absorption [%]	10[3]
	Indicative value inhalation exposure [mg/m^3]	76[1]
	Inhalation rate (m^3/h)	1.25[4]
Tier 2	Actual hand exposure [mg/min]	7.8[1] (inside gloves)
	Clothing type	Coated coveralls, 10% penetration[5]

[1] TNsG 2002
[2] According to the EXCEL Data Base on Human Exposure a total spray duration per day of 240 min is a realistic worst-case.
[3] CA Report on glutaraldehyde (RMS Finland, 2014)
[4] HEEG Opinion 17 on default human factor values for use in exposure assessments for biocidal products, TM II 2013
[5] HEEG Opinion 9 on default protection factors for protective clothing and gloves, TM I 2010

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [25]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [25] PT 12 - Exposure during Cleaning/Maintenance of Pulp Tanks and Exposure to Paper Mill White Water	1/-	0.00082	0.0257	n.a.	0.0266
	2/coated coveralls, 10% penetration and gloves	0.00082	0.0016	n.a.	0.0024

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m³]	
Scenario [25] PT 12 - Exposure during Cleaning/Maintenance of Pulp Tanks and Exposure to Paper Mill White Water	1/-	0.0099	0.0049
	2/coated coveralls, 10% penetration and gloves	0.0099	0.0049

<u>Secondary (Indirect) exposure of professional users</u>

Secondary (Indirect) inhalation exposure of workers to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry is calculated.

<u>Scenario [26]: PT 12 - Secondary (Indirect) exposure of professional users to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry</u>

Description of Scenario [26]		
Secondary (indirect) exposure of workers to aerosols and vapours of Protectol® GA 50 used as a slimicide in the paper mill industry is assessed using the *Advanced Reach Tool 1.5*. For exposure calculations during a full shift (480 min), the activity class 'Spraying liquids in a space' (small scale space spraying) was chosen. This scenario is regarded as a realistic worst-case, because paper mill workers at the wet-end and drying stages of the paper mill normally work remotely from the paper machines, controlling the paper manufacturing operations *via* computers located in air-conditioned rooms away from the noise, elevated temperatures and odours of the paper machines. The drying section of the paper mill is where the highest airborne concentrations of glutaraldehyde might be expected to occur. However, most of the glutaraldehyde was already removed together with about >90% of the water and due to the high temperature during the papermaking process the remaining glutaraldehyde will degrade very fast and the steam produced is extracted by means of powerful fans and any traces of volatilised glutaraldehyde are extracted at the same time. Also at the wet-end ventilation is available. Due to the described processes, no aerosol formation is expected. The maximum recommended use concentration of glutaraldehyde applied as slimicide in the paper wet-end production is 0.01% (i.e. 0.02% Protectol GA 50, i.e. max. 0.01% glutaraldehyde). Due to the high degradation of glutaraldehyde under high temperatures and the presence of powerful fans the actual glutaraldehyde present in the air will be considerable lower. However, this concentration is taken as worst-case assumption. The mole fraction for glutaraldehyde in the aqueous media was therefore calculated to be 1.8×10^{-5}. As the process temperature is above room temperature the vapour pressure of glutaraldehyde at 25°C, 62 Pa, was taken as worst-case into account. The inhalation rate is 1.25 m^3/h and a body weight of 60 kg was assumed. As worst-case only good natural ventilation is considered. A predicted 90th percentile of exposure was calculated. See table below for all parameters chosen (please refer also to the output table in Annex 3.2).		
	Parameters	Value
Tier 1	Glutaraldehyde max. concentration [%]	0.01
	Process temperature [°C]	20°C)
	Vapour pressure pure glutaraldehyde [Pa]	62 (at 25°C)
	Liquid mole fraction	1.8×10^{-5} [1]
	Exposure duration [min/shift]	480 min
	Activity coefficient	1
	Activity class	Spraying of liquids in a space
	Emission sources	Far field
	Work area	Indoors
	Room size	Large workrooms only
	Localised controls	No localized controls (0% reduction)

	Ventilation rate	Only good natural ventilation
	Inhalation rate [m^3/h]	1.25

[1] Calculation based on the molar masses of glutaraldehyde and water in the aqueous solution of 0.01% glutaraldehyde (0.001 mol glutaraldehyde and 55.6 mol water; mole fraction of glutaraldehyde = 0.001/(0.001+55.6).

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [26]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [26] PT 12 - Secondary (Indirect) exposure of professional users to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry	1/-	6.0E^{-4*}	n.a.	n.a.	6.0E^{-4} [1]

[1]: 0.0036 mg/m^3 x 1.25 m^3/h x 8 h/60 kg = 6.0E^{-5} mg/kg/bw/d

Summary table: estimated acute and daily (8 h TWA) inhalation dose from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA)**
		[mg/m^3]	
Scenario [26] PT 12 - Secondary (Indirect) exposure of professional users to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry	1/-	0.0036*	0.0036*

* A predicted 90th percentile

Slimicides for paper pulp: paper de-inking slimicides

During the recovery of pulp from old paper, the removal of ink is an important step. This is performed in special pulpers with surfactants and water. Most of the ink is collected with foam on the surface of the pulper but the recycled pulp remains a greyish colour and requires bleaching. Hydrogen peroxide (H_2O_2) is used for pulp bleaching. Many micro-organisms can grow in the pulper and they can secrete a fast reacting enzyme (catalase) that degrades H_2O_2. A biocide is required in order to kill the microorganisms before they can secrete catalase so that the bleaching step can be successfully performed thereby avoiding the degradation of H_2O_2. The addition of Protectol® GA 50 to the pulpers does not require the presence of a worker as this process is carried out remotely *via* dosing pumps which are controlled by a timer. The only operation that requires the intervention of a worker is the replacement of an empty container with a full one.

Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Paper de-inking

Protectol® GA 50 is automatically dosed into the pulper. Exposure of the worker is therefore limited during connecting/disconnecting of drums or IBCs. Potential primary exposures have been assessed for professional workers handling and connecting/disconnecting drums or intermediate bulk containers (IBCs) containing Protectol® GA 50 during product formulation. The task would be carried out approximately every 2 months. These scenarios are identical with PT6-scenarios [1a] and [1b] and calculations are not repeated.

Scenario [27a] PT 12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums) – Paper de-inking

See Scenario [1a]

Scenario [27b] PT 12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) – Paper de-inking

See Scenario [1b]

Exposure of professional users during cleaning/maintaining of pulp tanks - paper de-inking

The possibility of exposure during cleaning and other daily maintenance tasks of the pulp tank is considered in the primary exposure assessment of professional workers. Most tank cleaning is done automatically (not requiring human intervention) with fixed rotary jet spraying equipment installed in the tank, or semi-automatically with static spray balls. A complete manual cleaning is mainly done with a spray gun using water. As worst-case assumption, exposure of workers during manual cleaning is calculated. This scenario is identical with scenario [25] and calculations are not repeated (please refer to scenario [25] for more details).

Scenario [28]: PT 12 - Exposure of professional users during cleaning/maintenance of pulp tanks – paper de-inking

See Scenario [25]

Further information and considerations on scenario [24-28]

According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) glutaraldehyde (100%) glutaraldehyde is classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde is labelled with EUH071, Corrosive to respiratory tract. Skin sensitisation has been clearly demonstrated, and human data indicates that glutaraldehyde has to be considered as a respiratory sensitizer as well (Skin Sens. 1A, H317 May cause an allergic skin reaction and Resp. Sens. 1, H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled). The critical effects are therefore characterised by irritation and tissue damage at the site of contact, and by respiratory and skin sensitization. According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) there is a specific concentration limit of $0.5\% \leq C < 5$ concerning respiratory irritation. For the other local effects, the generic concentration limits of the CLP legislation apply (i.e. 0.1% for skin sensitisation and 1% for respiratory sensitisation and 5% for skin corrosion). Therefore, there is a risk regarding the described local effects when handling the pure biocidal product Protectol® GA 50, a 50% aqueous solution of glutaraldehyde. However, the risk of local effects induced by glutaraldehyde exposure can be controlled by using the respective PPE.
A qualitative and / or a (semi-)quantitative risk assessment is performed regarding these local effects (see Risk characterisation). According to BPR: Volume III Part B (ECHA; Oct 2015) the substance has to be assigned to the hazard category ‘very high’.

Non-professional exposure

There is no non-professional exposure as paper pulp production is an industrial/professional use only.

Exposure of the general public

There is no exposure of the general public as paper production is an industrial/professional use only.
In addition, secondary exposure of the general population towards glutaraldehyde *via* residues on paper is not expected. In separate investigations (GAFATEPP.DOC (1998); please refer to the CA report on glutaraldehyde (RMS Finland, 2014)) it has been shown that paper that is produced in paper mills that use 50% glutaraldehyde as a preservative for the additives do not contain detectable glutaraldehyde residues and can therefore be used to pack food. The US FDA clearance (FDA 21CFR 176.170/180), the German BfR 36 and the Dutch WarenWet confirm such paper to be safe for food wrapping. This conclusion is supported by the TNsG on human exposure, part II, 2002, where it is stated that for the application of biocidal products within PT 12, volatile or reactive biocides will have disappeared by the time paper is used.

2.2.6.2.3 Oilfield applications (PT 11 and PT 12)

Protectol® GA 50 is used as a biocide in the oilfield industries to prevent corrosion or biofilm formation in oilfield systems (i.e. in pipelines, transmission lines, storage systems). These applications pertain according to CA Sept14 Doc 8_4 to the following Product Types (PT):

- PT 11: Prevention of corrosion in liquid cooling and processing systems (hydrotesting fluid)
- PT 11: Prevention of corrosion during mineral oil extraction (production and oil injection water)

- PT 12: Prevention of biofilm formation in liquid cooling and processing systems (hydrotesting fluid)
- PT 12: Prevention of biofilm formation during mineral oil extraction (production and oil injection water)

PT 11: Prevention of corrosion in liquid cooling and processing systems (hydrotesting fluid)

Protectol® GA 50 is used to protect the inner surfaces of transit pipes used in oilfields from microbially induced corrosion during hydrostatic pressure testing (e.g. testing pressure vessels such as pipelines for strength and leaks).
The biocide is typically dosed to give a final in-use concentration in the hydrotesting fluid of between 12 – 2,000 ppm glutaraldehyde (0.0012- 0.2% w/w; corresponding to 24 and 4,000 ppm Protectol® GA 50). In hydrotesting applications, it is recommended that the water containing the biocide is "shut in" for up to 90 days prior to discharge. Residence times of 180 days are common practice, too. Please refer to the separate document about Protectol® GA 50 application in oilfield uses for further details (Tey & Lafuente Cerdá, 2016).

PT 11: Prevention of corrosion during mineral oil extraction (production water and oil injection water)

Protectol® GA 50 is added to oilfield injection water or to the produced fluids in order to protect the installation and maintain production efficiency.
In the field of oil extraction, depending on the local conditions water (known as injection water) is sometimes pumped into or around an oilfield in order to receive the maximum yield of oil (or gas) out of a production site. During this process, known as oilfield water injection[15], water is injected back into the oil pool or reservoir to increase pressure (e.g. voidage replacement) and stimulate oil production. Water injection wells can be found both on- and offshore to increase oil recovery from an existing reservoir. Water is injected to support the pressure of the reservoir and to sweep or displace oil from the reservoir and push it towards a well. Normally, only 30% of the oil in a reservoir can be extracted, but water injection increases the yield and maintains the production rate of a reservoir for a longer period of time.
Groundwater, both saline and non-saline, or surface water from rivers and lakes can be used for injection, although in more recent times there is increased pressure to use 'produced waters' (i.e. the water that is produced along with the oil extracted) and to minimise the use of freshwater which is lost from the natural water cycle during the process. Prior to use, the water can be filtered (sand filters are easiest to use) and de-oxygenated (to minimise corrosion and bacterial growth). Protectol® GA 50 is added to the water to prevent corrosion during mineral oil extraction process. The in-use concentration of glutaraldehyde is between 12 and 7500 ppm (0.0012- 0.075% w/w; corresponding to 24 and 1,500 ppm Protectol® GA 50). The water is not recoverable from such uses. Please refer to the separate document about Protectol® GA 50 application in oilfied uses for further details (S. L. Tey, O. Lafuente Cerá, Protectol GA® 50 BPR registration in Europe – Application in Oilfied Uses, 2016, report 2016ST01)

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[15] http://en.wikipedia.org/wiki/Water_injection_%28oil_production%29

Prevention of corrosion in seawater injection systems, in water treatment units (produced water re-injection), in hydrocyclones, gas floatation units and filters (produced water disposal), in gas/crude production and transmission pipelines and systems, in crude and gas storage wells and systems and during pipeline pigging and scraping operations are covered by the above described processes as handling of Protectol GA® 50 is identical within these applications. All these operations are carried out outdoors and in a highly automated, technical environment. Exposure of workers will primarily arise when connecting and disconnecting hoses from drums/containers. Please refer to the separate document about Protectol® GA 50 application in oilfield uses for further details (Tey & Lafuente Cerdá, 2016). The professional workers are well informed about the hazards and potential risks from handling and are wearing respective RMMs.

PT 12: Prevention of biofilm formation in liquid cooling and processing systems (hydrotesting fluid)

Protectol® GA 50 is used to protect the inner surfaces of transit pipes used in oilfields from microbially induced biofilm formation during hydrostatic pressure testing (e.g. testing pressure vessels such as pipelines for strength and leaks).
The biocide is typically dosed to give a final in-use concentration in the hydrotesting fluid of between 12 – 2,000 ppm glutaraldehyde (0.0012- 0.2%; corresponding to 24 and 4,000 ppm Protectol® GA 50). In hydrotesting applications, it is recommended that the water containing the biocide is 'shut in" for at least 24 hours. Residence times of 180 days prior to discharge are common practice. Please refer to the separate document about Protectol® GA 50 application in oilfield uses for further details (Tey & Lafuente Cerdá, 2016).

PT 12: Prevention of biofilm formation during mineral oil extraction (production water and oil injection water)

Protectol® GA 50 is added to oilfield injection water or to the produced fluids as a slimicide in order to protect the installation and maintain production efficiency.
In the field of oil extraction, depending on the local conditions water (known as injection water) is sometimes pumped into or around an oilfield in order to receive the maximum yield of oil (or gas) out of a production site. During this process, known as oilfield water injection[16], water is injected back into the oil pool or reservoir to increase pressure (e.g. voidage replacement) and stimulate oil production. Water injection wells can be found both on- and offshore to increase oil recovery from an existing reservoir. Water is injected to support the pressure of the reservoir and to sweep or displace oil from the reservoir and push it towards a well. Normally, only 30% of the oil in a reservoir can be extracted, but water injection increases the yield and maintains the production rate of a reservoir for a longer period of time.
Groundwater, both saline and non-saline, or surface water from rivers and lakes can be used for injection, although in more recent times there is increased pressure to use 'produced waters' (i.e. the water that is produced along with the oil extracted) and to minimise the use of freshwater which is lost from the natural water cycle during the process. Prior to use, the water can be filtered (sand filters are easiest to use) and de-oxygenated (to minimise corrosion and bacterial growth). Protectol® GA is added to the water to prevent biofilm formation. The in-use concentration of glutaraldehyde is between 12 and 750 ppm (0.0012-

0.075% w/w; corresponding to 24 and 1,500 ppm Protectol® GA 50). The water is not recoverable from such uses. Please refer to the separate document about Protectol® GA 50 application in oilfield uses for further details (Tey & Lafuente Cerdá, 2016).
Prevention of corrosion in seawater injection systems, in water treatment units (produced water re-injection), in hydrocyclones, gas floatation units and filters (produced water disposal), in gas/crude production and transmission pipelines and systems, in crude and gas storage wells and systems and during pipeline pigging and scraping operations are covered by the above described processes as handling of Protectol GA® 50 is identical within these applications. All these operations are carried out outdoors and in a highly automated, technical environment. Exposure of workers will primarily arise when connecting and disconnecting hoses from drums/containers. Please refer to the separate document about Protectol® GA 50 application in oilfield uses for further details (Tey & Lafuente Cerdá, 2016). The professional workers are well informed about the hazards and potential risks from handling and are wearing respective RMMs.

The uses of Protectol® GA 50 in PT 11 and 12 for applications in the oilfield industries are summarised in table below.

Product type	Field of use envisaged	Users	Likely concentration at which a.s. will be used in the Biocidal Product	Typical product
PT 11	**Oilfield industries:** Preservation of corrosion in hydrostatic pressure testing fluid	Industrial & Professional	In-use concentration: 12-2,000 ppm (0.0012- 0.2% w/w) glutaraldehyde	Protectol® GA 50: aqueous solution of 50% glutaraldehyde
PT 11	**Oilfield industries:** Preservation of corrosion in oilfield extraction fluids (production and injection water)	Industrial & Professional	In-use concentration: 12-750 ppm (0.0012-0.075% w/w) glutaraldehyde	Protectol® GA 50: aqueous solution of 50% glutaraldehyde
PT 12	**Oilfield industries:** Preservation of biofilm formation in hydrostatic pressure testing fluid	Industrial & Professional	In-use concentration: 12-2,000 ppm (0.0012- 0.2% w/w) glutaraldehyde	Protectol® GA 50: aqueous solution of 50% glutaraldehyde
PT12	**Oilfield industries:** Preservation of biofilm formation in oilfield extraction fluids (production and injection water)	Industrial & Professional	In-use concentration: 12-750 ppm (0.0012-0.075% w/w) glutaraldehyde	Protectol® GA 50: aqueous solution of 50% glutaraldehyde

Primary exposures to Protectol® GA 50 will occur only for certain professional users (i.e. service company workers) that handle Protectol® GA 50 and operate the biocide feeding system. Protectol® GA 50 can be dosed directly as a liquid by metered pump or *via* intermediate bulk containers (IBCs) in dedicated filling lines; open, manual pouring of the biocide does not occur. Professional workers are well informed about the hazards and potential risks from handling Protectol® GA 50 and operating the biocide system. Workers will therefore use appropriate personal protective equipment to prevent exposure.

Secondary exposures to residual amounts of Protectol® GA 50 can occur in workers during machine breakdown and repair, inspection of the oilfield machinery when checking for biofilm accumulation or cleaning out machinery. This type of exposure is expected to be negligible and to be by no means higher than exposure during mixing/loading due to the likely low concentrations of Protectol® GA 50 present (degradation in the process water can be assumed, which is also described in the CA report on glutaraldehyde (RMS Finland, 2014)) and will be significantly less than exposure to workers that are primarily exposed to Protectol® GA 50 (e.g. through handling the concentrate during mixing/loading tasks). Secondary exposure will also be mitigated as workers will be wearing an appropriate level of PPE.

Industrial exposure

Please refer to professional exposure

Professional exposure

PT 11/PT 12: Prevention of corrosion and biofilm formation in liquid cooling and processing systems (hydrotesting fluid)

Potential primary exposures have been assessed for professional workers using Protectol® GA 50 as a biocide to preserve water used in hydrostatic pressure operations carried out in the oilfield industries and to avoid biofilm formation and corrosion. These operations are carried out using predominantly closed systems and exposure of workers will primarily arise when connecting and disconnecting hoses from drums/containers. Two scenarios are considered. In scenario [29] exposure of professionals is estimated during connecting/disconnecting drums. Scenario [30] considers the exposure of professionals during connecting/disconnecting intermediate bulk containers (IBCs). Potential exposures arising from incidental sources during day to day processes are assumed to be negligible compared to the other operations such as loading for instance. Other exposures are not expected to be worse than those determined for these loading scenarios taking into account the closed system-like conditions of the application as such where contact with the injected waters is unlikely to occur.

Scenario [29] PT 11/12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)

The potential exposure of professional workers connecting/disconnecting drums in dedicated filling lines is evaluated. This work is done outdoors on the oil rig with natural ventilation. Furthermore, the worker is wearing gloves to protect from dermal exposure. The TNsG (2007) Use pattern (Excel database) informs that processes involving the loading of biocides are typically carried out for 10 minutes per day. As a reasonable worst–case scenario, it is assumed professional workers handle this product 1 day/week, every week (more intermittent use may be expected in reality). Since this scenario is identical with scenario [1a] and in agreement with HEEG Opinion 1 (TM I 08) the calculations were not repeated (please refer to scenario [1a] for details). The worker is wearing gloves to protect from local exposure *via* the dermal route. The indicative value for inhalation exposure (1.9 mg/m^3) is regarded as a worst-case for this use as the professional worker is performing this task outdoors with natural ventilation. Nevertheless, in accordance with precautionary principle, RPE (penetration 2.5%) is recommended for this use. This scenario is identical with scenario [1a] (please see Scenario [1a].

Scenario [30] PT 11/12 – Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers, IBCs)

The professional worker is connecting a pump on the tap of the IBC by means of a hose which resembles closed system conditions. After discharge of the IBC the tap is closed and the hose will be connected to the next IBC. During this work, the professional is wearing gloves. Dermal and inhalation exposure are regarded as negligible, because there is in principle a continuous closed system and no further exposure assessment is conducted. This is in agreement with Recommendation No. 6 of the Ad hoc Working Group on Human Exposure (agreed on 28th January 2015). This scenario is identical with scenario [1b] (please see scenario 1[b]).

PT 11/12: Prevention of corrosion and biofilm formation during mineral oil extraction (production and oil injection water)

During oil extraction processes, Protectol® GA 50 is added to the header reservoir of oilfield injection water to prevent corrosion and the formation of slimes. These operations are carried out using predominantly closed systems and exposure of workers will primarily arise when connecting and disconnecting hoses. Two scenarios are considered. In scenario [31] exposure of professionals is estimated during connecting/disconnecting drums. Scenario [32] considers the exposure of professionals during connecting/disconnecting intermediate bulk containers (IBCs). These scenarios and the associated exposure assessment approaches are identical to scenarios [1a] and [1b] and are therefore not repeated (for details please refer to scenarios [1a] and [1b], respectively). Potential exposure arising from incidental sources during day to day processes are assumed to be negligible compared to the other operations such as mixing and loading for instance. Other exposures are not expected to be worse than those determined for these mixing/loading scenarios taking into account the closed system-like conditions of the application as such where contact with the injected waters is unlikely to occur.

Further information and considerations on scenario [29-32]

According to the 9th ATP to Regulation (EC) No. 1272/2008 (CLP) glutaraldehyde (100%) is classified as Skin Corr. 1B; H314 Causes severe skin burns and eye damage. In addition, glutaraldehyde is labelled with EUH071, Corrosive to respiratory tract. Skin sensitisation has been clearly demonstrated, and human data indicates that glutaraldehyde has to be considered as a respiratory sensitizer as well (Skin Sens. 1A, H317 May cause an allergic skin reaction and Resp. Sens. 1, H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled). The critical effects are therefore characterised by irritation and tissue damage at the site of contact, and by respiratory and skin sensitization. According to the 9th

ATP to Regulation (EC) No. 1272/2008 (CLP) there is a specific concentration limit of 0.5% ≤ C < 5 concerning respiratory irritation. For the other local effects the generic concentration limits of the CLP legislation apply (i.e. 0.1% for skin sensitisation and 1% for respiratory sensitisation and 5% for skin corrosion). Therefore, there is a risk regarding the described local effects when handling the pure biocidal product Protectol® GA 50, a 50% aqueous solution of glutaraldehyde. However, the risk of local effects by glutaraldehyde exposure can be controlled by using the respective PPE.

A qualitative and / or a (semi-)quantitative risk assessment is performed regarding these local effects (see Risk characterisation). According to BPR: Volume III Part B (ECHA; Oct 2015) the substance has to be assigned to the hazard category 'very high'.

Non-professional exposure

There is no primary non-professional exposure as oilfield processes are related to industrial/professional uses only.

Exposure of the general public

There is neither primary nor secondary exposure of the general public as oilfield processes are related to industrial/professional uses only.

Monitoring data

In order to gain insight into human exposure to glutaraldehyde (Protectol® GA 50) under product type 6 (PT6, "Preservation of products during storage") application conditions two studies were performed. The first study focused on the degradation of glutaraldehyde in a representative PT6 organic particle formulation, during short-term storage and during application after short-term storage[16]. The second study focused on the amount of glutaraldehyde that evaporates from the same representative PT6 organic particle formulations during short-term storage, i.e. before use at customer sites[17].

There is a significant degradation of glutaraldehyde (Protectol® GA 50) in the representative organic particle formulation used under PT6 (a wall paint doped with 500 mg/L glutaraldehyde) over the test period of 4 weeks. The half-life time of glutaraldehyde is approx. 2 weeks, i.e. when a container for PT6 application is opened at customer sites after typical storage and transport periods, only 50% (approx. 250 mg/L) of the preservative is still available in the organic particle formulation. The degradation of glutaraldehyde is further increased (factor 2) after application and removal of the solvent by e.g. drying of the formulation. After a typical storage and transport period of 2 weeks only very low concentrations (approx. 3 µg/L of glutaraldehyde, corresponding to <0.001% of the initial preservative concentration) of evaporated glutaraldehyde (Protectol® GA 50) are available when opening the container at customer sites, i.e. exposure with Protectol® GA 50 by inhalation during e.g. 'PT6 mixing and loading' and 'PT6 application' is very low.

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[16] Rohwer, H., BASF SE (2016) Decomposition in wall paints. Analysis Report 15N01611 (*cf.* IUCLID Section 10.2)

[17] Rohwer, H., BASF SE (2016) Determination of Glutaraldehyde concentration in vapor phase over paint. Analysis Report 16N00791 (*cf.* IUCLID Section 10.2)

The applied wall paint contains substantial amounts of caolin, calcium carbonate and acrylate. Therefore, these results are also regarded as representative for additives in the paper production and for glues. In general, the human exposure calculations are performed without considerations on decomposition to represent the worst-case scenario. In the scenarios [10a] and [12] the degradation is considered and represented as an individual Tier in the exposure assessments.

Dietary exposure

Food, drinking water and livestock exposure of the biocidal product can be excluded when applied according to the recommended uses.

Information of non-biocidal use of the active substance

The a.s. glutaraldehyde is a disinfectant, preservative and slimicide and is applied in various areas. It is used as an intermediate and cross-linker in different chemical applications, as tanning agent in the leather manufacturing process, in the treatment of beets and in hoof baths for cattle. It is listed in Annex V of Regulation (EC) No 1223/2009 on cosmetic products as approved preservative for use in cosmetics. Not all of these applications are supported by the applicant. They are addressed under other EU legislation (e.g. Regulation (EC) No 1907/2006 (REACh) or Regulation (EC) No 1223/2009 on cosmetic products) and therefore not repeated under Regulation (EU) 528/2012 (BPR).

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure of glutaraldehyde can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

The biocidal product is used in industrial and professional applications, e.g. in the paper making process. A migration from the paper treated with the product to food can be excluded as no glutardehyde residues was detected from paper procuded in the paper mills using 50% glutardehyde as a preservative. Livestock exposure can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Glutaraldehyde will degrade very fast already in the preserved formulations and will further degrade during drying processes. Taking into account the very low concentrations of glutaraldehyde in the formulations resulting potentially in food contact (e.g. during dishwashing) dietary exposure *via* such uses is expected to be negligible. This is proven by the exposure estimate of scenario [22] were the secondary oral exposure from consuming residues of liquid detergent present on crockery following washing was assessed.

Exposure associated with production, formulation and disposal of the biocidal product

The potential exposure of industrial workers during the production and formulation of the b.p. is addressed under REACh and not repeated under Regulation (EU) 528/2012 (BPR), as the manufacturing is not exclusively for biocidal purposes. The risk assessments performed have focused on the use of the product once formulated and the potential exposure to both humans and the environment.

2.2.6.2.4 Summary of exposure assessment

Systemic exposure

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
PT 6			
Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs))			
[1a]	Professional – Connecting/Disconnecting drums	1/-	$3.82E^{-2}$
		2/Coated coveralls, gloves, eye protection and RPE (10%)	$3.82E^{-3}$
		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	$9.6E^{-4}$
[1b]	Professional – Connecting/Disconnecting IBCs	1/-	Negligible[1]
Professional users applying detergents preserved with Protectol® GA 50			
[2]	Professional – Mixing and loading liquid dish washing detergent	1/-	$1.6E^{-4}$
[3]	Professional – Applying liquid dish washing detergent	1/-	$1.9E^{-4}$
[4]	Professional –Loading liquid detergent for hand washing	1/-	$1.6E^{-4}$
[5]	Professional - Applying liquid hand washing detergent	1/-	0.0034
[6]	Professional - Loading laundry softener	1/-	$1.6E^{-4}$
[7a]	Professional – Applying undiluted wax emulsion	1/-	$1.0E^{-2}$
[7b]	Professional – Applying diluted wax emulsion	1/-	$5.0E^{-3}$
[8]	Professional – Applying car polish	1/-	$3.6E^{-3}$
Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals			
[9]	Professional – Applying	1/gloves	$3.1E^{-3}$

	organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals	2/Impermeable coveralls, gloves	$8.8E^{-4}$
Professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics			
[10a]	Professional - Spraying paints	1/-	0.305
		2/Gloves, Coated coveralls (10%), RPE (10%)	$2.2E^{-2}$
		3/Gloves, Coated coveralls (10%), glutaraldehyde degradation 50%	$1.6E^{-2}$
		4/ Gloves, Coated coveralls (10%), RPE (10%), glutaraldehyde degradation 50%	$1.1E^{-2}$
[10b]	Professional – Rolling/brushing paints	1/-	$4.1E^{-3}$
Professional use as preservative for paper wet-end additives and paper coatings			
[11a]	Professional - Use as preservative for paper wet-end additives and paper coatings preservation - fully preserved pulp (cellulose and additives)	1/-	$2.4E^{-2}$
		2/Coated coveralls and gloves	$5.6E^{-3}$
		3/Coated coveralls, gloves and RPE	$2.4E^{-3}$
[11b]	Professional - Use as preservative for paper wet-end additives and paper coatings preservation – preserved paper additive(s) only	1/-	$2.6E^{-4}$
Professional use as preservative for polymer dispersions e.g. glues and raw material thereof			
[12]	Professional - Use as preservative for polymer	1/-	$5.8E^{-3}$
		2/ RPE (10%)	$3.9E^{-3}$

	dispersions e.g. glues and raw material thereof	3/ glutaraldehyde degradation 50%, no RPE	1.9E^{-3}
Combined exposure			
[2]&[3]	Professional – Mixing and loading/Applying liquid dish washing detergent	1/-	3.5E^{-4}
[4]&[5]	Professional - loading/Applying liquid detergent for hand washing	1/-	3.8E^{-3}
Non-professional users applying detergents preserved with Protectol® GA 50			
[13]	Non-professional – Mixing and loading liquid dish washing detergent	1/-	1.6E^{-4}
[14]	Non-professional – Applying liquid dish washing detergent	1/-	1.9E^{-4}
[15]	Non-professional – Loading liquid detergent for hand washing	1/-	1.6E^{-4}
[16]	Non-professional - Applying Liquid Hand Washing Detergent	1/-	0.0034
[17]	Non-professional - Loading laundry softener	1/-	1.6E^{-4}
[18a]	Non-professional – Applying undiluted wax emulsion	1/-	1.0E^{-2}
[18b]	Non-professional – Applying diluted wax emulsion	1/-	5.0E^{-3}
[19]	Non-professional - Applying car polish	1/-	0.0022
Non-professional users applying organic particle dispersions preserved with Protectol® GA 50 e.g. pigment and polymer dispersions used in paints and plastics			
[20]	Non-professional - Applying spray paint	1/-	0.005
Combined exposure			
[13]&[14]	Non-professional – Mixing and loading/Applying liquid dish washing detergent	1/-	3.5E^{-4}

[15]&[16]	Non-professional Loading/Applying liquid detergent for hand washing	1/-	$3.8E^{-3}$
Secondary (indirect) exposure of the general public			
[21]	General population - Post application laundry softener / liquid dish washing detergent	1/-	$4.4E^{-3}$
[22]	General population - Post application liquid dish washing detergent	1/-	$2.7E^{-6}$
[23]	Toddler -dermal contact with wet paint	1/-	$7.9E^{-4}$
PT 12			
Slimicides for paper pulp: wet-end slimicides			
Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Wet end slimicides			
[24a]	Professional - Connecting/Disconnecting drums – Wet end slimicides	1/-	$3.82E^{-2}$
		2/Coated coveralls, gloves, eye protection and RPE (10%)	$3.82E^{-3}$
		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	$9.6E^{-4}$
[24b]	Professional - Connecting/Disconnecting intermediate bulk containers (IBCs) – Wet end slimicides	1/-	Negligible[1]
Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water			
[25]	Professional - Cleaning/Maintenance of pulp tanks and exposure to paper mill white water	1/-	$2.7E^{-2}$
		2/Coated coveralls, gloves and RPE	$2.4E^{-3}$
Secondary (Indirect) exposure of professional users			
[26]	Professional - Secondary (Indirect) exposure of professional users to vapours and aerosols	1/low level of containment	$6.0E^{-4}$
Slimicides for paper pulp: paper de-inking slimicides			

Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Paper de-inking			
[27a]	Professional - Connecting/Disconnecting drums– Paper de-inking	1/-	$3.82E^{-2}$
		2/Coated coveralls, gloves, eye protection and RPE (10%)	$3.82E^{-3}$
		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	$9.6E^{-4}$
[27b]	Professional - Connecting/Disconnecting intermediate bulk containers (IBCs) – Paper de-inking	1/-	Negligible[1]
Exposure of professional users during cleaning/maintaining of pulp tanks - paper de-inking			
[28]	Professional - Cleaning/Maintenance of pulp panks – Paper de-inking	1/-	$2.6E^{-2}$
		2/Coated coveralls, gloves and RPE	$2.4E^{-3}$
Oilfield applications			
PT 11/PT 12			
Prevention of corrosion and biofilm formation in liquid cooling and processing systems (hydrotesting fluid)			
[29]	Professional - Connecting/Disconnecting drums	1/-	$3.82E^{-2}$
		2/Coated coveralls, gloves, eye protection and RPE (10%)	$3.82E^{-3}$
		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	$9.6E^{-4}$
[30]	Professional - Connecting/Disconnecting intermediate bulk containers (IBCs)	1/-	Negligible[1]
Prevention of corrosion and biofilm formation during mineral oil extraction (production and oil injection water)			
[31]	Professional - Connecting/Disconnecting drums	1/-	$3.82E^{-2}$
		2/Coated coveralls, gloves, eye protection and RPE (10%)	$3.82E^{-3}$

		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	$9.6E^{-4}$
[32]	Professional - Connecting/Disconnecting intermediate bulk containers (IBCs)	1/-	Negligible[1]

[1] Exposure is regarded as negligible as process is conducted under closed conditions.

Acute exposure (local inhalation exposure)

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated acute concentration**	**Estimated daily concentration (8 h TWA / 24 h TWA)**
			[mg/m^3]	
PT 6				
Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs))				
[1a]	Professional – Connecting/Disconnecting drums	1/-	11	n.a.
		2/Protective coveralls, gloves, eye protection and RPE (10%)	1.1	n.a.
		3/ Coated coveralls, gloves, eye protection and RPE (2.5%)	0.275	n.a.
[1b]	Professional – Connecting/Disconnecting IBCs	1/-	Negligible[1]	Negligible[1]
Professional users applying detergents preserved with Protectol® GA 50				
[2]	Professional – Mixing and loading liquid dish washing detergent	1/-	$1.6E^{-5}$	$2.5E^{-7}$
[3]	Professional – Applying liquid dish washing detergent	1/-	$1.3E^{-6}$	$1.3E^{-6}$
[4]	Professional – Loading liquid detergent for hand washing	1/-	$3.9E^{-5}$	$6.09E^{-7}$
[5]	Professional - Applying liquid hand washing detergent	1/-	$9.4E^{-4}$	$1.2E^{-3}$
[6]	Professional - Loading laundry softener	1/-	$3.9E^{-5}$	$6.1E^{-7}$
[7a]	Professional – Applying undiluted wax emulsion	1/-	$5.8E^{-2}$	$7.3E^{-3}$

[7b]	Professional – Applying diluted wax emulsion	1/-	$9.7E^{-3}$	$9.7E^{-3}$
[8]	Professional – Applying car polish	1/-	$3.9E^{-2}$	$9.8E^{-3}$
Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals				
[9]	Professional – Applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals	1/gloves	$5.4E^{-4}$	$4.1E^{-4}$
Professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics				
[10a]	Professional - Spraying paints	1/-	0.095	0.071
		2/ Gloves, Coated coveralls (10%), RPE (10%)	0.0095	0.0071
		3/ Gloves, Coated coveralls (10%), glutaraldehyde degradation 50%	0.048	0.036
		4/ Gloves, Coated coveralls (10%), RPE (10%), glutaraldehyde degradation 50%	0.0048	0.0036
[10b]	Professional – Rolling/brushing paints	1/ -	$1.6E^{-3}$	$8.0E^{-4}$
Professional use as preservative for paper wet-end additives and paper coatings				

[11a]	Professional - Use as preservative for paper wet-end additives and paper coatings preservation - fully preserved pulp (cellulose and additives)	1/-	0.087	0.022
		2/Coated coveralls and gloves	0.087	0.022
		3/Coated coveralls, gloves, RPE (10%)	0.0087	0.0022
[11b]	Professional - Use as preservative for paper wet-end additives and paper coatings preservation – preserved paper additive(s) only	1/-	$1.9E^{-3}$	$4.7E^{-4}$
Professional use as preservative for polymer dispersions e.g. glues and raw material thereof				
[12]	Professional - Use as preservative for polymer dispersions e.g. glues and raw material thereof	1/-	$8.1E^{-2}$	$1.3E^{-2}$
		2/ RPE (10%)	$8.1E^{-3}$	$1.3E^{-3}$
		3/ glutaraldehyde degradation 50%, no RPe	$4.1E^{-2}$	$6.4E^{-3}$
Non-professional users applying detergents preserved with Protectol® GA 50				
[13]	Non-professional – Mixing and loading liquid dish washing detergent	1/-	$1.6E^{-5}$	$2.5E^{-7}$
[14]	Non-professional – Applying liquid dish washing detergent	1/-	$1.3E^{-6}$	$1.3E^{-6}$ [2]
[15]	Non-professional – Loading liquid detergent for hand washing	1/-	$3.9E^{-5}$	$6.09E^{-7}$
[16]	Non-professional - Applying liquid hand washing detergent	1/-	$9.4E^{-4}$	$1.2E^{-3}$
[17]	Non-professional - Loading laundry softener	1/-	$3.9E^{-5}$	$6.1E^{-7}$

[18a]	Non-professional – Applying undiluted wax emulsion	1/-	$5.8E^{-2}$	$7.3E^{-3}$
[18b]	Non-professional – Applying diluted wax emulsion	1/-	$9.7E^{-3}$	$9.7E^{-3}$
[19]	Professional – Applying car polish	1/-	n.a.	n.a.
Non-professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics				
[20]	Non-professional - Applying spray paint	1/-	0.28	$4.9E^{-3}$
PT 12				
Slimicides for paper pulp: wet-end slimicides				
Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Wet end slimicides				
[24a]	Professional - Connecting/ Disconnecting drums – Wet end slimicides	1/-	11	n.a.
		2/Coated coveralls, gloves, eye protection and RPE (10%)	1.1	n.a.
		3/Coated coveralls, gloves, eye protection and RPE (2.5%)	0.275	n.a.
[24b]	Professional - Connecting/ Disconnecting intermediate bulk containers (IBCs) – Wet end slimicides	1/-	Negligible[1]	Negligible[1]
Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water				
[25]	Professional - Cleaning/Maintenance of pulp tanks and exposure to paper mill white water	1/- 2/Coated coveralls, gloves and RPE	0.0099	0.0049
Secondary (Indirect) exposure of professional users				

[26]	Professional - Secondary (Indirect) exposure of professional users to vapours and aerosols	1/low level of containment	0.0036	0.0036
Slimicides for paper pulp: paper de-inking slimicides				
Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) – Paper de-inking				
[27a]	Professional - Connecting/ Disconnecting drums– Paper de-inking	1/-	11	n.a.
		2/Coated coveralls, gloves, eye protection and RPE (10%)	1.1	n.a.
		3/Coated coveralls, gloves, eye protection and RPE (2.5%)	0.275	n.a.
[27b]	Professional - Connecting/ Disconnecting intermediate bulk containers (IBCs) –Paper de-inking	1/-	Negligible[1]	Negligible[1]
Exposure of professional users during cleaning/maintaining of pulp tanks - paper de-inking				
[28]	Professional - Cleaning/Maintenance of pulp panks – Paper de-inking	1/- 2/Coated coveralls, gloves and RPE	0.0099	0.0049
Oilfield applications				
PT 11/PT 12				
Prevention of corrosion and biofilm formation in liquid cooling and processing systems (hydrotesting fluid)				
[29]	Professional - Connecting/ Disconnecting drums	1/-	11	n.a.
		2/Coated coveralls, gloves, eye protection and RPE (10%)	1.1	n.a.

		3/Coated coveralls, gloves, eye protection and RPE (2.5%)	0.275	n.a.
[30]	Professional - Connecting/ Disconnecting intermediate bulk containers (IBCs)	1/-	Negligible[1]	Negligible[1]
Prevention of corrosion and biofilm formation during mineral oil extraction (production and oil injection water)				
[31]	Professional - Connecting/ Disconnecting drums	1/-	11	n.a.
		2/Coated coveralls, gloves, eye protection and RPE (10%)	1.1	n.a.
		3/Coated coveralls, gloves, eye protection and RPE (2.5%)	0.275	n.a.
[32]	Professional - Connecting/ Disconnecting intermediate bulk containers (IBCs)	1/-	Negligible[1]	Negligible[1]

[1] Exposure is regarded as negligible as process is conducted under closed conditions.

[2] As the overall duration is 600 min (10 × 60 min) which correlates to a 10 h working shifty, no 8 h TWA but rather a 10 h TWA (which is similar to the estimated acute dose) was calculated.

[3] As the overall exposure duration is > 480 min (4 × 240 min) the TWA is similar to the estimated acute dose.

2.2.6.3 Risk characterisation for human health

The critical effects induced by glutaraldehyde exposure are irritation and tissue damage at the site of contact, and respiratory and skin sensitization. No distinct systemic effects were seen in any of the studies, however the effects, when observed in long-term studies, were nevertheless ascribed as systemic effects in those cases in which they were not clearly resulting from local effects. Both systemic and local risk characterisation is performed.

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
AEL$_{\text{acute}}$	Not derived, because the acute effects are considered to be exclusively local in nature. Consequently, only local risk characterisation is performed for acute scenarios. Additionally, a comparison to ARfD is given in acute scenarios to accompany this assessment.				
AEL$_{\text{medium-term}}$	Rat carcinogenicity study	NOAEL: 3.5 mg GA/kg bw/day	100	40%	14 µg/kg bw/day
AEL$_{\text{long-term}}$	Rat carcinogenicity study	NOAEL: 3.5 mg GA/kg bw/day	100	40%	14 µg/kg bw/day
AEC$_{\text{dermal}}$	Not derived				
AEC$_{\text{inhalation}}$	Mouse 2 years and 90 days study[1]	LOAEC: 255 µg/m^3	24[2]	/	10.6 µg/m^3 (2.6 ppb)
AEC$_{\text{acute inhalation}}$	Human study on odour detection and chemesthetic	Human irritation threshold: 1.60 mg/m^3 (390 ppb)	3.2[3]	/	500 µg/m^3 (122 ppb)
ARfD	Rabbit teratogenicity study	NOAEL: 15 mg/kg bw/day	25		0.60 mg/kg bw/day
ADI	Not derived, because glutaraldehyde is not expected to be present in food				

[1] Same LOAEC in the two mouse studies

[21]AF 2.5 for interspecies variation, 3.2 for intraspecies variation and 3 for LOAEC to NOAEC extrapolation; this value is used for repeated exposure scenarios and scenarios exceeding individual exposure situations of 15 min or more

[3]AF 3.2 for human variations

AEC$_{\text{inhalation}}$

Glutaraldehyde is classified as respiratory sensitiser category 1 according to the CLP Regulation. No scientific concept is available to derive a threshold value for safe exposure on the basis of the existing data concerning respiratory sensitisation. The evidence does however support the general principle that sensitization occurs in workplaces where high exposure rates take place either regularly or as high peak concentrations. The available data seem to suggest that where sensitization has occurred, exposure has occurred to at least 20-30 ppb, and often much higher. This should, however, not be understood as a proposal for a threshold value. Nevertheless, as the data indicate that sensitization has occurred at significantly higher concentrations than the AEC$_{\text{inhalation}}$ (2.6 ppb), this is considered as a reference value that is likely to be protective for sensitization effects as well.

Regarding **acute systemic effects** an AEL is not derived for acute effects because all signs of toxicity were based on local rather than systemic effects. The relevant assessment for acute scenarios is the local risk characterization. In order to verify the absence of risk, a complementary systemic assessment is made by comparing systemic exposure to the ARfD (the value of ARfD is the same as was originally proposed as the AEL_{acute}). This approach should not be considered as a true systemic risk characterization but merely a complementary verification of the absence of acute health effects.

A semi-quantitative risk characterization has been performed **for chronic inhalation exposure** by estimating the glutaraldehyde concentration in the air and comparing that to the calculated $AEC_{inhalation}$. The decision criteria of the chronic scenarios have been expressed as follows:

Decision criteria for inhalation exposure, chronic scenarios		
Exposure level	MOE	Conclusion
Exposure conc. ≤ $AEC_{inhalation}$ (2.6 ppb)	MOE ≥ 1	There is no concern of adverse health effects
Exposure conc. > $AEC_{inhalation}$ (2.6 ppb)	MOE < 1	The scenario indicates risk and is not acceptable

A semi-quantitative risk characterization has also been performed for **acute inhalation exposure** estimating the glutaraldehyde concentration in the air and comparing that to the calculated $AEC_{acute\ inhalation}$, as relevant. This reference value has been derived on the basis of human data on respiratory irritation. Respiratory sensitization has been linked with high peak exposure concentrations, and therefore $AEC_{acute\ inhalation}$ (122 ppb) should be regarded as a threshold that should never be exceeded. The use of this reference value can be considered for non-repetitive exposure durations of up to 15 min.

Decision criteria for inhalation exposure, acute scenarios		
Exposure level	MOE	Conclusion
Exposure conc. ≤ $AEC_{acute\ inhalation}$ (122 ppb)	MOE ≥ 1	There is no concern of adverse health effects
Exposure conc. > $AEC_{acute\ inhalation}$ (122 ppb)	MOE < 1	The scenario indicates risk and is not acceptable

No reference values have been derived for dermal or oral exposure. These effects will depend on the glutaraldehyde exposure concentration and not on area dose (mg/cm^2). The risk characterization is not quantitative but does take into account the exposure concentration. Non-recurring dermal exposure to glutaraldehyde concentrations below 0.5% are unlikely to cause any adverse health effects apart from mild, reversible skin irritation.

Maximum residue limits or equivalent

For glutaraldehyde, no maximum residue limits (MRLs) are available or have been set.

Specific reference value for groundwater

No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply.

2.2.6.3.1 Product Type 6

Risk for industrial users

See risk for professional users

Risk for professional users

Systemic risk characterisation

The possibility that a professional operator is chronically exposed to glutaraldehyde during normal usage has been considered. The exposure for scenario [1b] Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers (IBCs)) is regarded as negligible and therefore no risk characterisation is conducted. In addition, scenarios [2] & [3] and [4] & [5] are assessed in combination as these will be performed in sequence.

Systemic effects – chronic scenarios

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1a]	1	3.5	0.014	$3.82E^{-2}$	273	no
	2	3.5	0.014	$3.82E^{-3}$	27	yes
	3[1]	3.5	0.014	$9.6E^{-4}$	6.8	yes
[2]	1	3.5	0.014	$1.6E^{-4}$	1.1	yes
[3]	1	3.5	0.014	$1.9E^{-4}$	1.4	yes
[4]	1	3.5	0.014	$1.6E^{-4}$	1.1	yes
[5]	1	3.5	0.014	0.0034	24	yes
[6]	1	3.5	0.014	$1.6E^{-4}$	1.1	yes
[7a]	1	3.5	0.014	$1.0E^{-2}$	71	yes
[7b]	1	3.5	0.014	$5.0E^{-3}$	36	yes
[8]	1	3.5	0.014	$3.6E^{-3}$	26[1]	yes
[9]	1	3.5	0.014	$3.1E^{-3}$	22	yes
	2	3.5	0.014	$8.8E^{-4}$	6.3	yes
[10a]	1	3.5	0.014	0.305	2200	no
	2	3.5	0.014	$2.2E^{-2}$	160	no
	3	3.5	0.014	$1.6E^{-2}$	114	no
	4	3.5	0.014	$1.1E^{-2}$ [3]	79	yes
[10b]	1	3.5	0.014	$4.1E^{-3}$	29	yes

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
[11a]	1	3.5	0.014	$2.0E^{-2}$	170	no
	2[1]	3.5	0.014	$5.6E^{-3}$	40	yes
	3[1]	3.5	0.014	$2.4E^{-3}$	17	yes
[11b]	1	3.5	0.014	$2.6E^{-4}$	1.8	yes
[12]	1	3.5	0.014	$5.8E^{-3}$	42	yes
	2[1]	3.5	0.014	$3.9E^{-3}$	28	yes
	3[1] [2]	3.5	0.014	$1.9E^{-3}$	14	yes

[1] Tier 2 & 3 estimations necessary to reduce local chronic inhalation exposure to an acceptable risk
[2] Degradation of glutaraldehyde 50%

Combined scenarios

Scenarios combined	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
[2] & [3]	1	3.5	0.014	$3.5E^{-4}$	2.5	yes
[4] & [5]	1	3.5	0.014	$3.8E^{-3}$	27	yes

Local effects

Local risk characterization: Inhalation Exposure

Acute inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC acute inhalation mg/m³	Estimated acute concentration mg/m³	Estimated concentration in air/ AEC (%)	Acceptable (yes/no)
[1a]	1	0.5	11	2200	no
	2	0.5	1.1	220	no
	3	0.5	0.275	55	yes
[2]	1	0.5	$1.6E^{-5}$	< 1	yes
[3]	1	0.5	$1.3E^{-6}$	< 1	yes
[4]	1	0.5	$3.9E^{-5}$	< 1	yes
[5]	1	0.5	$9.4E^{-4}$	< 1	yes
[6]	1	0.5	$3.9E^{-5}$	< 1	yes
[7a]	1	0.5	$5.8E^{-2}$	12	yes
[7b]	1	0.5	$9.7E^{-3}$	1.9	yes
[8]	1	0.5	$3.9E^{-2}$	26	yes
[9]	1	0.5	$5.4\ E^{-4}$	< 1	yes
[10a]	1	0.5	$9.5E^{-2}$	19	yes
	2[1]	0.5	$9.5E^{-3}$	1.9	yes
	3[3]	0.5	$4.8E^{-2}$	9.6	yes
	4[3]	0.5	$4.8E^{-3}$	< 1	yes
[10b]	1	0.5	$1.6E^{-3}$	< 1	yes
[11a]	1	0.5	0.087	17.4	yes
	2[1]	0.5	0.087	17.4	yes
	3[1]	0.5	0.0087	1.74	yes
[11b]	1	0.5	$1.9E^{-3}$	< 1	yes
[12]	1	0.5	$8.1E^{-2}$	16	yes
	2[2]	0.5	$8.1E^{-3}$	1.6	yes

[1] Tier 2 & 3 estimations necessary to reduce systemic effects and local chronic inhalation exposure to an acceptable risk

[2] Tier 2 estimation necessary to reduce local chronic inhalation exposure to an acceptable risk

[3] Degradation of glutaraldehyde 50%

Chronic inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC inhalation mg/m³	Daily concentration (8 h TWA) mg/m³	Estimated daily dose/ AEC (%)	Acceptable (yes/no)
[1a]	1	0.0106	n.a.	-	-
[2]	1	0.0106	$2.5E^{-7}$	< 1	yes
[3]	1	0.0106	$1.3E^{-6}$	< 1	yes

Task/ Scenario	**Tier**	**AEC $_{\text{inhalation}}$ mg/m^3**	**Daily concentration (8 h TWA) mg/m^3**	**Estimated daily dose/ AEC (%)**	**Acceptable (yes/no)**
[4]	1	0.0106	$6.1E^{-7}$	< 1	yes
[5]	1	0.0106	$1.2E^{-3}$	11	yes
[6]	1	0.0106	$6.1E^{-7}$	< 1	yes
[7a]	1	0.0106	$7.3E^{-3}$	69	yes
[7b]	1	0.0106	$9.7E^{-3}$	92	yes
[8]	1	0.0106	$9.8E^{-3}$	92	yes
[9]	1	0.0106	$4.1E^{-4}$	3.9	yes
[10a]	1	0.0106	$7.1E^{-2}$	672	no
	2	0.0106	$7.1E^{-3}$	67	yes
	3^1	0.0106	$3.6E^{-2}$	340	no
	4^1	0.0106	$3.6E^{-3}$	34	yes
[10b]	1	0.0106	$8.0E^{-4}$	8	yes
[11a]	1	0.0106	0.022	207	no
	2	0.0106	0.022	207	no
	3	0.0106	0.0022	21	yes
[11b]	1	0.0106	$4.7E^{-4}$	4.4	yes
[12]	1	0.0106	$1.3E^{-2}$	122	no
	2	0.0106	$1.3E^{-3}$	12	yes
	3^1	0.0106	$6.4E^{-3}$	60	yes

[1] Degradation of glutaraldehyde 50%

Local risk characterization: Dermal Exposure

Quantitative local risk assessment for dermal effects is not performed. The effects of glutaraldehyde are concentration-dependent rather than dose-dependent. Protectol® GA 50 is an aqueous solution of 50% glutaraldehyde. The product is classified for the corrosivity and therefore a qualitative risk assessment for local effects is performed (TAB 08/2017; TOX14). The systemic risks induced by primary exposure for Protectol GA 50 are covered by the local risk characterisation (please see matrix table below). The maximum concentration of glutaraldehyde in treated article is 0.0979%. However, glutaraldehyde degrades during storage, hence it could be assumed that the concentration in treated articles is actual considerably lower when using the treated article. The risk of local dermal effects for the professional users is highest during handling of pure Protectol® GA 50. However, direct exposure will mostly be excluded by automatization of the processes and the use of protective gloves and coveralls.

A qualitative risk assessment matrix for local effects via primary exposure both via use of and use of application solutions is presented below.

A qualitative risk assessment matrix for local effects / primary exposure / use of product (50%)

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
Very high	Skin corr 1B, Eye Dam 2 H314; Resp Sens 1 H334; Skin sens 1 H317	6	Industrial Professio-nals	Loading (Scenario 1)	dermal	10 minutes 2/year	Accidentaly touching the contaminated hose of pump	gloves, coated coveralls, eye protection and RPE (2.5%)	Acceptable: - Low frequency of use - Short duration of use - Professionals using RMM and following instructions of use - Minimisation of manual phases -Good standard of personal hygiene

A qualitative risk assessment matrix for local effects / primary exposure / use of application solutions (0.0979%)

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
Low	-	6	Industrial Professio-nals	Applying e.g. detergents / organic emulsions preserved with Protectol GA 50 (Scenarios [2-9])	dermal	max. 10 times per day	-	No RMM required	Acceptable
Low (brush application) - Very high (spray application)	-	6	Industrial Professio-nals	Applying organic particle dispersions (Scenarios [10a, 10b])	dermal inhalation	max 360 min	-	No RMM required (brush); coated coveralls, eye protection and RPE (10 %), glutaraldehyde degradation 50% (spray)	Acceptable with RMM
High	-	6	Industrial Professio-nals	Use as preservative for paper wet end additives and paper coatings (Scenarios [11a, 11b])	dermal inhalation	120 min	-	coated coveralls, eye protection and RPE (10%)	Acceptable with RMM

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
High	-	6	Industrial Professionals	Use as preservative for polymer dispersions e.g. glues (Scenario [12]	dermal	75 min 260 times /year	-	glutaraldehyde degradation 50% (no RPE)	Acceptable with RMM

Conclusion

Scenario [1a]: This scenario is acceptable using coated coveralls, gloves (10% penetration), eye protection and RPE (2.5% penetration). This scenario also covers the filling of the preserved liquids in drums in dedicated filling lines mainly with local exhaust ventilation. In the preserved products glutaraldehyde is only present in concentrations up to 0.0979% which is a factor 500 lower than the worst-case assumption used in this calculation. Therefore, no RPE is required for the filling of preserved liquids.
Scenario [2]-[8]: All scenarios are acceptable as glutaraldehyde concentrations are below the acute and chronic reference values.
Scenario [9]: The scenario is acceptable when worker is wearing gloves. In addition, an impermeable coverall is usually recommended to be used when handing leather/textiles but the risk is below the reference values without using impermeable coveralls.
Scenario [10a]: This scenario is acceptable using gloves, coated coveralls and RPE (10% penetration) when the 50% degradation of the product during storage period is considered. If paints are used containing pigments preserved with Protectol® GA 50 there is an additional dilution step when applying the preserved pigments in the paints. In this step, pigments are further diluted to paints to form 20-25 % dilution. In addition to this, glutaraldehyde degrades during storage period. For the 20-25% dilution there is no requirement for RPE based on the risk assessment. However, RPE is always recommended in a spraying process.
Scenario [10b]: The scenario is acceptable. The use of gloves is recommended when exposure to glutaraldehyde is possible.
Scenarios [11a] and [11b]: The conservative approach of scenario [11a] for fully preserved pulp (cellulose and additives) is acceptable with coated coveralls, gloves and RPE (10% penetration). However, in the more realistic approach of Scenario [11b] for dilutions of preserved paper additives/coatings the glutaraldehyde concentrations are below the acute and chronic reference values. Gloves are recommended when exposure of glutaraldehyde is possible.
Scenario [12]: The scenario is acceptable without RPE when 50% degradation of glutardehyde during storage period is considered. Taking degradation into account, the glutaraldehyde concentrations are below the acute and chronic reference values.

There is no concern for professionals using the biocidal product as preservative for different aqueous formulations when considering the recommended uses and the above mentioned personal protective equipment.

Risk for non-professional users

Protectol® GA 50 is used as an in-can preservative for different types of water-based products. The maximum concentration of glutaraldehyde is 0.0979%. However, glutaraldehyde degrades during storage, hence it could be assumed that the concentration in consumer products is actual considerably lower. The possibility that a non-professional is exposed to glutaraldehyde during normal usage has been considered. The assessment of scenarios [13] – [18b] is identical with the professional exposure, except that the frequency is lower for non-professional use. The exposure of non-professionals for scenarios [13] – [18b] is therefore covered by scenarios [2] – [7b]. In addition, scenarios [13] & [14] and [15] & [16] are assessed in combination as these will be performed in sequence. These combined exposure assessment is also covered by the combined exposure assessment of scenario [2] & [3] and [4] & [5]. Please prefer to the risk characterisation of the professional users for details.

The risk for non-professionals during application of car polish [19] and during application of spray paints [20] are provided below.

Since amateur users can be assumed to apply the product occasionally and only if required, the application regime for amateurs resembles an acute exposure scenario and a comparison of the estimated primary exposure with the reference value for acute exposures (i.e. ARfD, $AEC_{\text{acute inhalation}}$) is justified. As a worst-case assumption, a comparison with the respective medium-/long-term AEL derived for glutaraldehyde is made for systemic exposure. Regarding local effects induced by inhalation exposure both acute and medium-term/chronic assessments are necessary for each scenario.

Systemic effects – acute scenarios

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**ARfD mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ ArfD (%)**	**Acceptable (yes/no)**
[19]	1	15	0.6	0.0022	< 1	yes
[20]	1	15	0.6	0.005	< 1	yes

Systemic effects – chronic scenarios

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
[19]	1	3.5	0.014	0.0022	16	yes
[20]	1	3.5	0.014	0.005	36	yes

Local effects

Local risk characterization: Inhalation Exposure

Acute inhalation exposure

Task/ Scenario	Tier	AEC acute inhalation mg/m³	Acute dose mg/m³	Estimated concentration in air/ AEC (%)	Acceptable (yes/no)
[19]	1	0.5	n.a.	-	-
[20]	1	0.5	0.28	56	yes

Chronic inhalation exposure

Task/ Scenario	Tier	AEC inhalation mg/m³	Daily dose (24 h TWA) mg/m³	Estimated daily intake/ AEC (%)	Acceptable (yes/no)
[19]	1	0.0106	n.a.	-	-
[20]	1	0.0106	0.0049	46	yes

Local risk characterization: Dermal Exposure

Quantitative local risk assessment for dermal effects is not performed. The effects of glutaraldehyde are concentration-dependent rather than dose-dependent. Protectol® GA 50 is an aqueous solution of 50% glutaraldehyde. The maximum concentration of glutaraldehyde in treated article is 0.0979%. However, glutaraldehyde degrades during storage, hence it could be assumed that the concentration in treated articles is actual considerably lower when using the treated article. Non-professionals will not be in contact with the pure biocidal product Protectol® GA 50. Hence, the risk regarding local dermal effects is very low.

Local risk characterisation: Oral exposure

Oral exposure could only occur *via* ingestion of the non-respirable fraction during spraying paint. The concentration there is considered negligible for local risk characterization.

Conclusion

Scenarios [13]-[20]: All scenarios are acceptable as glutaraldehyde concentration is below the acute and chronic reference values.

Risk for the general public

The possibility of dermal exposure to glutaraldehyde from contact with laundry softener and liquid hand washing detergent [21] and from oral exposure with liquid detergent used in dish washing [22] has been assessed. The dietary risk has been compared to AEL instead of

ARfD to represent the worst case scenario is ADI has not been derived during the evaluation of the active substance.

Systemic effects – chronic scenarios

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[21]	1	3.5	0.014	0.0044	31	yes
[22]	1	3.5	0.014	$2.7E^{-6}$	< 1	yes
[23]	1	3.5	0.014	$7.9E^{-4}$	5.6	yes

Local risk characterisation: Dermal Exposure

Quantitative local risk assessment for dermal effects is not attempted. Chronic dermal exposure may take place through residues in washed laundry, but the exposure is very low and is considered not to cause concern. Dermal exposure may also take place through residues in washed dishes but this is considered negligible for local risk characterisation.

Local risk characterisation: Oral exposure

Chronic oral exposure may take place through residues in washed dishes. The concentration is considered negligible for local risk characterization.

A qualitative risk assessment matrix for local effects / primary exposure / use of application solutions (0.0979%)

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
Low	-	6	Non-professional users	Applying wax emulsions / spray paints	dermal inhalation	2-6 times /year	-	No RMM required	Acceptable
Low	-	6	General public	Secondary exposure	dermal oral	1 /year	-	No RMM required	Acceptable

Conclusion

Scenarios [21]-[23]: All scenarios are acceptable as glutaraldehyde concentration is below the acute and chronic reference values. Therefore, there is no concern for general population.

2.2.6.3.2 Product Type 12

Risk for industrial users

See professional risk characterisation.

Risk for professional users

Slimicides for paper pulp: wet-end slimicides

The possibility that a professional worker is exposed to Protectol® GA 50 during normal usage has been considered. Scenarios [24a] and [24b] (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) concerns exposure situations that are expected to take place approximately once a month, while scenario [25] concerns exposure during daily maintenance. The dermal and inhalation exposure for scenario [24b] is regarded as negligible and therefore no risk characterisation is conducted.

For scenario [24a] acute exposure is considered because local effects are based on concentration and because there is a 1-month period between the concerned exposure scenarios. For those professionals performing this task more frequently also chronic exposure is evaluated. Scenario [25] is a chronic exposure scenario.

In addition, the possibility of worker inhalation exposure to glutaraldehyde aerosols and vapour phases (scenario [26]) has been assessed.

Systemic risk characterisation

Systemic effects – acute scenarios

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ ArfD (%)	Acceptable (yes/no)
[24a]	1	15	0.014	1.19	8500	no
	2	15	0.014	0.0153	109	no
	3	15	0.014	0.0125	89	yes

Systemic effects – chronic scenarios

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[24a]	1	3.5	0.014	1.19	8500	no
	2	3.5	0.014	0.0153	109	no
	3	3.5	0.014	0.0125	89	yes
[25]	1	3.5	0.014	0.0266	190	no
	2	3.5	0.014	0.0024	17	yes
[26]	1	3.5	0.014	$6.0E^{-4}$	4.3	yes

Local effects

Local risk characterization: Inhalation Exposure

Acute inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC acute inhalation mg/m³	Acute dose mg/m³	Estimated concentration in air/ AEC (%)	Acceptable (yes/no)
[24a]	1	0.5	11	2200	no
	2	0.5	1.1	220	no
	3	0.5	0.275	55	yes
[25]	1	0.5	0.0099	1.98	yes
	2[1]	0.5	0.0099	1.98	yes
[26]	1	0.5	0.0036	< 1	yes

[1] Tier 2 estimations necessary to reduce chronic systemic exposure to an acceptable risk

Chronic inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC inhalation mg/m³	Daily dose (8 h TWA) mg/m³	Estimated daily dose/ AEC (%)	Acceptable (yes/no)
[24a]	1	0.0106	n.a.	-	-
[25]	1	0.0106	0.0049	46	yes
	2[1]	0.0106	0.0049	46	yes
[26]	1	0.0106	0.0036	34	yes

[1] Tier 2 estimation necessary to reduce chronic systemic exposure to an acceptable risk

Local risk characterization: Dermal Exposure

Quantitative local risk assessment for dermal effects is not performed. The effects of glutaraldehyde are concentration-dependent rather than dose dependent. Protectol® GA 50 is an aqueous solution of 50% glutaraldehyde. The risk of local dermal effects for the professional users is highest during handling of pure Protectol® GA 50. However, direct exposure will mostly be excluded by automatization of the processes and the use of protective gloves and coveralls.

A qualitative risk assessment matrix for local effects / primary exposure / use of application solutions

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
Very high	Skin corr 1B, Eye Dam 2 H314; Resp Sens 1 H334; Skin sens 1 H317	12	Industrial Professional	Slimicides	dermal	240 min daily - 10 minutes 2/year	-	coated coveralls, eye protection and RPE (2.5%)	Acceptable: - Low frequency of use - Short duration of use - Professionals using RMM and following instructions of use - Minimisation of manual phases -Good standard of personal hygiene

Conclusion

Scenario [24a]: This scenario is acceptable using coated coveralls, gloves (10 % penetration), eye protection and RPE (2.5% penetration).
Scenario [25]: This scenario is acceptable using coated coveralls and gloves (10 % penetration). In addition, RPE is recommended to reduce inhalation exposure.
Scenario [26]: The use is acceptable in large workrooms with low level of containment with good natural ventilation. As paper production is conducted in an industrial/professional field also general housekeeping practices are in place.

There is no concern for professionals using Protectol® GA 50 during wet-end paper production processes when considering the recommended uses and the above mentioned personal protective equipment.

Slimicides for paper pulp: paper de-inking slimicides

The possibility that a professional worker is exposed to Protectol® GA 50 during normal usage has been considered. The calculated exposure levels are tabled below for the risk characterization of systemic and local effects.

Scenarios [27a] and [27b] (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) concern exposure situations that are expected to take place approximately once every 2 months. The dermal and inhalation exposure for scenario [27b] is regarded as negligible and therefore no risk characterisation is conducted. For scenario [27a] acute exposure is considered because local effects are based on concentration and because there is a 2-month period between exposure situations. For those professionals performing this task more frequently also chronic exposure is evaluated. Scenario [28] concerns exposure during daily maintenance and the assessment is performed for chronic exposure.

Systemic risk characterisation

Systemic effects – acute scenarios

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	ARfD mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ ARfD (%)	Acceptable (yes/no)
[27a]	1	15	0.6	1.19	198	no
	2[1]	15	0.6	0.0153	2.6	yes
	3	15	0.6	0.0125	2.1	yes

[1] Tier 2 estimations necessary to reduce local acute inhalation exposure concentrations to an acceptable local risk

Systemic effects – chronic scenarios

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[27a]	1	3.5	0.014	1.19	8500	no
	2	3.5	0.014	0.0153	109	no
	3	3.5	0.014	0.0125	89	yes
[28]	1	3.5	0.014	0.0266	190	no
	2	3.5	0.014	0.0024	17	yes

Local effects

Local risk characterization: Inhalation Exposure

Acute inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC acute inhalation mg/m³	Acute dose mg/m³	Estimated concentration in air/ AEC (%)	Acceptable (yes/no)
[27a]	1	0.5	11	2200	no
	2	0.5	1.1	220	no
	3	0.5	0.275	55	yes
[28]	1	0.5	0.0099	1.98	yes
	2[1]	0.5	0.0099	1.98	yes

[1] Tier 2 estimations necessary to reduce chronic systemic exposure to an acceptable risk

Chronic inhalation exposure

Task/ Scenario	**Tier**	**AEC** inhalation **mg/m^3**	**Daily dose (8 h TWA) mg/m^3**	**Estimated daily dose/ AEC (%)**	**Acceptable (yes/no)**
[27a]	1	0.0106	n.a.	**-**	**-**
[28]	1	0.0106	0.0049	47	yes
	2[1]	0.0106	0.0049	47	yes

[1] Tier 2 estimation necessary to reduce chronic systemic exposure to an acceptable risk

Local risk characterization: Dermal Exposure

Quantitative local risk assessment for dermal effects is not performed. The effects of glutaraldehyde are concentration-dependent rather than dose dependent. Protectol® GA 50 is an aqueous solution of 50% glutaraldehyde. The risk of local dermal effects for the professional users is highest during handling of pure Protectol® GA 50. However, direct exposure will mostly be excluded by automatization of the processes and the use of protective gloves and coveralls.

A qualitative risk assessment matrix for local effects / primary exposure / use of application solutions

Hazard		Exposure						Risk	
Hazard category	C&L	PT	Who is exposed	task, uses, processes	exposure route	frequence and duration of potential exposure	potential degree of exposure	Relevant RMM and PPE	Conclusion
Very high	Skin corr 1B, Eye Dam 2 H314; Resp Sens 1 H334; Skin sens 1 H317	12	Industrial Professionals	Slimicides	dermal	Every 2 months / maintenace 240 min daily	-	coated coveralls, eye protection and RPE (2.5%) / maintenance coated coveralls, 10% penetration and gloves	Acceptable: - Low frequency of use - Short duration of use - Professionals using RMM and following instructions of use - Minimisation of manual phases -Good standard of personal hygiene

Conclusion

Scenario [27a]: This scenario is acceptable using coated coveralls, gloves (10 % penetration), eye protection and RPE (2.5% penetration).
Scenario [28]: This scenario is acceptable using coated coveralls and gloves (10 % penetration). In addition, RPE is recommended to reduce inhalation exposure.

There is no concern for professionals using Protectol® GA 50 during paper de-inking processes when considering the recommended uses and the above mentioned personal protective equipment.

Risk for non-professional users

There is no primary non-professional exposure as paper production is related to an industrial/professional use only.

Risk for the general public

There is neither primary nor secondary exposure of the general public as paper production is related to industrial/professional uses only.

2.2.6.3.3 Product Types 11 and 12

Oilfield applications

Risk for industrial users

See professional risk characterisation.

Risk for professional users

PT 11 & PT12: Prevention of corrosion and biofilm formation in liquid cooling and processing systems (hydrotesting fluid)

The possibility that a professional worker is exposed to Protectol® GA 50 during normal usage has been considered. Scenarios [29] and [30] (Connecting/Disconnecting drums or intermediate bulk containers (IBCs)) concerns exposure situations that are expected to take place once a week. The dermal and inhalation exposure for scenario [30] is regarded as negligible and therefore no risk characterisation is conducted (see scenario [1b]). For scenario [29] chronic exposure is considered for systemic risk characterisation. Regarding the local risk characterisation *via* the inhalation exposure route, only acute exposure is considered relevant as exposure duration is only 10 min/day.

Systemic risk characterisation

Systemic effects – chronic scenarios

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[29]	1	3.5	0.014	1.19	8500	no
	2	3.5	0.014	0.0153	109	no
	3	3.5	0.014	0.0125	89	yes

Local effects

Local risk characterization: Inhalation Exposure

Acute inhalation exposure

(Grey background indicates an assessment where risk is identified but refinement is possible.)

Task/ Scenario	Tier	AEC $_{acute\ inhalation}$ mg/m^3	Acute dose mg/m^3	Estimated concentration in air/ AEC (%)	Acceptable (yes/no)
[29]	1	0.5	11	2200	no
	2	0.5	1.1	220	no
	3	0.5	0.275	55	yes

Local risk characterization: Dermal and Oral Exposure

Quantitative local risk assessment for dermal effects is not performed. The effects of glutaraldehyde are concentration-dependent rather than dose-dependent. Professional workers are expected to be well trained and wear suitable protective equipment to protect from exposures to the product. Direct exposure will mostly be excluded by the use of coated coveralls, protective gloves, boots and eye/face protection. Splashes may occur and result in exposure to up to 50% glutaraldehyde. The use of PPE will be obligatory.

Conclusion

Scenario [29]: The use of coated coveralls, gloves (10 % penetration) and eye protection and RPE (2.5% penetration) is is required for scenario [29].

There is no concern for professionals handling Protectol® GA 50 during oilfield applications.

PT 11 & 12: Prevention of corrosion and biofilm formation during mineral oil extraction (flooding and oil injection water)

The possibility that a professional worker is exposed to Protectol® GA 50 during normal usage has been considered. Scenario [31] (Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)) concerns exposure situations that are expected to take place once a week and therefore chronic exposure is considered for systemic risk characterisation. Regarding the local risk characterisation *via* the inhalation exposure route, only acute exposure is considered as exposure duration is only 10 min/day. In scenario [32] (Professional users loading Protectol® GA 50 (Connecting/Disconnecting intermediate bulk containers, IBCs)) dermal and inhalation exposure is regarded as negligible and therefore no risk characterisation is conducted (see scenario [1b]). These scenarios are identical to scenarios [29] and [30] and risk characterisation is therefore not repeated (please refer to scenarios [29] or [30] for details). There is no concern for professionals handling Protectol® GA 50 during oilfield applications.

Conclusion

Scenario [31 (see scenario [29] for details): The use of coated coveralls, gloves (10 % penetration), eye protection and RPE (2.5% penetration) is required for scenario [31].

There is no concern for professionals handling Protectol® GA 50 during oilfield applications.

Risk for non-professional users

There is no primary non-professional exposure as oilfield processes are related to industrial/professional uses only.

Risk for the general public

There is neither primary nor secondary exposure of the general public as oilfield processes are related to industrial/professional uses only.

Risk for consumers via residues in food

Food, drinking water or livestock exposure of glutaraldehyde can be excluded when applied according to the recommended uses. In addition, it was shown that oral exposure with liquid detergent used in dish washing [22] is very low. Therefore, no unacceptable risk to consumer health *via* residues in food needs to be expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

As the b.p. Protectol® GA 50 consists only of a 50% solution (w/w) of glutaraldehyde in water, no risk characterisation from combined exposure to several active substances or substances of concern with the b.p. is conducted.

2.2.7 Risk assessment for animal health

Food, drinking water or livestock exposure of glutaraldehyde can be excluded when applied according to the recommended uses. Therefore, no unacceptable risk to animal health needs to be expected.

2.2.8 Risk assessment for the environment

2.2.8.1 *Effects assessment on the environment*

The risk characterization for the environment is performed using the following PNECs from the assessment report (AR, 2014) for glutaraldehyde.

PNECs for STP, freshwater, seawater and soil		
Unit	**Unit**	**Value**
Water	[µg/L]	2.5
STP	[mg/L]	0.51
Soil	[mg/kg ww]	0.184
Marine	[µg/L]	0.25

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The formulation is toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. The proposed classification/labelling of the biocidal product according to GHS is Aquatic Chronic 2, including the hazard statements H411. However, if the endpoints derived with the 50% solution of glutaraldehyde are calculated to a 100% glutaraldehyde solution, pure glutaraldehyde is then very toxic to aquatic organisms and may cause long-term adverse effects in aquatic environment. Thus, pure glutaraldehyde has to be classified as Aquatic Acute 1 (H400) and Aquatic Chronic 2 (411) according to GHS. However, the classification proposed for pure glutaraldehyde is not relevant the b.p. formulation.

Further ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required
Justification	The biocidal product (b.p.) Protectol® GA 50 is a 50% solution of glutaraldehyde in water. It is intended for private and professional use as in-can preservatives for products prone to microbial spoilage (PT 6) as well as for professional use in the offshore oil exploration industry (PT 11 and PT 12) and uses in paper mills (PT 12). All available experimental studies investigating the ecotoxicological effects were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100 % solution). The available data on the b.p. glutaraldehyde allow for environmental classification according to Regulation (EC) No 1272/2008 (CLP, 6th ATP). The b.p. has to be classified as H411 (Toxic to aquatic life with

	long-lasting effects) based on the studies with 50% solution of glutaraldehyde. The legal classification for pure glutaraldehyde is not relevant for b.p., i.e. for the 50 % solution since in all available studies the 50 % solution was tested. The classification based on tests with the formulation is generally more relevant than the derivation *via* calculation based on mixture rules according to GHS. However, the risk assessment for the relevant environmental compartments is based on glutaraldehyde itself, i.e. taking into account the concentration of glutaraldehyde in the b.p. and on the endpoints related to 100 % glutaraldehyde. The route of environmental exposure for PT 6 to surface water is mainly *via* the sewage treatment plant (STP) or *via* direct releases to soil and surface water. The environmental risk assessment did not indicate a risk for sewage treatment plants and indirect exposure of the aquatic and terrestrial compartment *via* STP (PEC/PNEC ratios < 1). The assessed risk for the aquatic compartment after direct release to surface water is deemed acceptable taking into account the reactivity of the a.s. as well as a more realistic parameter setting for the environmental risk assessment. To mitigate the risk for the terrestrial compartment a direct release of directly with Protectol® GA 50 preserved paint in spray applications to soil has to be avoided by covering the soil during application. After the use in the offshore oil exploration industry (PT 11 and PT 12) a direct release to seawater is possible. No unacceptable risk for marine organisms was determined (PEC/PNEC ratios < 1). The environmental release route for the use in paper mills (PT12) is *via* STP. The label states that the use is only allowed in paper mills, where the discharge of wastewater to seawater is *via* STP. A risk was not identified (All PEC/PNEC ratios < 1). Furthermore, bioaccumulation of the a.s. in aquatic or terrestrial organisms is unlikely based on the low log Kow of the a.s. (log Kow: -0.36 (according to the Guidance on BPR IV/B (2015)). Regarding Article 21 (1(a)) of EU Regulation No 528/2012 (22 May 2012), and owing to the use and exposure considerations as mentioned above, there is no need to further investigate the ecotoxicological effects for the b.p..

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	Information on effects on any other specific, non-target organisms (flora and fauna) is not required for the biocidal product.
Justification	The biocidal product (b.p.) Protectol® GA 50 is a 50% solution of glutaraldehyde in water. It is intended for private and professional use as in-can preservatives for products prone to microbial spoilage (PT 6) as well as for professional use in the offshore oil exploration industry (PT 11 and PT 12) and uses in paper mills (PT 12). All available experimental studies investigating the ecotoxicological effects were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100 % solution). The available data on the b.p. glutaraldehyde allow for environmental classification according to Regulation (EC) No 1272/2008 (CLP, 6th ATP). The b.p. has to be classified as H411 (Toxic to aquatic life with long-lasting effects) based on the studies with 50% solution of glutaraldehyde. The legal classification for pure glutaraldehyde is not relevant for b.p., i.e. for the 50 % solution since in all available studies the 50 % solution was tested. The classification based on tests with the formulation is generally more relevant than the derivation *via* calculation based on mixture rules according to GHS. However, the risk assessment for the relevant environmental compartments is based on glutaraldehyde itself, i.e. taking into account the concentration of glutaraldehyde in the b.p. and on the endpoints related to 100 % glutaraldehyde. The route of environmental exposure for PT 6 to surface water is mainly *via* the sewage treatment plant (STP) or *via* direct releases to soil and surface water. The environmental risk assessment did not indicate a risk for sewage treatment plants and indirect exposure of the aquatic and terrestrial compartment *via* STP (PEC/PNEC ratios < 1). The assessed risk for the aquatic compartment after direct release to surface water is deemed acceptable taking into account the reactivity of the a.s. as well as a more realistic parameter setting for the environmental risk assessment. To mitigate the risk for the terrestrial compartment a direct release of directly with Protectol® GA 50 preserved paint in spray applications to soil has to be avoided by covering the soil during application.

	After the use in the offshore oil exploration industry (PT 11 and PT 12) a direct release to seawater is possible. No unacceptable risk for marine organisms was determined (PEC/PNEC ratios < 1). The environmental release route for the use in paper mills (PT12) is *via* STP. The label states that the use is only allowed in paper mills, where the discharge of wastewater to seawater is *via* STP. A risk was not identified (All PEC/PNEC ratios < 1). Furthermore, bioaccumulation of the a.s. in aquatic or terrestrial organisms is unlikely based on the low log Kow of the a.s. (log Kow: -0.36 (according to the Guidance on BPR IV/B (2015)). Regarding Article 21 (1(a)) of EU Regulation No 528/2012 (22 May 2012), and owing to the use and exposure considerations as mentioned above, there is no need to further investigate the ecotoxicological effects for the b.p..

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	Information on the risks to non-target organisms under field conditions is not required.
Justification	The b.p. does not contain any lure which could be attractive for non-target organisms. Therefore, ingestion by non-target organisms is no matter of concern. Moreover, the b.p. is not marketed in the form of baits or granules.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	Information on the acceptance by ingestion of the biocidal product by any non-target organisms is not required.
Justification	The b.p. does not contain any lure which could be attractive for non-target organisms. Therefore, ingestion by non-target organisms is no matter of concern. Moreover, the b.p. is not marketed in the form of baits or granules.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Protectol® GA 50 is not intended for large scale treatment of habitats like water bodies, wetland, forest or fields. The b.p. is not expected to persist in the environment or to bioaccumulate along the food chain based on the ready biodegradability and very low bioaccumulation potential of the a.s. Therefore, information on secondary ecological effects is not required.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Information on how the a.s. can be released into the environment during application and service life in PT 6, 11 and 12 and the potential emissions have been assessed in this PAR. Sources for emissions as well as target environmental compartments have been considered and concentrations in the compartments of concern have been calculated. For detailed information, please refer the relevant sections in the PAR.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification	All available experimental studies investigating the fate and behaviour in the environment were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100% solution). There are no indications of risk due to specific properties of the b.p. as it does not contain any substance of concern for the environment. Therefore, the fate of the b.p is covered by the data provided for the a.s.

However, the decomposition of glutaraldehyde in paints was studied (please refer to 10.2 in Iuclid, Rohwer, 2016a). The study was conducted based on the ”Guidance on a laboratory leaching test method for materials that are treated with biocides”, 12 October 2015, established for the determination of the leaching of biocides of product types 7, 9, 10. In the study, wall paint was doped with 500 mg/L glutaraldehyde and the concentration of the substance was monitored over a period of 4 weeks using HPLC. Furthermore, the wall paint was applied onto a glass plate after two weeks of storage.

Degradation of glutaraldehyde in the wall paint could be demonstrated with a half-value period of approx. 2 weeks. The degradation half-life is based on the results obtained with sample A after 14 and 28 days for the wet state representing the worst case of all results obtained. For sample A the remaining glutaraldehyde concentration after 14 and 28 days was 51.8% or 25.3% respectively. In sample B degradation was higher (42.2% and 20.7% glutaraldehyde remaining). When applied onto a glass plate, approx. 75% of the a.s. present at the time of application degraded within 2 weeks resulting in a half-life of approx. 7 days. The applicant proposed the qualitative use of this study to support safe use of Protectol GA 50. However, the study was not fylly accepted by all commenting Member States and it has not been used even for the qualitative refinmenet of the risk assessment.

Furthermore, the decomposition of glutaraldehyde was elaborated in substitute ocean water (please refer to 10.2 in Iuclid, Carstens-Roth, 2016). Therefore, a substitute ocean water was doped with approximately 25 and 50 mg/kg glutaraldehyde (equivalent to 50 and 100 mg/kg Protectol® GA 50), respectively. Bisulfite concentrations at different concentration levels have been added and the kinetics of the glutaraldehyde concentration was monitored. Additional experiments on caustic degradation of 25 mg/kg glutaraldehyde in Rhine river water were also conducted.

A fast removal of glutaraldehyde in substitute ocean water was shown (within a few minutes), which strongly depends on the added bisulfite concentration. To achieve residual glutaraldehyde concentration below 0.2 mg/kg ($PNEC_{marine}$), it is required to add at least 2.5 parts of sodium bisulfite for each part of glutaraldehyde. Caustic (NaOH) degradation is slower than bisulfite method, but it is very effective in freshwater.

Leaching behaviour (ADS)

The b.p. is used as a preservative in PT 6, 11 and 12. The leaching behaviour of the a.s. is assessed within the exposure assessment by using adequate models where relevant. Further studies regarding the leaching behaviour are therefore not necessary.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in soil is not required.
Justification	All available experimental studies investigating the distribution and dissipation in soil were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100% solution). Furthermore, the a.s. can be considered as readily biodegradable. For the environmental exposure assessment, a default degradation half-life of 30 days in soil is used according to the Guidance for BPR IV/B (2015). Further testing for distribution and dissipation in the soil is therefore not deemed reasonable.

Testing for distribution and dissipation in water and sediment (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in water and sediment is not required.
Justification	All available experimental studies investigating the distribution and dissipation in water and sediment were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100% solution). The components of the b.p. do not influence the distribution characteristics of the a.s as it only contains the a.s. and water. Further testing for distribution and dissipation in water and sediment is therefore not deemed reasonable.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in air is not required.
Justification	The a.s. glutaraldehyde is volatile, but does not easily evaporate from water due to high water solubility. As the substance is subjected

	to rapid photodegradation in air with a half-life of 8.2 h, a risk for the atmosphere and a long-range transport is therefore not to be expected.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Data waiving	
Information requirement	Further information on acute aquatic toxicity is not required.
Justification	The b.p. is used as preservative and the a.s. degrades rapidly in the environment. The risk assessment indicates acceptable risks for the relevant uses. Thus, an overspray study under field conditions is therefore considered to be unnecessary.

Data waiving	
Information requirement	Further information on chronic aquatic toxicity is not required.
Justification	All available experimental studies investigating the ecotoxicological effects were conducted with the b.p., i.e. the 50% solution of glutaraldehyde. However, all endpoints were related to the a.s. (100% solution). Therefore, there are no indications of risk due to specific properties of the b.p.

Data waiving	
Information requirement	Further information on aquatic bioconcentration is not required.
Justification	As the a.s. has a low log Kow, the bioconcentration potential is very low. Furthermore, there are no indications of bioconcentration due to specific properties of the b.p. as it only contains water and the a.s.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

The b.p. may be applied as in-can preservative in paints, which are used outside. However, this type of application cannot be considered as large scale and therefore, there is no potential for large scale formation of dust. Therefore, the risk to bees and non-target arthropods under field conditions has not further to be assessed.

2.2.8.2 Exposure assessment

Exposure assessment - Product type 6: In-can preservatives

The b.p. Protectol® GA 50, a 50% solution of glutaraldehyde in water, may be used as in-can preservative in formulations (PT 6) to prevent deterioration during storage in containers. Protectol® GA 50 is dosed at 979 ppm a.s. (100 % glutaraldehyde) based on final formulation volume (equivalent to 0.0979% w/w glutaraldehyde in product).
The intended uses are the following (Sub-categories are taken from the Draft Revision of the Emission Scenario Document for Product Type 6, UBA, 2015[18]):

1) PT 6.1 – Preservation of detergents and cleaning fluids: Preservative for organic solutes e.g. liquid cleaning formulations for the application in dishwashing application, laundry application and fabric softener or the use as preservative for floor waxes and car polishes. Furthermore, it used for the preservation of raw materials for detergents and cleaning laundry products.
2) PT 6.2 – Preservation of paints and coatings: Preservative for polymer emulsions, polymer dispersions and organic particle dispersions for the use in paints
3) PT 6.3.1 – Paper production: Preservative for organic/inorganic particle dispersions and pigment dispersion used for mainly paper applications
4) PT 6.3.2 – Textile production: Preservative for organic emulsions or pigment dispersions used for textile treatment chemicals
5) PT 6.3.3. – Leather production: Preservative for organic emulsions, e.g. leather re-fattening agents and preservation of other leather treatment chemicals (auxiliaries)
6) PT 6.6 – Glues and adhesives: Preservative for polymer dispersion used for glues

According to the Draft Emission Scenario Document for Product Type 6 (UBA, 2015), the life cycle steps formulation, application and service life (only relevant for PT 6.2 – Paints and coatings) need to be considered. The formulation step is considered to be negligible compared to the application step and service life. It is thus not further considered here. This can be explained by the fact that the formulation takes place in closed industrial systems according to national legislations minimizing the emissions to the environment. Therefore, the life cycle steps application and treatment for the relevant sub PTs are assessed in following.

The environmental risk assessment for the b.p. is based on the Draft ESD PT 6 (2015) and on the Guidance on Biocidal Products Regulations Volume IV Environment Part B (Guidance on BPR IV/B, 2015)[19]. The relevant information for all Protectol® GA 50 uses, e.g. the ESDs where the Draft ESD for PT 6 (2015) referred to, are listed in the following table.

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[18] DRAFT version v1 – Revision of the Emission Scenario Document for Product Type 6: Preservatives for Products during Storage. UBA, 3711 65 413, 2015.

[19] Guidance on Biocidal Products Regulation: Volume IV Environment Part B Risk Assessment (active substances), European Chemicals Agency – ECHA-15-G-01-En, 2015.

General information

Assessed PTs	PT 6.1 Detergent and cleaning fluids PT 6.2 Paints and Coatings PT 6.3.1 Paper production PT 6.3.2 Textile production PT 6.3.3 Leather production PT 6.6 Glues and adhesives
Assessed scenarios	*PT 6.1:* Scenario 6.1 - 1: Use in detergents (private use) Scenario 6.1 - 2: Use in detergents (professional use) *PT 6.2:* Scenario 6.2 - 1: City (outdoor use) Scenario 6.2 - 2: Countryside (outdoor use) *PT 6.3.1:* Scenario 6.3.1 - 1: Wet-end additives and paper coatings *PT 6.3.2:* Scenario 6.3.2 - 1: Textile processing *PT 6.3.3:* Scenario 6.3.3 - 1: Leather processing *PT 6.6:* Glues - covered by scenario 6.1 - 1 and 6.2 – 1/2
ESD(s) used	**General:** Draft Revision of the Emission Scenario Document for Product-Type 6: Preservatives for Products during Storage (2015) **Sub PT specific:** *PT 6.1:* Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector) (2001) Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (2011) *PT 6.2:* Emission scenario document for biocides used as masonry preservatives (product type 10) (2002) Revised Emission Scenario Document for Wood Preservative – PT 8 (2013) Leaching from paints, plasters, and fillers applied in urban areas (Netherlands, Ctgb, Version 6, 2015) The assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10) (Germany, UBA, Version 3, 2014) *PT 6.3.1*: Emission Scenarios Document PT 6, 7 and 9: Biocides used as preservatives in paper coating and finishing. Assessment of the environmental release of biocides used in paper coating and finishing (2001)

	PT 6.3.2: Series on Emission Scenario Documents Number 7: Emission scenario document on textile finishing industry. (2004) *PT 6.3.3:* OECD Series on Emission Scenario Documents Number 8; Emission Scenario Document on Leather Processing. (2004) *PT 6.6:* Covered by scenario 6.1 - 1 and 6.2 – 1/2
Approach	All scenarios are assessed using average consumption approaches
Distribution in the environment	Calculation based on Guidance for BPR IV/B (2015)
Groundwater simulation	Yes (Focus PEARL 4.4.4 for PT 6.2 - 2)
Life cycle steps assessed	Production: No Formulation: Yes (Qualitative Assessment) Use/Application: Yes Service life: Yes (only relevant for PT 6.2 uses)
Remarks	[-]

Exposure assessment - Product type 11: Preservatives for liquid-cooling and processing systems

The b.p. Protectol® GA 50, a 50% solution of glutaraldehyde in water, may be used as preservative for processing systems (PT 11) in the offshore oil exploration industry. As the in-use concentration and use scenarios in PT 11 (prevention of microbially induced deterioration and corrosion in injections systems, transmission lines, storage systems and pipelines) are identical to those in PT 12, the risk assessment for PT 12 covers the risks for PT 11. Therefore, for the exposure assessment and risk assessment in PT 11; please refer to the relevant PT 12 sections.

Exposure assessment - Product type 12: Slimicides

Protectol® GA 50 may be used as slimicide (PT 12) in paper mills to supress the growth of microorganisms in water.

The intended uses in paper mills are the following:

1) One-off shock dose (short term) of 5 - 200 ppm glutaraldehyde in-use concentration providing a defouling treatment to protect the wet stock
2) Use in paper-wet-end production for the protection of process water by continuous or semi-continuous dose of 5 - 150 ppm glutaraldehyde in-use concentration providing a maintenance treatment
3) Use in the de-inking in paper production with a dose of 5 - 125 ppm glutaraldehyde in-use concentration

In the AR for glutaraldehyde (2014), the uses defouling treatment (75 ppm a.s. in-use concentration), maintenance treatment (37.5 ppm a.s. in-use concentration) and paper de-inking (tonnage approach with release to sewage treatment plant, STP) were assessed. As higher in-use concentrations are used for product authorization, 200 ppm a.s. in-use concentration is assessed in the following environmental risk characterization covering as worst-case all types of PT 12 applications. The assessment has been carried out for continuous dosing. As the assessed concentration is the highest concentration used for shock/intermittent dosing, also intermittent dosing is covered."

According Emission Scenario Document for PT 12 (EUBEES, 2003)[20], the life cycle steps formulation and application need to be considered. The formulation step is considered to be negligible compared to the application step. It is thus not further considered here. This can be further explained by the fact that the formulation takes place in closed industrial systems according to national legislations minimizing the emissions to the environment. Therefore, the life cycle step application is assessed in the following.

Next to the PT 12 use in paper mills, the b.p. Protectol® GA 50 may be used in the offshore oil exploration industry to supress the growth of microorganisms in water.
The intended uses in the offshore oil exploration industry are the following:

1) For seawater injection to prevent biofilm in equipment upstream of injection wellhead with 12.5 – 750 ppm a.s. in-use concentration
2) For produced water re-injection to prevent biofilm in water treatment units before produced water is re-injected with 12.5 -750 ppm a.s. in-use concentration
3) For produced water disposal to prevent biofilm in hydrocyclones, gas floatation units and filters (in-use concentration: 12.5 – 130 ppm a.s.)
4) In transmissions pipelines and systems to prevent biofilm formation, where low amounts of water occur with an in-use concentration of 12.5 – 1000 ppm a.s. (depends on length of transmission pipelines)
5) In crude and gas storage wells and systems to prevent biofilm formation applying an in-use concentration of 12.5 – 750 a.s. ppm a.s.
6) For pipeline pigging and scraping operations to prevent the formation of biofilms in pipelines during the cleaning process (12.5 – 750 ppm a.s.)
7) For hydrotesting to prevent the formation of biofilms in pipelines with an in-use concentration of 12.5 – 2000 ppm a.s.

The concentration and amount of a.s. to be used in the offshore oil exploration industry varies and depends e.g. on the pipeline length, storage duration, soiling of the water, the level of degradation of the a.s. and the reuse of the production water. Furthermore, not for all scenarios mentioned above a direct release to seawater is anticipated (see below for further information).

In the AR for glutaraldehyde (2014), the use as production chemical for PT 11 (50 – 300 ppm a.s. in-use concentration) has been assessed. As the in-use concentration and use scenarios in PT 12 are identical to those in PT 11 (prevention of corrosion in injections systems, transmission lines, storage systems and pipelines), the risk assessment for PT 12 covers the risks for PT 11.

As higher in-use concentrations are used for product authorization compared to the AR (2014), 750 ppm in-use concentration is assessed in the following environmental risk characterization covering as worst-case all types of application; i.e. 1, 2, 4, 5 and 6. It is

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[20] Harmonisation of Environmental Emission Scenarios for Slimicides (product type 12), EUBEES, Royal Haskoning, 4L1784.A0/R0009/FBA/TL/Nijm, 2003.

assumed that the higher maximum in-use concentration of 1000 ppm a.s of scenario 4) is covered by the calculated exposure scenario due to the very low amount of water used in this scenario and since no direct release in seawater is expected (see below).

Regarding hydrotesting, an in-use concentration of 5 ppm was assessed in the AR (2014) with the further refinement to limit the maximum a.s. concentration in the hydrotest water to 0.05 ppm prior to disposal. As higher in-use concentrations are used for product authorization compared to the AR (2014); i.e. 12.5 – 2000 ppm, three different scenarios for hydrotesting are assessed, depending on the project.

Regarding the application to produced water prior disposal to prevent biofilm formation in different structures, e.g., hydrocyclones, gas floatation units and filters, the scenario was not assessed in the AR (2014). A maximum in-use concentration of 130 ppm a.s. is further assessed.

For the use of the b.p. in oil and gas exploration industry, the application step needs to be considered.

The environmental risk assessment for the b.p. uses in PT 12 is based on the ESD for PT 12 (2003), the scenario document “Environmental risk assessment of biocides applied in the offshore oil exploration industry” (Netherlands, Ctgb, 2015), the CHARM-model (2005), the calculations presented in the AR (2014) and on the Guidance on Biocidal Products Regulations Volume IV Environment Part B (Guidance on BPR IV/B, 2015). The relevant information for all Protectol® GA 50 PT 12 uses are listed in the following table.

General information

Assessed PTs	PT 12 (covers the PT 11 uses in the offshore oil exploration industry)
Assessed scenarios	*PT 12* Scenario 12.1 - 1: Reasonable worst case Scenario 12.1 - 2: Typical case Scenario 12.2 - 1: Production chemicals/Reservoir injection Scenario 12.2 - 2: Hydrotesting Scenario 12.2.2 – 1: Slow release Scenario 12.2.2 - 2: Disposal/re-use of the hydrotesting water Scenario 12.2.2 - 3: Degradation of glutaraldehyde in the pipeline Scenario 12.2 – 3: Produced water disposal
ESD(s) used	**General:** [-] **Sub PT specific:** Harmonisation of Environmental Emissions Scenarios for Slimicides (product type 12) (2003)

	Environmental risk assessment of biocides applied in the offshore oil exploration industry (Netherlands, Ctgb, 2015)[21] Chemical Hazard Assessment and Risk Management – For the use and discharge of chemical used offshore (CHARM User Guide Version 1.4, 2005) Zipperle A., Gils v.J., Hattum v.B., Heise S. (2011): Guidance for a harmonized Emission Scenario Document (ESD) on Ballast Water discharge; Umweltbundesamt; Project No. (FKZ) 363 01 205. (UBA, 2011)
Approach	All scenarios are assessed using average consumption approaches
Distribution in the environment	Calculation for the use in paper mills is based on Guidance for BPR IV/B (2015). For the use in the offshore oil exploration industry, the calculation is based on the MAMPEC-model (Deltares, Version 3.01) and CHARM (2005)
Groundwater simulation	No
Life cycle steps assessed	Production: No Formulation: Yes (Qualitative Assessment) Use/Application: Yes Service life: No
Remarks	[-]

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[21] https://echa.europa.eu/documents/10162/16908203/esd_pt_11-12_final_en.pdf. Retrieved: 21.06.2016.

Emission estimation

Emission estimation - Product type 6: In-can preservatives

6.1: Detergents and cleaning fluids

Scenario 6.1 - 1: Use in detergents (private use)

Protectol® GA50 containing the a.s. glutaraldehyde is used as in-can preservative for laundry softener, liquid dishwashing detergents and other organic liquid cleaning formulations used in households and for industrial and institutional cleaning. It may also be used for the preservation of raw materials for liquid detergents and cleaning fluids. However, it is assumed that this use is covered by the use as in-can preservative in liquid detergents. The formulations are discarded to the drain with the waste water subsequently reaching the sewage treatment plant (STP). According to Draft ESD for PT 6 (2015), four scenarios were considered:

- Use in detergents (domestic use)
- Use in detergents (professional use)
- Use in laundry (domestic use)
- Use in laundry (professional use)

For the application as preservative in polymer emulsion like floor waxes and car polishes pouring into the drain of those products is not to be expected according to the AR for glutaraldehyde (2014). The application in car polishes and floor waxes is therefore not further quantitatively assessed. During the drying of the floor polish and wax, glutaraldehyde will polymerize due to water removal further preventing losses to the environment (CAR, DocIIA, p. 5) for a description of this property: "If the amount of glutaraldehyde in water exceeds 50 %, a change in composition of glutaraldehyde takes place because of gradual polymerization reaction of glutaraldehyde molecules. It is possible to distil and concentrate glutaraldehyde but the distillate becomes viscous, and glassy solid (oligomers) will be formed within hours. The polymerization reaction is reversible. The mobile liquid is recovered by heating and refluxing above 40 ºC (Olson 1998)."

Scenario 6.1 - 1: Use in detergents (domestic use)

The emission scenario to calculate the release of detergents for non-professional use (Draft ESD for PT 6, 2015) is applied to cover this use.

Input parameters for calculating the local emission of glutaraldehyde for the use as in-can preservative in detergents for sanitary purposes – domestic use (Scenario 6.1 – 1)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Number of inhabitants feeding one STP	Nlocal	10000	[-]	D*
Fraction released to wastewater	F_{water}	1	[-]	D*
Concentration of a.s. in detergent	C_{form}	0.000979	[kg/L]	S
Consumption per capita (general purposes: tiles, floors, sinks)	V_{form}	0.005	[L/cap./d]	D*

Input parameters for calculating the local emission of glutaraldehyde for the use as in-can preservative in detergents for sanitary purposes – domestic use (Scenario 6.1 – 1)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Consumption per capita (lavatory)	V_{form}	0.002	[L/cap./d]	D*
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D*
Penetration factor of preservative	F_{penetr}	0.5	[-]	D*
Output				
Emission rate to waste water	Elocal	0.03	[kg/d]	O
Elocal = Nlocal*V_{form}*C_{form}*F_{penetr}*(1-F_{dis})*F_{water} Vform = 0.005 + 0.002 = 0.007				

*Default values are taken from the ESD for PT 2 (2011)

The emission rate to waste water is calculated according to the equation shown in Table 4 in ESD for PT 2 (2011).

This results in a local emission to wastewater of **0.03 kg/d**.

Scenario 6.1 - 2: Use in detergents (professional use)

The emission scenario to calculate the release of detergents by professionals (Draft ESD for PT 6, 2015) is applied to cover this use.

Input parameters for calculating the local emission of glutaraldehyde for the use as in-can preservative in detergents for sanitary purposes – professional use (Scenario 6.1 – 2)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Application rate	V_{form}	0.0002	[-]	D*
Concentration of a.s. in detergent	C_{form}	0.979	[g/L]	S
Surface area to be cleaned	$AREA_{surface}$	1000	[m²]	D*
Number of applications per day	Nappl	1	[-]	D*
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D*
Fraction released to wastewater	F_{water}	1	[-]	D*
Penetration factor of preservative	F_{penetr}	0.5	[-]	D*
Output				

Emission rate to waste water	Elocal	9.79×10^{-5}	[kg/d]	O
Elocal = $V_{form}*C_{form}*AREA_{surface}*Nappl*(1-F_{dis})*F_{water}*F_{penetr}/1000$				

*Default values are taken from the Draft ESD for PT 6 (2015)

The emission rate to waste water is calculated according to the equation shown in Table A6 in Draft ESD for PT 6 (2015).

This results in a local emission to wastewater of **9.79×10^{-5} kg/d**.

Scenario 6.1 - 3: Use in laundry (domestic use)

Protectol® GA50 is formulated as preservative in liquid cleaning formulations like laundry detergents, softeners and cleaners used e.g. in households. It may also be used for the preservation of raw materials (e.g. brighteners and surfactants) for liquid laundry products. The emission scenario to calculate the release of detergents used for laundry for non-professional use (Draft ESD for PT 6, 2015) is applied to cover these uses.

Input parameters for calculating the local emission of glutaraldehyde for the use as in-can preservative for detergents – laundry (domestic use) (Scenario 6.1 – 3)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Number of houses feeding one STP	N_{house}	4000	[-]	D*
Number of laundry washes per household per day	N_{wash}	0.61	[d^{-1}]	D*
Fraction released to wastewater	F_{water}	1	[-]	D*
Fraction of washes performed with liquid laundry detergents	F_{liquid}	0.6	[-]	D*
Dosage of liquid laundry detergents	$Dose_{liquid}$	0.075	[L]	D*
Dosage of fabric softeners	$Dose_{fabricsoftener}$	0.04	[L]	D*
Concentration of a.s. in detergent	C_{form}	0.000979	[kg/L]	S
Output				
Emission rate to waste water	Elocal	0.20	[kg/d]	O
Elocal = $N_{house}*N_{wash}*F_{water}*C_{form}*[(F_{liquid}*Dose_{liquid})+Dose_{fabricsoftener}]$				

*Default values are taken from the Draft ESD for PT 6 (2015)

The emission rate to waste water is calculated according to the equation as shown in Table A8 in the Draft ESD for PT 6 (2015).

This results in a local emission to wastewater of **0.20 kg/d**.

Scenario 6.1 - 4: Use in laundry (professional use)

Protectol® GA50 is formulated as preservative in liquid cleaning formulations like laundry detergents, softeners and cleaners used by professionals. It may also be used for the preservation of raw materials (e.g. brighteners and surfactants) for liquid laundry products. However, it is assumed that this use is covered by the professional use as in-can preservative in laundry products. The emission scenario to calculate the release of detergents used for laundry from hospital in washing streets (ESD for PT 2, 2001) is applied to cover these uses. According to the draft ESD for PT 6 (2015), 6 g detergent per kg of dirty laundry is used. Furthermore, the calculations are done with a market share of 0.5, as it is stated in the Draft ESD for PT 6 (2015).

Input parameters for calculating the local emission of glutaraldehyde for the use as in-can preservative for detergents – professional use (Scenario 6.1 – 4)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Number of washing tubes (with disinfectant)	Nm	3	[-]	D*
Capacity of washing tube	Cap	8000	[kg/d]	D*
Amount of detergent for laundry	$V_{product}$	0.035	[L/kg]	S
Concentration of a.s. in detergent	C_{disinf}	0.000979	[kg/kg]	S
Density of product	RHO_{prod}	1000	[kg/m³]	D*
Concentration reduction in washing process	F_{red}	0	[-]	D*
Market share of preservative	F_{penetr}	0.5	[-]	D*
Output				
Emission rate to waste water	Elocal	0.41	[kg/d]	O
Elocal = $Nm*Cap*V_{product}*C_{disinf}*(1-F_{red})*F_{penetr}$				

*Default values are taken from the ESD for PT 2 (2001) and the Draft ESD for PT 6 (2015)

The emission rate to waste water is calculated according to the equation shown in Table 9 in the Draft ESD for PT 6 (2015).

This results in a local emission to wastewater of **0.41 kg/d**.

Combined exposure

Due to the fact that all emissions could entry in one STP, the local emissions of each sub use were summarized.

This results in a local total emission to wastewater of **0.64 kg/d**.

6.2: Preservation of paints and coatings

Protectol® GA50 containing the a.s. glutaraldehyde is formulated as preservative in paints and in organic/inorganic particle dispersions and polymer dispersion, which are used as raw materials in paints. Furthermore, Protectol® GA50 can be used directly in paints with the highest recommended concentration of 979 mg/L. This is the worst-case application and where following calculations are based on covering all other PT 6-2 uses. According to the Draft ESD for PT 6 (2015), the life cycle steps "application" and "service life" need to be assessed. Paints may be used indoor and outdoor. The outdoor uses are chosen as worst case covering also the indoor use.

Furthermore, the Draft ESD for PT 6 (2015) differs between the scenarios countryside and city. In the city, the a.s. is likely to enter paved ground during application and service life and is washed with rain to the sewer system subsequently reaching the sewage treatment plant (STP) or directly the surface water *via* STP bypass or direct rainwater discharge. It was agreed during the commenting period that direct emission to surface water is notassessed for Protectol GA 50 in the city, i.e. scenarios STP bypass and direct rainwater discharge will be removed. In addition, it will be discussed in the ENV WG-II 2018 whether these scenarios should be included or not

In the countryside, the a.s. directly reaches the soil or surface water. Therefore, after application and service life the exposure routes to the environment are different if the substance is used in a city or countryside. However, the initial releases of a.s. after application and service life are identical for both, the city and countryside scenario. Therefore, the general input parameters are presented in the following two sections, while scenario specific input parameter for the exposure calculation after application and service life, the calculation methods and the local emissions to the environment are further explained in the scenario specific sections "Exposure calculations for Scenario 6.2 - 1 (city scenario) and "Exposure calculations for Scenario 6.2 - 2 (countryside).

Initial releases after application; Scenario 6.2 - 1 and 6.2 - 2

In the Draft ESD for PT 6 (2015) a consumption approach is presented to assess the outdoor use of paints containing glutaraldehyde as preservative. Two types of applications can be distinguished for the outdoor use. The Draft ESD for PT 6 (2015) proposes the use of the scenarios described in ESD for PT 10 (2002) to calculate the emissions during brush/roll application. For paint spraying, the spray scenario from the ESD for PT 8 (2013) is the agreed scenario.

According to the Draft ESD for PT 6, spray application is mainly performed by professionals. Therefore, a differentiation between professional and amateur use is not necessary, whereas the application by brush/roller can be performed by amateurs and professionals.
According to Draft ESD for PT 6 (2015), the worst-case application rate of 0.25 L/m² and a product density of 1.4 kg/L can be adapted as default values.

The general input parameters for calculating the initial local emissions during spray and brush/roller application are shown in the following table. The parameter, the calculation methods and the resulting local releases to the environment are further explained below, in the scenario specific sections ("Exposure calculations for Scenario 6.2 - 1 (city scenario)" and "Exposure calculations for Scenario 6.2 - 2 (countryside)").

Input parameters for calculating the local releases during application (spray and brush application) for scenario 6.2				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Scenario: 6.2 - 1/2				
Treated area of a façade per day	$AREA_{facade}$	125	[m²/d]	D*
Treated wood area - bridge	$AREA_{bridge}$	10	[m²/d]	D*
Application rate of the paint	$Q_{application.product}$	0.25	[L/m²]	D*
Density of paint	$RHO_{product}$	1400	[kg/m^3]	D*
Fraction of substance.s. in paint	F_{ai}	0.000979	[-]	S
Fraction of paint lost during application by spray drift	F_{drift}	0.1	[-]	D*
Fraction of paint lost during application by runoff	F_{runoff}	0.2	[-]	D*
Fraction of paint lost during brush application due to dripping	$F_{dripping}$	0.03 (professional 0.05 (amateur)	[-]	D*
Output				
Local emission due to spray drift (façade)	Elocalspray _drift	4.28E-03	[kg/d]	O
Local emission due to run off after spaying (façade)	Elocalrunoff	8.57E-03	[kg/d]	O
Local emission due to dripping after brush/roller application, amateur (façade)	Elocaldrip,roll ,facade	2.14E-03	[kg/d]	O
Local emission due to dripping after brush/roller application, professional (façade)	Elocaldrip,roll ,facade	1.28E-03	[kg/d]	O
Local emission due to spray drift (bridge	Elocalspray _drift	3.43E-04	[kg/d]	O
Local emission due to run off after spaying (bridge)	Elocalrunoff	6.85E-04	[kg/d]	O
Local emission due to dripping after brush/roller application, amateur (bridge)	Elocaldrip,roll ,facade	1.71E-04	[kg/d]	O

Input parameters for calculating the local releases during application (spray and brush application) for scenario 6.2				
Local emission due to dripping after brush/roller application, professional (bridge)	Elocaldrip,roll ,facade	1.03E-04	[kg/d]	O
Spray application for facade: Spray drift: Elocalspray_drift = Areafacade* Qapplication.product* Fai*RHOproduct*Fdrift*10^{-3} Run off: Elocalrunoff = Areafacade* Qapplication.product* Fai*RHOproduct*Frunoff*10^{-3} Brush application for facade: Elocaldrip,roll,facade = Areafacade*Qapplication.product*Fai*RHOproduct*Fdripping*10^{-3} Spray application for bridge: Spray drift: Elocalspray_drift = Areabridge* Qapplication.product* Fai*RHOproduct*Fdrift*10^{-3} Run off: Elocalrunoff = Areabridge* Qapplication.product* Fai*RHOproduct*Frunoff*10^{-3} Brush application for bridge: Elocaldrip,roll,facade = Areabridge*Qapplication.product*Fai*RHOproduct*Fdripping*10^{-3}				

*Default values are taken from the Draft ESD for PT 6 (2015), the ESD for PT 8 (2013) and the ESD for PT 10 (2002)

Initial releases from treated surfaces during service life; Scenario 6.2 – 1 and 6.2 - 2

Emissions during service life result from leaching of a substance from treated substrates. The cumulative quantity of a.s. emitted to the relevant environmental compartment due to leaching from a treated surface is considered for the assessment.

An initial assessment period is assumed to be 30 days and the remaining service life, i.e. the further assessment period is set to 1825 days resulting in a complete service life period of 5 years. For worst case consideration, it is assumed that the total applied amount of glutaraldehyde is leached to the ground during service life of 30 and 1825 days. Therefore, the cumulative leaching of the substance out of 1 m² treated surface is the same for the initial and the longer assessment period ($Q_{leach,time1} = Q_{leach,time2}$) and calculated using the following equation:

$$Q_{leach,\ time1/2} = Q_{application,\ product} \times F_{ai} \times RHO_{product} \times 0.001$$

The general input parameters for calculating the local emissions during service life are shown in the following table. The parameter, the calculation methods and the resulting local releases to the environment are further explained below, in the scenario specific sections ("Exposure calculations for Scenario 6.2 - 1 (city scenario)" and "Exposure calculations for Scenario 6.2 - 2 (countryside)").

Input parameters for calculating the local releases during service life for scenario 6.2				
Input	**Definition**	**Value**	**Unit**	**D/S/O/P**
Scenario: 6.2 - 1/2				
Treated area of a façade per day (house)	$AREA_{facade}$	125	[m²/d]	D*
Treated area of a bridge per day (bridge over pond)	$AREA_{brige}$	10	[m²/d]	D*
Cumulative leaching over the initial and longer assessment period	$Q_{leach,time1/2}$	3.43×10^{-4}	[kg/m²]	S
Duration of the initial assessment period (service life - leaching)	TIME1	30	[d]	D*
Duration of the longer assessment period (service life - leaching)	TIME2	1825	[d]	D*

*Default values are taken from the Draft ESD for PT 6 (2015) and the ESD for PT 8 (2013)

Exposure calculations for Scenario 6.2 - 1 (City scenario)

The Draft ESD for PT 6 differs between the places countryside and city after the exposure *via* application and service life. In the city scenario, losses due to spray drift and runoff during spray application and dripping during brush application are likely to enter paved ground and are washed with rain to the sewer system subsequently reaching the STP (see section "Scenario 6.2 – 1 – City - Direct emissions to surface water – PECwater" for further information). The local emissions during brush application are calculated according equation 14 of the ESD for PT 10 (2002) and during spray application according to equation 4.114 and 4.115 listed in Table 4.38 of the ESD for PT 8 (2013) taking the input parameters presented in section "Initial releases after application; Scenario 6.2 -1 and 6.2 - 2" into account. The local emissions are **4.28×10^{-3} kg/d** due to drift after spray application, **8.57×10^{-3} kg/d** due to runoff after spray application and **2.14×10^{-3} kg/d** or **1.28×10^{-3} kg/d** due to dripping after brush/roller application by amateur or professional, respectively. In the city scenario, the simultaneous treatment of three houses has to be taken into account, which is in accordance to the city scenario from the Netherlands (Ctgb, 2015). Therefore, the local emissions for the application step have to be multiplied by 3. The emissions to the sewer after the treatment *via* spray and brush/roller application are calculated according to Table 13 of the Draft ESD for PT 6 (2015).

The local emission for service life in the city is calculated according the city scenario (2015) assuming 4000 houses N_{house} in a city, a fraction f_{house} of 1 (fraction of the houses on which paints are applied, market share of the product), cumulative leaching (100%) over the assessment period Q_{leach} of 0.04 kg and the parameters shown in section "Initial releases from treated surfaces during service life; Scenario 6.2 – 1 and 6.2 -2" using equations 4-6 of the city scenario (2015).

The resulting local emissions $Elocal_{water}$ for scenario 6.2 – 1 are shown in the following table.

Resulting local emissions (Elocal) to the sewage treatment plant (STP) or the surface water for scenario 6.2 - 1 (city scenario)					
Parameter	**Definition**	**Compartment**	**Value**	**Unit**	**D/S/O/P**
Local emission of a.s. during spray application to storm water (runoff and drift)	$Elocal_{spray.facade.water}$	STP/Surface water	0.04	**[kg/d]**	O
$Elocal_{spray.facade.water}$ = 3*(Elocalspray_drift_tier1+ Elocalrunoff)					
Local emission of a.s. during brush application due to dripping– amateur use	$Elocal_{roll.facade.water.}$	STP/Surface water	6.42×10^{-3}	**[kg/d]**	O
$Elocal_{roll.facade.water}$ = Elocaldrip,roll,façade*3					
Local emission of a.s. during brush application due to dripping– professional use	$Elocal_{roll.facade.water.}$	STP/Surface water	3.85×10^{-3}	**[kg/d]**	O
$Elocal_{roll.facade.water}$ = Elocaldrip,roll,façade*3					
Local daily emission to storm water during service life	$Elocal_{service\ life}$	STP/Surface water	0.09	**[kg/d]**	O
$Elocal_{service\ life}$= Nhouse*fhouse*Qleach/TIME2					

For worst case considerations, the type of application with the highest local emission, i.e. spray application with **0.04 kg/d**, is used for the life cycle step application and further evaluated in the subsequent risk assessment. Regarding the service life, the local daily emission to sewer is **0.09 kg/d**, which is used for further calculations. Local emissions due to brush applications are not considered further.

Exposure calculations for Scenario 6.2 - 2 (countryside)

In the countryside (scenario 6.2 -2 in this document), the a.s. reaches the soil due to spray drift, runoff and dripping during spray or brush/roll application and due to leaching during service life. In the countryside scenario one house has to be taken into account to calculate the emission during application according to the Draft ESD for PT 6 (2015).

During spraying, losses of paint occur due to runoff and drift. Runoff immediately affects a zone, which has a 50 cm width and 50 cm depth adjacent to the treated house with a circumference of 50 m resulting in a soil volume of 13 m³. During spray application to walls, a fraction of paint droplets deposits on ground after drift. According to the ESD for PT 8 (2013), the degree of drift mainly depends on wind velocity and droplet size. For the spray application assessment, wind stillness and a low wind speed are considered resulting in a deposition of the entire spray drift on the 50 cm ground adjacent to the treated wall. The local emissions due to runoff and drift during spray application are calculated according to equation 4.114-4.116 listed in Table 4.38 of the ESD for PT 8 (2013). For brush application, the local emissions are calculated for amateur use, which represents the worst-case, according to equation 14 of the ESD for PT 10 (2002). The emissions for spraying and brushing/rolling are calculated taking the input parameters presented in section "Initial releases after application; Scenario 6.2 - 1 and 6.2 - 2" into account.

For the exposure assessment of direct emission to surface water in the countryside, the bridge over pond scenario in the ESD for PT 8 (2013) is used. The emission of substance to water during the day of application (brush/roller) is calculated according to equation 4.41 of the ESD.

For the service life, the average daily emission of glutaraldehyde to soil due to leaching over the assessment period is calculated according to equation 3.5 and 3.6 of the ESD for PT 8 (2013) with the parameters mentioned in section "Initial releases from treated surfaces during service life; Scenario 6.2 – 1 and 6.2 - 2". For the direct leaching to surface water (bridge over pond scenario), the equations 3.14 and 3.15 are used.

The resulting local emissions to soil and surface water during application and service life in the countryside (scenario 6.2 -2) are shown in the following table.

Resulting local emissions to soil and surface water for scenario 6.2 - 2 (countryside scenario)				
Parameter	**Definition**	**Value**	**Unit**	**D/S/O/P**
Local emission of a.s. during spray application due to spray drift	$\text{Elocal}_{\text{spray\_drift,façade}}$	4.28×10^{-3}	[kg/d]	O
Local emission of a.s. during spray application due to runoff	$\text{Elocal}_{\text{runoff, façade}}$	8.57×10^{-3}	[kg/d]	O
Local emission of a.s. during brush application due to dripping – amateur	$\text{Elocal}_{\text{drip,roll,façade}}$	2.14×10^{-3}	[kg/d]	O
Local emission of a.s. to surface water during brush application due to dripping – amateur	$\text{Elocal}_{\text{roll, façade water,brush}}$	1.71×10^{-4}	[kg/d]	O
$\text{Elocal}_{\text{roll, façade water}}$ = Areabridge*Qapplication, product*Fai*RHOproduct*Fdripping, amateur*10^{-3}				
Average daily emission of substance due to leaching over initial assessment period	$E_{\text{soil,leach,time1}}$	1.43×10^{-3}	[kg/d]	O
$E_{\text{soil,leach,time1}}$ = (Areafacade*Qleach,time1)/time1				
Average daily emission of substance due to leaching over longer assessment period	$E_{\text{soil,leach,time2}}$	2.35×10^{-5}	[kg/d]	O
$E_{\text{soil,leach,time2}}$ = (Areafacade*Qleach,time2)/time2				
Average daily emission of substance to surface water due to leaching over initial assessment period	$E_{\text{water,leach,time1}}$	1.14×10^{-4}	[kg/d]	O
$E_{\text{water,leach,time1}}$ = (Areabridge*Qleach,time1)/time1				
Average daily emission of substance to surface water due to leaching over longer assessment period	$E_{\text{water,leach,time2}}$	1.88×10^{-6}	[kg/d]	O
$E_{\text{water,leach,time2}}$ = (Areabridge*Qleach,time2)/time2				

Summary of local emissions for PT 6.2

In summary, emissions of glutaraldehyde during the use of paints may occur due to application losses due to runoff, dripping or spray drift and leaching during service life. The receiving environmental compartments are either STP (city - scenario 6.2 - 1) or soil or surface water (countryside - scenario 6.2 - 2).

6.3.1 Preservation of additives in paper production

The b.p. Protectol® GA 50 is used for the in-can preservation of slurries and pigment dispersion used for paper production. The preservative must be added to these formulations during their production in the manufacturing plant to prevent the bio-deterioration of these systems until they are used. This use was evaluated during a.s. authorization (AR for glutaraldehyde, 2014), where OECD ESD No. 16 (2006) and the ESD for PT 6, 7 and 9 (2001) were used for the exposure assessment. For the product assessment, a higher concentration of the a.s. in the additive is foreseen ($C_{a.i}$ = 979 mg/kg). As a refinement (Tier 2), an elimination of 99.6 % during paper production is considered, which is in accordance to the AR (2014).

The following input parameters from the AR (2014) are used for calculating the releases of glutaraldehyde used as preservative in additives in paper production.

Input parameters for calculating the local emission for Scenario 6.3.1 – 1 (paper production)					
Input	**Definition**	**Value**		**Unit**	**D/S/O/P**
		Newsprint	Printing and writing paper		
Quantity of paper produced per day	$Q_{product}$	449	66	[t/d]	D*
Quantity of additives used per tonne	$Q_{additive}$	79	289	[kg/t]	D*
Fraction of additives with a.s. (market share)	F_{ai}	0.5	0.5	[-]	D*
Concentration of a.s. in the additive	$C_{a.i.}$	979	979	[mg/kg]	S
Fraction of broke recycling	F_{broke}	1	1	[-]	D*
Fraction of a.i. fixed on paper	F_{fix}	0	0	[-]	D*
Degree of closure of the water cycle	$F_{closure}$	0.75	0.55	[-]	D*
Fraction of substance eliminated in the wet-end operations (Tier 2)	F_{elim}	0.996	0.996	[-]	S
Output					

Input parameters for calculating the local emission for Scenario 6.3.1 – 1 (paper production)					
Input	**Definition**	**Value**		**Unit**	**D/S/O/P**
Local emission to wastewater during episode – Tier 1	$Elocal_{water}$	4.34	4.20	[kg/d]	
Local emission to wastewater during episode – Tier 2	$Elocal_{water}$	0.02	0.02	[kg/d]	
Tier 1: Elocalwater = Qproduct * Qadditive * Ca.i. * 10^{-6} * Fa.i. * Fbroke * (1-Ffix) * (1-Fclosure) Tier 2: Elocalwater = Qproduct * Qadditive * Ca.i. * 10^{-6} * Fa.i. * Fbroke * (1-Ffix) * (1-Fclosure) * (1-F_{elim})					

*Default values are taken from the Assessment Report for glutaraldehyde (2014)

6.3.2 Preservation of additives in textile production

6.3.2 – 1: Textile processing

Protectol® GA50 containing the a.s. glutaraldehyde may be formulated as in-can preservative in organic emulsions, like textile treatment chemicals.

According to the OECD ESD no. 7 (2004), the process categories pre-treatment, exhaust and padding can be distinguished for textile processing. For every process, several types of products are listed in Table 10 (OECD ESD no. 7, 2004). According to the TAB (2015), the amount of additive per tonne of textile ($Q_{product}$) is 120 kg/t for pre-treatment. For exhaust processes, an application amount of 20 kg/t (Auxiliaries, Finishing, exhaust processes, worst-case) is considered for calculations and for padding processes, the application amount is 300 kg/t (Printing paste, Printing, worst-case). The quantity of fibre/fabrics treated per day ($Q_{textile}$) is 13 t/d and no fixation is considered according to TAB (2015).

For worst-case considerations, no elimination of the a.s. during textile processing and before discharge to STP is expected for Tier 1 calculations. However, this assumption is not deemed realistic for glutaraldehyde as it is classified as readily biodegradable and dissipates rapidly from the waste water according to the AR (2014). This is supported by the BREF/BAT (Best available technique) document for the textile industry from 2003 which supports a complete decomposition of glutaraldehyde used to preserve auxiliaries in the textile industry before entering surface water. This can be explained by the fact that the effluents of the textile industry contain high amounts of organic load (5000 to 200 000 mg Chemical Oxygen Demand/L). Large amounts of organic material, e.g. fibre monomers/solvents, sizing agents, waxes or proteins in wet-end textile finishing processes are described in OECD ESD no. 7 (2004) as well. Glutaraldehyde, a highly reactive di-aldehyde, reacts with these other contaminants in the waste streams. In addition, bleaching takes place in the textile treatment resulting in peroxide residues in the waste streams leading to a further decomposition of glutaraldehyde. Part of the waste streams, especially those from mercerizing and bleaching are strong alkaline effluants containing 40-50 g NaOH/L leading to a decomposition of glutaraldehyde before entering the waste water treatment plant. Due to the high organic load, textile industry waste water is treated e.g. with oxidising agents resulting in a decomposition of glutaraldehyde, too.

The applicant proposed to use the elimination factor of 99.6 % derived from the monitoring studies in paper mills and agreed as a refinement for uses in paper industry (AR 2014). Similar high loadings of organic material as in paper mills prevails in the textile industry as described above. Glutaraldehyde reacts with these other contaminants in the waste streams. Another factor contributing to decomposition of glutaraldehyde is high pH in the waste streams. (Integrated Pollution Prevention and Control (IPPC). Reference Document on Best Available Techniques for the Textile Industry, European Commission, 2013.)

The elimination factor derived from paper industry was exceptionally agreed for glutaraldehyde in the textile industry due to specific properties of glutaraldehyde, i.e. its high reactivity with organic matter and subsequent decomposition. An RMM will be set for this use where waste water treatment according to above mentioned BAT document is required.

The input parameters for calculating the local emissions of glutaraldehyde as in-can preservative for textile processing additives are shown in the following table.

Input parameters for calculating the local emission for Scenario 6.3.2 – 1 (Textile processing)

Input	**Definition**	**Value**	**Unit**	**D/S/O/P**
Mass of textile processes per day	$Q_{textile}$	13	[t/d]	D*
Mass of auxiliary per mass of fabric – pre-treatment	$Q_{product}$	120	[kg/t]	D*
Mass of auxiliary per mass of fabric – exhaust processes	$Q_{product}$	20	[kg/t]	D*
Mass of auxiliary per mass of fabric – padding processes	$Q_{product}$	300	[kg/t]	D*
Content of a.s. in preparation	$C_{substance}$	0.000979	[-]	S
Degree of fixation – all processes	$F_{fixation}$	0	[-]	D*
Fraction of fabric treated with one auxiliary, basic chemical or dyestuff	$F_{product}$	0.3	[-]	D*
Amount of residual liquors	$F_{residual\ liquor}$	0.25	[-]	D*
Market share of in-can preservative	F_{pentr}	1	[-]	D*
Fraction of a.s. eliminated during textile processing – Tier 1	$F_{elim,tier1}$	0	[-]	D*
Fraction of a.s. eliminated during textile processing – Tier 2**	$F_{elim,tier2}$	0.996	[-]	S

*Default values are taken from the OECD ESD no. 7 (2004), the Draft ESD for PT 6 (2015) and the Technical Agreements for Biocides (2015)

** Tier 2: 99.6% elimination in the waste water due to the high reactivity of glutaraldehyde

The calculated local emissions to the wastewater are calculated according to equations 1-3 of the OECD ESD no. 7 (2004) and are shown in the following table.

Resulting local emissions to sewage treatment plant for scenario 6.3.2 - 1		
Parameter	**Definition**	**Value [kg/d]**
Local emission of a.s. to waste water for pre-treatment	$\text{Elocal}_{\text{pre-treatment}}$	1.53
$\text{Elocal}_{\text{pre-treatment}}$ = Qtextile*Qproduct*Csubstance*(1-Ffixation)*Fpenetr		
Local emission of a.s. to waste water for exhaust processes	$\text{Elocal}_{\text{exhaust}}$	0.08
$\text{Elocal}_{\text{exhaust}}$ = Qtextile*Qproduct*Csubstance*(1-Ffixation)*Fpenetr*Fproduct		
Local emission of a.s. to waste water for padding processes	$\text{Elocal}_{\text{padding}}$	1.43
$\text{Elocal}_{\text{padding}}$ = (Qtextile*Fproduct*Qproduct*Csubstance *(1-Ffixation)*Fpenetr)+(Qtextile*Fproduct*Qproduct*Csubstance*Fresidualliquor*Fpenetr)		
Total local emission of a.s. to waste water – Tier 1	$\text{Elocal}_{\text{water,tier1}}$	3.04
$\text{Elocal}_{\text{water,tier1}}$= ($\text{Elocal}_{\text{pre-treatment}}$ + $\text{Elocal}_{\text{exhaust}}$ + $\text{Elocal}_{\text{padding}}$)		
Total local emission of a.s. to waste water – Tier 2 (99.6% elimination)*	$\text{Elocal}_{\text{water,tier2}}$	0.01
$\text{Elocal}_{\text{water,tier2}}$ = $\text{Elocal}_{\text{water,tier1}}$ *(1-0.996)		

* Tier 2: 99.6% elimination in the waste water due to the high reactivity of glutaraldehyde

6.3.3 Preservation of additives in leather production

6.3.3 – 1: Leather processing

Protectol® GA50 containing the a.s. glutaraldehyde may be formulated as in-can preservative for organic emulsions like leather re-fattening agents or other leather treatment chemicals.

According to the OECD ESD no. 8 (2004), four processes, i.e., beamhouse, tanning, post-tanning and finishing can be distinguished for leather processing. For every process, several types of leather treatment chemicals, which may contain glutaraldehyde as in-can preservative, are listed in Table 4 (OECD ESD no. 8, 2004). The leather treatment chemicals are chosen regarding worst-case, i.e. highest mass of chemical used per mass of leather, and are used for the exposure assessment.

For worst-case considerations, no elimination of the a.s. by on-site waste water treatment before discharge to STP is expected for Tier 1 calculations. However, glutaraldehyde is readily biodegradable and dissipates rapidly from the waste water according to the AR (2014). This is supported b ythe BREF/BAT (Best available technique) document for tanning from 2013 which describes a complete decomposition of used Glutaraldehyde in the leather industry before entering surface water. The effluents of the leather industry contain high amount of proteins and Glutaraldehyde reacts completely with the available proteins.

Furthermore, if still residual Glutaraldehyde enters a STP, it reacts again completely with the proteins of other waste streams. In addition, the waste water from the leather industry is generally treated using sulphide oxidation (aeration in the presence of manganese salts) and adding alkali (e.g. calcium hydroxide, magnesium oxide, sodium carbonate, sodium hydroxide….) increasing the pH to 8 or above as best available technique. This treatment ensures additionally a complete decomposition of Glutaraldehyde in a STP receiving waste water from leather industry.

The decomposition of Glutaraldehyde in the waste streams from leather industry is justified and a degradation of 99.6 % by on-site treatment was used for the exposure assessment. An elimination of up to 99.6 % was shown in paper mills characterized by similar high loadings of organic material and was accepted as refinement during a.s. evaluation for the PT 6 and PT 12 use in paper production (AR for glutaraldehyde, 2014). The elimination factor of 99.6 % was exceptionally accepted for glutaraldehyde for above explained reasons. An RMM will be set for this use where waste water treatment according to above mentioned BAT document is required.

The input parameters for calculating the local emissions during application of the additives for leather productions are shown in the following table.

Input parameters for calculating the local emission for Scenario 6.3.3 – 1				
Input	**Definition**	**Value**	**Unit**	**D/S/O/P**
Mass of processed raw hide per day	$Q_{rawhide}$	15	[t/d]	D*
Degree of fixation - Proportion of the substance chemically converted or fixed to the hide during processing	$F_{fixation}$	0	[-]	D*
Content of a.s. in product	$F_{chemical}$	0.000979	[-]	S
Fraction of daily production that is treated with the specific chemical	$F_{daily\text{-}production}$	1	[-]	D*
Fraction of chemical eliminated by on-site waste water treatment before discharge to municipal sewage treatment plant – Tier 1	$F_{on\text{-}site\text{-}treatment,\ tier\ 1}$	0	[-]	D*
Fraction of chemical eliminated by on-site waste water treatment before discharge to municipal sewage treatment plant – Tier 2	$F_{on\text{-}site\text{-}treatment,\ ier\ 2}$	0.996	[-]	S
Market share	$F_{penetration}$	1 0.5	[-]	S
Beam House				
Factor of remaining mass of rawhide at specific step beam house	$F_{remaining\text{-}mass}$	1	[-]	D*
Mass of chemical formulation ($Ca(OH)_2$) used per mass at step house	$Q_{chemical\text{-}formulation}$	63	[kg/t]	D*
Tanning				
Factor of remaining mass of rawhide at specific step tanning	$F_{remaining\text{-}mass}$	0.5	[-]	D*
Mass of chemical formulation (Fatliquor) used per mass at step tanning	$Q_{chemical\text{-}formulation}$	45	[kg/t]	D*
Post-Tanning				
Factor of remaining mass of rawhide at specific step post-tanning	$F_{remaining\text{-}mass}$	0.35	[-]	D*
Mass of chemical formulation (Fatliquor) used per mass at step post-tanning	$Q_{chemical\text{-}formulation}$	395	[kg/t]	D*
Finishing				
Factor of remaining mass of rawhide at specific step finishing	$F_{remaining\text{-}mass}$	0.2	[-]	D*

Input parameters for calculating the local emission for Scenario 6.3.3 – 1				
Input	**Definition**	**Value**	**Unit**	**D/S/O/P**
Mass of chemical formulation (Washing + spraying losses) used per mass at step finishing	$Q_{chemical\text{-}formulation}$	15	[kg/t]	D*

*Default values are taken from the OECD ESD no. 8 (2004) and the Draft ESD for PT 6 (2015)

The calculated local emissions to the wastewater are calculated according to equation 1 of the OECD ESD no. 8 (2004) and are shown in the following table.

Resulting local emissions to sewage treatment plant for scenario 6.3.3 - 1		
Parameter	**Definition**	**Value [kg/d]**
Local emission of a.s. to waste water for process beamhouse	$Elocal_{beamhouse,water}$	0.93
Local emission of a.s. to waste water for process tanning	$Elocal_{tanning,water}$	0.33
Local emission of a.s. to waste water for process post-tanning	$Elocal_{post\text{-}tanning,water}$	2.03
Local emission of a.s. to waste water for process finishing	$Elocal_{finishing,water}$	0.04
Elocal = Qrawhide*Qchemical-formulation*Fremaining-mass*Fchemical*(1-Ffixation)		
Total local emission of a.s. to waste water – Tier 1	$Elocal_{water,\ tier\ 1}$	3.33
$Elocal_{water,\ tier\ 1} = (Elocal_{beamhouse,water} + Elocal_{tanning,water} + Elocal_{post\text{-}tanning,water} + Elocal_{finishing,water}) * Fpen$		
Total local emission of a.s. to waste water – Tier 2 (99.6% elimination)*	$Elocal_{water,\ tier\ 2}$	0.01
$Elocal_{water,\ tier\ 2} = Elocal_{water,\ tier\ 1} * (1-0.996)$		

* Tier 2: 99.6% elimination in the waste water due to the high reactivity of glutaraldehyde

6.6: Glues and adhesives

Protectol® GA50 containing the a.s. glutaraldehyde is formulated as in-can preservative in polymer dispersions like glues. No emissions scenario has been described for the application phase of glues according to the previous version of the ESD PT 6 (EUBEES, 4L1784.A0/R018/FBA/TL/Nijm, 2004). Glues are normally applied indoors under dry conditions in industrial areas and also in private households and a direct release of the a.s. is therefore not to be expected (Draft ESD fort PT 6, 2015). During service life, the a.s. remains in the dry material and a release to the environment is also not likely. Glues are also applied outdoors. Nevertheless, glues are usually between two other materials and therefore shielded off from rainfall. Moreover, if exposed to weather, the total surface is significantly lower than for paints. Therefore, no quantitative exposure assessment for the use of the b.p. in glues has been conducted. It is further assumed, that the application and service life is covered by the emissions calculated for the use in PT 6.1 and PT 6.2.

Emission estimation - Product type 12: Slimicides

12.1: Paper mills

Protectol® GA50 containing the a.s. glutaraldehyde is used as a slimicide in paper mills. According to the ESD for PT 12 (2003), two sub-scenarios need to be assessed. The reasonable worst-case scenario is based on the assumption that short and long circulation water are treated with the b.p. and that there is no connection to a pulp mill. The primary receiving compartment is the surface water.

Scenario 12.1 - 1 – Reasonable worst-case scenario (direct emissions to surface water)

The reasonable worst-case scenario is assessed using the parameter described in the AR for glutaraldehyde (2014). The total fraction of biocide lost in the dry end is set to 10% in Tier 1. As Tier 2 approach, the fraction lost in the dry end Floss is set to 99.6% based on monitoring studies from paper mills, which is in accordance to the AR (2014).

The following input parameters are used to calculate the average concentration in sewage before wastewater treatment.

Input parameters for calculating the theoretical average concentration of glutaraldehyde in sewage before wastewater treatment (PT 12.1 - 1 – Reasonable worst case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/O /P**
Concentration in process water prescribed in the user's instruction	Cprod	0.20	[kg/m³]	S
Treatment of both long and short circulation with slimicide	APPL	Yes	[-]	D*
Fraction of total waste water flow coming from the short circulation of the wire part	Fww1	1	[-]	O
Connection to pulp mill	CONN	No	[-]	D*
Fraction dilution of waste water with waste water from pulping	Fww2	0	[-]	O
Total fraction of biocide lost in the dry end of the paper making machine – Tier 1	Floss_tier1	0.1	[-]	D*
Total fraction of biocide lost in the dry end of the paper making machine – Tier 2	Floss_tier2	0.996	[-]	S
Output				
Concentration in water Tier 1	Cpaper_tier 1	180	[g/m³]	O

Input parameters for calculating the theoretical average concentration of glutaraldehyde in sewage before wastewater treatment (PT 12.1 - 1 – Reasonable worst case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/O/P**
Concentration in water Tier 2	Cpaper_tier 2	0.80	[g/m³]	O
Cpaper = Cprod*(1-Floss)				

*Defaults are taken from the ESD for PT 12 (2003) and the AR for glutaraldehyde (2014)

The theoretical concentrations (i.e. assuming no degradation) before waste water treatment are calculated according to Table A of the ESD for PT 12 (2003), which is accordance to the AR (2014). They are **180 g/m³** for Tier 1, i.e. 10% loss in the dry end of the paper making machine and **0.80 g/m³** for Tier 2 with 99.6% loss, respectively.

However, degradation processes like hydrolysis and biodegradation may occur during the papermaking process and water treatment (primary settling and chemical/mechanical wastewater treatment). According to the AR (2014), the hydrolysis for the a.s. is 1.8 x 10^{-3} d^{-1} and the rate for biodegradation is 1.54 d^{-1} at 25 °C.

Emission scenario for calculating the concentration of glutaraldehyde in wastewater after primary settling and mechanical/chemical treatment (PT 12.1 - 1 – Reasonable worst case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/O/P**
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment: Tier 1 – 10% loss in dry end	Cpaper_tier 1	180	[g/m³]	O
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment: Tier 2 – 99.6% loss in dry end	Cpaper_tier 2	0.80	[g/m³]	O
Retention time for paper making process	Tpr	0.167	[d]	D
Retention time for primary settling	Tps	0.167	[d]	D
Retention time for chemical/mechanical treatment	Tcm	0.167	[d]	D
Rate constant for hydrolysis (at 25 °C)	$khydr_{water}$	1.8 x 10^{-3}	[1/d]	S
Rate constant for total degradation (hydrolysis and biodegradation at 25°C)	$ktot_{water}$	1.54	[1/d]	S

Emission scenario for calculating the concentration of glutaraldehyde in wastewater after primary settling and mechanical/chemical treatment (PT 12.1 - 1 – Reasonable worst case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Fraction of the biocide adsorbed to particles during primary settling	$Fads_{PS}$	0	[-]	D
Fraction of the biocide adsorbed to particles during chemical/mechanical treatment	$Fads_{CM}$	0	[-]	D

Using the equations presented in the EUSES 2.1 Documentation; Model Calculations; III.3.6.: Local emission rates: release estimation for biocides, the following concentration in wastewater can be calculated.

Resulting concentrations of glutaraldehyde in waste water after primary settling and chemical/mechanical process conditions (neutral process conditions; PT 12.1 – 1 – Reasonable worst case scenario)		
Parameter	**Definition**	**Value [kg/m³]**
Concentration after primary settling for neutral process conditions: Tier -1	Cneutr_tier1	0.14
Concentration after primary settling for neutral process conditions: Tier -2*	Cneutr_tier2	6.18×10^{-4}
$Cneutr = Cinf*(1/(1+khydrwater*Tpr))*e^{((-ktotwater*Tps)*(1-Fads,PS))}$		
Concentration after chemical/mechanical treatment for neutral process conditions: Tier -1	$Cneutr_{CM}$_tier1	0.11
Concentration after chemical/mechanical treatment for neutral process conditions: Tier -2*	$Cneutr_{CM}$_tier2	4.78×10^{-4}
$Cneutr_{CM} = Cneutr*e^{((-ktotwater*TCM)*(1-Fads,CM))}$		

The wastewater is directed to the surface water, which is the primary receiving compartment.

Scenario 12.1 - 2 – Typical case scenario (indirect release *via* industrial STP)

In the typical case scenario, the short circulation of a paper mill is solely treated with the b.p. and there is also a connection to a pulp mill resulting in lower waste water concentrations. The primary receiving compartment is an industrial waste water treatment plant (further referred to as industrial STP). The typical case scenario is assessed using the parameter described in the AR for glutaraldehyde (2014).

The following input parameters are used to calculate the average concentration in sewage before wastewater treatment.

Input parameters for calculating the theoretical average concentration in sewage before waste water treatment of glutaraldehyde for the use as slimicide (PT 12.1 - 2 – Typical case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Concentration in process water prescribed in the user's instruction	Cprod	0.20	[kg/m³]	S
Treatment of both long and short circulation with slimicide	APPL	No	[-]	D*
Fraction of total waste water flow coming from the short circulation of the wire part	Fww1	0.6	[-]	O
Connection to pulp mill	CONN	Yes	[-]	D*
Fraction dilution of waste water with waste water from pulping	Fww2	0.5	[-]	O
Total fraction of biocide lost in the dry end of the paper making machine – Tier 1	Floss_tier1	0.1	[-]	D*
Total fraction of biocide lost in the dry end of the paper making machine – Tier 2	Floss_tier2	0.996	[-]	S
Output				
Concentration in paper Tier 1	Cpaper_tier 1	54.0	[g/m³]	O
Concentration in paper Tier 2	Cpaper_tier 2	0.24	[g/m³]	O
Cpaper = Cprod*Fww1*(1-Fww2)*(1-Floss)				

*Defaults are taken from the ESD for PT 12 (2003) and the AR for glutaraldehyde (2014)

The theoretical concentrations in sewage (i.e. assuming no degradation) before waste water treatment Cpaper for the typical case scenario are calculated according to Table A of the ESD for PT 12 (2003), which is accordance to the AR (2014). They are **54.0 g/m³** for Tier 1, i.e. 10% loss in the dry end of the paper making machine and **0.24 g/m³** for Tier 2 with 99.6% loss, respectively.

However, as described for the reasonable worst-case scenario, degradation of the a.s. during the paper making process may occur due to hydrolysis and biodegradation.
The concentrations after primary settling are calculated using the following input parameter, which are in accordance to the AR (2014).

Emission scenario for calculating the releases of glutaraldehyde for the use as slimicide in paper mills (PT 12.1 - 2 – Typical case scenario)				
Input	**Definition**	**Value**	**Unit**	**S/D/O/P**
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment: Tier 1 – 10% loss in dry end	Cpaper_tier 1	54.0	[g/m³]	O
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment: Tier 2 – 99.6% loss in dry end	Cpaper_tier 2	0.24	[g/m³]	O
Retention time for paper making process	Tpr	0.167	[d]	D
Retention time for primary settling	Tps	0.167	[d]	D
Rate constant for hydrolysis (at 25 °C)	$khydr_{water}$	1.8×10^{-3}	[1/d]	S
Rate constant for degradation (biodegradation at 25°C)	$ktot_{water}$	1.54	[1/d]	S
Fraction of the biocide adsorbed to particles during primary settling	$Fads_{PS}$	0	[-]	D
Fraction of the biocide adsorbed to particles during chemical/mechanical treatment	$Fads_{CM}$	0	[-]	D
Concentration after primary settling for neutral process conditions – Tier 1	Cneutr	0.04	[kg/m³]	O
Concentration after primary settling for neutral process conditions – Tier 2	Cneutr	1.86×10^{-4}	[kg/m³]	O
$Cneutr = Cpaper*(1/(1+khydrwater*Tpr)*e^{((-ktotwater*Tps)*(1-Fadsps))}$				

According to AR for glutaraldehyde (2014), the effluent discharge of the local industrial STP is set to 5000 m³/d resulting in the following local emissions.

Resulting local emissions to a STP (industrial) for scenario 12.1 – 2 – Typical case scenario		
Parameter	**Definition**	**Value [kg/d]**
Local emission to waste water for neutral process conditions after primary settling only – Tier 1 (10% loss)	$Elocal_{water\_neutr\_Tier\ 1}$	209

Resulting local emissions to a STP (industrial) for scenario 12.1 – 2 – Typical case scenario		
Parameter	**Definition**	**Value [kg/d]**
Local emission to waste water for neutral process conditions after primary settling only – Tier 2 (99.6% loss)	$Elocal_{water\_neutr\_Tier\ 2}$	0.93
$Elocal_{water\_neutr}$ = $EFFLUENT_{STP}$ * Cneutr $EFFLUENT_{STP}$ = 5000 m^3		

The local emissions in the typical case scenario are directed to an industrial STP.

12.2: Oil and gas exploration industry

Scenario 12.2 - 1 – Production chemicals/Reservoir injection (covering the uses in PT 11)

Protectol® GA50 containing the a.s. glutaraldehyde is used as a slimicide for the oil and gas exploration industry and is added either to the injection water or to the produced fluids as a production chemical. According to the offshore oil exploration scenario from the Netherlands (Ctgb, 2015), the presented reservoir injection scenario can be considered as worst-case scenario due to the vast amount of produced water covering other oil and gas exploration uses, e.g. use in pipelines, transmission lines or surface facilities. This scenario is identical to the "injection chemicals and surfactants" scenario from the CHARM (2005) model, which was assessed in the AR (2014; "Production chemicals, PT 11"), but includes additionally the calculation of the background concentrations using the MAMPEC-model. The scenario used is considered as a worst-case covering all other scenarios described above (please see in section "Exposure Assessment"). Furthermore, it should be noted that oilfield uses are additionally regulated under other national and international legislations (e.g. OSPAR). A more detailed exposure assessment has to be conducted under these regulations taking into account the local environmental and use conditions before authorization. In addition, not for all use scenarios a direct release to seawater is anticipated and thus, a direct exposure to seawater might not occur (Tey & Lafuente Cerda, 2016). The exposure pathways for the different scenarios are summaries in following:

1) Seawater injection: Raw seawater is treated with glutaraldehyde and is pumped into the reservoir *via* the injector well to maintain pressure to facilitate the flow of hydrocarbons to the surface. For this use, there is no intentional discharge of the injection water into the sea. Depending on the flow rate, it takes generally weeks or even months before the active substance is detectable in produced water, but reach eventually plateau as the biocide is applied continuously or at regular intervals. Due to the elevated temperatures in an oil reservoir, the presence of hydrocarbons combined with the high reactivity of glutaraldehyde, it can be assumed that no or only very low levels of glutaraldehyde are present in the production water. According to CAR, 2014 and agreed in TM III 2013, an 85 % dissipation after one day in the reservoir at elevated temperature was used for the further calculation. This one day is a worst-case since the real hydraulic retention time in the reservoir is much longer than one day resulting in much higher levels of dissipation for the used glutaraldehyde. The produced water is further processed (see in following).

2) Produced water re-injection: The produced water is treated and re-used (see above, point 1). Consequently, there is no intended direct discharge for scenario 1 and 2 since the water is used in a closed system.

3) For produced water disposal: Direct exposure to seawater might occur. To be covered by the following conducted exposure assessment (scenario 12.2 – 3).

4) In transmissions pipelines: Transmission pipelines supply the treated natural gas and crude oil to gas plant or refinery. The hydrocarbons are treated in the specific facilities and there is no release to seawater.

5) In crude and gas storage wells: The systems are linked to the gas plant or refinery. This scenario is identical to the use described under point 4). There is no direct release to seawater.

6) In pipeline pigging and scraping operations: Used liquids are disposed/incinerated according to local regulations. There is no direct exposure to seawater.

7) Hydrotesting: Direct discharge to seawater is possible and this scenario is considered in the following exposure assessment. Some pipelines are pigged from offshore to onshore and the water could be stored in holding ponds onshore. In this case there is no direct release to seawater.

	Use description in the PAR	**Scenario in the PAR**	**Use # in SPC**
1	Seawater injection: Raw seawater is treated with glutaraldehyde and is pumped into the reservoir *via* the injector well to maintain pressure to facilitate the flow of hydrocarbons to the surface *via* the production well. For this use, there is no intentional discharge of the injection water into the sea. It takes weeks or even months before the water is reproduced from the production well. Due to the very long use period and elevated temperatures in an oil reservoir, the presence of hydrocarbons combined with the reactivity of glutaraldehyde, it can be assumed that no or only very low levels of glutaraldehyde are present in the production water. The produced water is further processed (see in following).	12.2.-1 Production chemicals/reservoirs injection (covers as worst case scenario 2, 4, 5, 6)	Use #7 and #9
2	Produced water re-injection: The produced water is treated and re-used (see above, point 1). Consequently, there is no intended direct discharge for scenario 1 and 2 since the water is used in a closed system.	Covered by 12.2.-1 Production chemicals/ reservoirs injection	Use #7 and #9
3	For produced water disposal: Direct exposure to seawater might occur. To be covered by the following conducted exposure assessment (scenario 12.2 – 3).	12.2.-3 Produced water disposal	Use #7 and #9
4	In transmissions pipelines: Transmission pipelines supply the treated natural gas and crude oil to gas plant or refinery. The hydrocarbons are treated in the specific facilities and there is no release to seawater.	Covered by 12.2.-1 Production chemicals/ reservoirs injection and 12.2.-3 Produced water disposal, but no release to seawater foreseen	Use #7 and #9
5	In crude and gas storage wells: The systems are linked to the gas plant or refinery. This scenario is identical to the use described under point 4). There is no direct release to seawater.	Covered by 12.2.-1 Production chemicals/reservoirs injection and 12.2.-3 Produced water disposal, but no release to seawater foreseen	Use #7 and #9

	Use description in the PAR	Scenario in the PAR	Use # in SPC
6	In pipeline pigging and scraping operations: Used liquids are disposed/incinerated according to local regulations. There is no direct exposure to seawater.	Covered by 12.2.-1 Production chemicals/ reservoirs injection and 12.2.-3 Produced water disposal, but no release to seawater foreseen	Use #7 and #9
7	Hydrotesting: Direct discharge to seawater is possible and this scenario is considered in the following exposure assessment. Some pipelines are pigged from offshore to onshore and the water could be stored in holding ponds onshore. In this case there is no direct release to seawater.	12.2.-2 Hydrotesting, 12.2.2-1 Slow release 12.2.2-2 Disposal/re-use of the hydro-testing water 12.2.2-3 Degradation of glutaraldehyde in the pipeline	Use #6 and #8

Glutaraldehyde is added at concentration of up to 750 ppm in the injection water stream. According the AR (2014), the interval between applications needs to be considered in a first dosing option. Therefore, the concentration of the a.s. in the fluid is 31.3 mg/L assuming a dose of 750 mg/L for 1 h per day.

As a second dosing option, the application interval is taken into account as it is described in the AR (2014), i.e., two hours of dosing once a week or a dosage not more than 6 h once a week, resulting in a concentration of a.s. in the fluid of 10.7 mg/L.
According to the AR (2014), 85% dissipation of the a.s. is assumed after one day at 55°C as a possible refinement, which is used in the following calculations.

The following input parameters are used to calculate the concentration in the produced water.

Input parameters for calculate the concentration of glutaraldehyde in produced water after reservoir injection (covering all uses as a production chemical) – 12.2 - 1				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Fraction released	f_r	0.01	[-]	D*
Concentration of chemical in the fluid_Tier 1	C_i	31.3**	[mg/L]	S
Concentration of chemical in the fluid_Tier 2	C_i	10.7***	[mg/L]	S
Concentration of chemical in the fluid used for MAMPEC calculations	$C_{i,MAMPEC}$	750	[mg/L]	S
Fluid injected	F_i	17000	[m³/d]	D*
Volume of produced water discharged per day	F_{pw}	15000	[m³/d]	D*
Duration of the treatment according to the user instructions of use	t	1	[h]	S
Dissipation of 85% after one day at 55 °C according to AR (2014)	F_{dis}	0.85	[-]	S
Output				
Concentration of the chemical in the produced water – Dosing option 1	C_{pw_tier1}	53.1	**[µg/L]**	O
Concentration of the chemical in the produced water – Dosing option 2	C_{pw_tier2}	18.2	**[µg/L]**	O

$C_{pw} = ((f_r * C_{inj} * V_{inj}) / V_{pw}) * (1 - F_{dis})$

where:

– C_{pw}	concentration in the produced water (mg/L)	O
– f_r	fraction of biocide released to the open sea (0.01)	D
– C_{inj}	the concentration of the active substance in the injection fluid according to the instructions of use (mg/L)	S
– V_{inj}	volume of the water injected daily (17 000 m³/d)	D
– V_{pw}	volume of the produced water (15 000 m³/d)	

*Default values are taken from the offshore oil exploration scenario (Ctgb, 2015)

**Shock dose of 750 ppm applied for 1h. Daily average concentration 750 x (1/24) = 31.3 mg/L

*** Daily average concentration of 10.7 mg/L covers dosage of 750 mg/L applied for 2 h once a week and dosage of 600 mg/L for 6 h every two weeks according to the AR (2014), 600 x 6 / (24 x 7 x 2) = 10.7 mg/L

Using the equation 2 presented in the scenario document from the Netherlands (Ctgb, 2015), which is identical to equation 2a from CHARM (2005), the following concentration in produced water can be calculated.

Resulting concentrations of glutaraldehyde in produced water after reservoir injection (covering all uses as a production chemical) – 12.2 – 1		
Parameter	**Definition**	**Value [µg/L]**
Concentration of the chemical in the produced water – Dosing option 1	$C_{pw\_dosing1}$	53.1
Concentration of the chemical in the produced water – Dosing option 2	$C_{pw\_dosing2}$	18.2

The concentration in the produced water is used to derive the daily emission from a single oil platform applying equation 3 from the offshore oil exploration scenario (Ctgb, 2015). For worst-case considerations, the concentration in the injected fluid without time normalization ($C_{i,\ MAMPEC}$: 750 mg/L) and without the dissipation of 85% is used to calculate the local emission to seawater from one platform. However, to calculate the background concentration in the open sea with the MAMPEC model, 20 platforms need to be considered resulting in the following total emission to seawater.

Resulting local emissions to seawater after reservoir injection (covering all uses as a production chemical) – 12.2 - 1				
Input	**Definition**	**Value**	**Unit**	**S/D/O**
Shock dose concentration	Cinj	750	mg/L	S
Fraction released	fr	0.01	[-]	D
Volume of fluid injected	Vinj	17000	m³/d	D
Volume of produced water discharged per day	Vpw	15000	m³/d	D
Duration of treatment	t	1	h	S
Output				
Local emission to seawater from one platform	Elocal	5.31	kg/d	O
Elocal = (Cinj x fr x Vinj / Vpw) x t x Vpw/24				
Local emission to seawater from 20 platforms	E_{MAMPEC}	106.3	kg/d	O
E_{MAMPEC} = Elocal x 20				

The local emission is used as input parameter to calculate the mean concentration in seawater and subsequently PEC_{marine}.

Scenario 12.2 - 2 – Hydrotesting (covering the uses in PT 11)

Hydrotesting of pipelines is mostly done on segments of pipelines and only occasionaly on larger parts. Water (seawater, freshwater or production water) is mixed with additives (e.g. colourants for detection of leaks) and shut in the pipeline. After pressure testing, especially in pipelines, the water used for testing is shut in and often left in the pipeline (segments) for months before release and start of the production. The initial concentration of glutaraldehyde shut in at the start of the pressure test potentially needs to be higher (the stated higher concentration) to take the degradation of glutaraldehyde as reactive chemical due to the soiling of water and the potential long shut-in-times into account. Additionally, oxygen scavengers (e.g. bisulfite) are often added to the testing water leading to reaction with glutaraldehyde and partly inactivation, therefore higher initial amounts of the biocidal product are needed to compensate these losses.[22]

As it is not possible to cover all potential soilings/shut-in-times, the applicant proposed an requirement to run degradation tests for the user for all oilfield uses with the water relevant for the actual test/well situation on the draft label submitted and in the SPC. The user determines if degradation takes place and how much glutaraldehyde is left and needs to be treated in order to define the correct dosage needed at the start of the pressure test and what is left over at the end of the pressure test. This is common practice in the oil industry.

In addition, a restriction of 0.2 mg/L ($PNEC_{marine}$) glutaraldehyde is proposed for the hydrotesting water to be discharged in order to make sure that a safe concentration is discarded. Depending on the outcome of this tests/measurements of the remaining glutaraldehyde concentration, the local permit situation and structural situation on the platform or terminal, the user will decide if a slow release is possible (e.g. if only low volumes are discarded) or if an onshore treatment/disposal is necessary or if a use as re-injection water is possible or if a treatment with bisulfite or sodium hydroxide makes sense.

OSPAR requires a permit for each oilfield procedure, including separate permits for hydrotesting/discharge operations taking the local situation of currents etc. into account. Under this OSPAR Recommendation, every chemical needs a registration (HCNOF, available for glutaraldehyde for the described oilfield applications for the countries where approval of the oilfield use is applied under BPR) and each operator needs a permit including discharge and applied chemicals assessment.[23] Thus, no treated water will be discharged without permit of the relevant authority.

Further information on hydrotesting can be found in Tey S. L. IUCLID chapter 13.

The b.p. Protectol® GA 50, a 50% solution of glutaraldehyde in water, may be used as slimicide and to prevent microbially induced deterioration and corrosion (PT 11 + 12) in water for hydrotesting of pipelines onshore/offshore. Installed pipelines or parts of pipelines after repair have to be pressure-tested to ensure that its structural integrity is fit for

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[22] SPE, Chris Carpenter, Feb. 2017 "Use of Preservation Chemicals Following Hydrostatic Testing of Pipelines", available under https://www.spe.org/en/print-article/?art=2711

[23] Danish Comment to the Ctgb 2015 ESD paper dating 7.2.2014 referring to the emission calculation using the more detailed programme DREAM under OSPAR

operational use. Glutaraldehyde prevents the bacteria growth in the water and in biofilms during testing to avoid pipeline failures due to microbially induced corrosion.

There exist several scenarios for hydrotesting depending on the project. The parameters influencing the exposure assessment vary with respect to the fluid: The glutaraldehyde concentration, the location where the fluid is discharged (i.e. onshore, offshore, in the sea or in tanks), the volume and duration of discharge, treatment of the fluid during discharge and the duration of storage of the water in the pipeline.

The length and diameter of the pipes can vary. In general, they are several hundred kilometers long with diameters of 12 – 15 inches (equals to 0.305 to 0.381 m). Hydrotesting can be carried out in sections or the full length of the pipeline. However, hydrotesting performed in sections of the pipeline is generally preferred. Sections are generally 50 – 100 km long. Thus, the volume of hydrostatic test water needed for sections of a pipeline is thus between 3,500 m³ and 11,300 m³.

The glutaraldehyde concentration needed depends for example on the amount of soiling in the water, the pH, the microbial contamination, the length of the pipeline (segment) and the inclusion time of the test water. Therefore, three different scenarios with different concentrations, release volumes and release pathways are included in this PAR. Furthermore, a combination of these options is possible.

1) Slow release: The dilution of a fluid discharged in the sea depends on the daily release volume. A worst-case dilution factor of 50 is taken for the shipping lane scenario as proposed in the ESD for ballast water discharge (Zipperle et al. 2001 and cited in NL, Ctgb, 2015) and is based on a daily discharge volume of 180,000 m³ ballast water. According to the ESD, the dilution factor increases by smaller discharges and larger discharge depths. Thus, the dilution factor proposed by Zipperle et al. (2001) is a worst-case figure since the discharge of hydrotesting water occurs in much larger depths than the release from vessels.

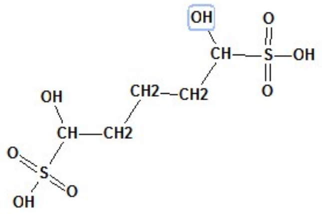
   The daily maximum discharge volume depends on the glutaraldehyde concentration in the fluid before discharge. Therefore, the exposure assessment is conducted for two scenarios: For a minimum concentration of 25 and a maximum concentration of 200 mg/L Protectol® GA 50 corresponding 12.5 and 100 mg a.s./L, respectively. A justification of higher use concentrations is given on p. 268.

2) Disposal/re-use of the hydrotesting water: After completion of hydrotesting, the treated water will be collected in used tanks (from cementing or stimulation jobs) and send onshore for treatment and/or disposal. Another possibility is that the hydrotesting water directly used or mixed with produced water and disposed by injection into a disposal well or re-used as injection water in the oil and gas production. Furthermore, glutaraldehyde degrades during storage and mixing with production water. Therefore, the exposure to the marine environment is considered as negligible for these scenarios and thus, a quantitative risk assessment is not conducted. This scenario could be typically used in case of higher concentrations of glutaraldehyde to be expected after the pressure tests.

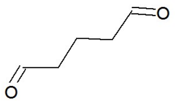
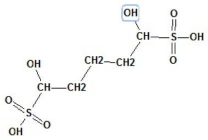
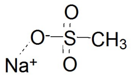
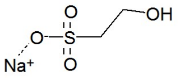
3) Degradation of glutaraldehyde in the pipeline: When hydrotesting is completed, water is often left in the pipeline for weeks or even months. A biodegradation test showed (Reference BPD ID A.7.1.1.2.3) that glutaraldehyde degrades in marine water by 30% within 70 days, even when a concentration was used which is considered as toxic to microorganisms (100 mg Protectol® GA 50/L). Thus, the worst-

case assumption is made that 50% of the initial glutaraldehyde concentration used for hydrotesting in the pipeline degrades generally within 180 days storage. The applicability of the result where texdt concentration has been toxic to bacteria was not fully accepted by one Member State during the commenting period, but unfortunately no better test is available. It is possible that during the long shut-in period also hydrolysis can contribute somewhat to the degradation. According to the applicant the complete disinfection of large water volumes may not be possible and there may remain some bacteria which degrade glutaraldehyde.

Glutaraldehyde can be inactivated by adding sodium bisulfite before release (e.g. in empty tanks from completion processes etc.). Glutaraldehyde (i.e. the aldehyde groups) degrades rapidly by adding sodium bisulfite to form a glutaraldehyde bisulfite adduct ($C_5H_{12}O_8S_2$, MW 264.27 g/mol).



The glutaraldehyde bisulfite adduct has low predicted toxicity to fish, Daphia and algae. QSAR estimations (ECOSAR v1.11) are shown here and presented in more detail in IUCLID 9.2.1.1-9.2.1.3 (ECOSAR v1.11): Fish LC50 (96 hours), Daphnia LC50 (48 hours) and green algae EC50 (96 hours) >> 100 mg/L. In addition, the applicant has provided a comparison of glutaraldehyde bisulfite adduct to structurally related molecules and glutaraldehyde in order to demonstrate the lower toxicity of glutaraldehyde bisulfite adduct compared to glutaraldehyde (see below).

	Glutaraldehyde **CAS 111-30-8**	**Glutaraldehyde bisulfite adduct**	**Sodium methane sulphonate*** **CAS 2386-57-4**	**Sodium 2-hydroxy ethane sulphonate*** **CAS 1562-00-1**
Structural formula				
LogPow	-0.36 at pH 7**	-4.09***	-4.53**	-4.6**
Short-term toxicity to fish [LC_{50} in mg/L]	0.8**	>100***	n.a.	>100**
Long-term toxicity to fish [EC_{10} / NOEC in mg/L]	1.6**	>100***	n.a.	n.a.
Short-term toxicity to invertebrates	2.1**	>100***	260**	>570**

	Glutaraldehyde **CAS 111-30-8**	**Glutaraldehyde bisulfite adduct**	**Sodium methane sulphonate*** **CAS 2386-57-4**	**Sodium 2-hydroxy ethane sulphonate*** **CAS 1562-00-1**
[EC_{50} in mg/L]				
Long-term toxicity to invertebrates [EC_{10} / NOEC in mg/L]	5.0**	>100***	n.a.	100**
Short-term toxicity to algae [EC_{50} in mg/L]	0.6**	>100***	>100**	>100**
Long-term toxicity to Algae [EC_{10} / NOEC in mg/L]	0.025**	>100***	>100**	>100**

*data ware taken from ECHA disseminated dossier
**experimental value
***calculation (QSAR), ECOSAR v.1.11

The initial concentration of 50 mg glutaraldehyde/L degrades to 0.15 mg a.s./L after 120 minutes (Carstens-Roth, 2016) and a glutaraldehyde-to-sodium bisulfite ratio of 1:2.5 (w/w). Concentrations below 0.2 mg/L will ensure safe use as the $PNEC_{marine}$ is 0.25 mg/L. Thus, an exposure calculation is conducted by using an initial glutaraldehyde concentration of 50 mg/L (100 mg/L Protectol® GA 50). Additionally, a degradation of glutaraldehyde is taken into account if the water is left in the pipeline for more than 180 days.

Another option would be to add NaOH for the inactivation of Glutaraldehyde before the release into the marine environment. The initial concentration of 50 mg Protectol® GA 50/L corresponding to 25 mg glutaraldehyde/L decreases to levels of 0.03 mg glutaraldehyde/L within 16 hours (Carstens-Roth, 2016). By adding NaOH, the extent of glutaraldehyde degradation is higher in comparison to the addition of bisulfite and thus, the risk assessment with bisulfite covers the use of NaOH.

Bisulfite is a chemical commonly used in the oil processes, e.g. as oxygen scavenger at different points of the oil process, therefore available in the oil production process and approved under the HCNOF/OSPAR regime.

Hydrotesting water is either collected in tanks or pigged (that is: pressed) to an onshore terminal or pig slug catcher for further disposal treatement onshore (see Tey p. 16). The hydrotesting water can be (e.g. mixed with produced water or seawater) used for re-injection (see PAR p. 269, item 2).

Alternatively, the chemical deactivator (sodium hydroxide or sodium bisulfite) can be injected at the outlet of each pipe section from which hydrotesting water is pumped into tanks (from previous cementing or stimulation jobs) with sufficient holding times for complete deactivation before discharge.

This doesn't mean that the full pipeline content is released/pumped in a tank at once. In the oil-industy, the post-treatment for deactiviation is known practice, especially for the more persistent biocides such as quats. The tanks can be empty tanks from completion processes as described in the PAR p. 254 or be located on FSPO units (Floating Production Storage and Offloading Unit).

Justification of higher use concentrations in SPC/PAR and exemplary situations used for the environmental risk assessments for the application of Protectol® GA 50 for hydrotesting

The higher maximum concentrations in the SPC/draft label are based on the feedback from the applicant's customers from "real life" application experience. They need higher starting concentrations depending on the project/real situation at the well or hydrotesting conditions due to potential loss of glutaraldehyde in practice. The initial dose of glutaraldehyde depends on the following factors:

1) Degradation of glutaraldehyde due to soiling of the test water (e.g. use of produced water for hydrotesting containing more or less residual oil or other process additives from the produced water treatment, use of coastal water or river water, thus not "clean", drinking water quality etc.)

2) Degradation of glutaraldehyde due to other additives, e.g. bisulfite added to the hydrotesting water (or to the produced water) as oxygen scavenger to de-aerate the water phases for corrosion prevention and not completely consumed by remaining oxygen when glutaraldehyde is added.

3) Degradation of glutaraldehyde due to more or less microbial contamination – glutaraldehyde reacts as designated

4) Degradation of glutaraldehyde during the hydrotesting tests – the pipeline (segments) are left filled with the testing water sometimes for quite a long time – even in the ranges of months and a year.[24] GA hydrolyses depending on the pH, temperature, time etc and due to the factors mentioned under 1-3) – dependent on the project timing, a higher concentration has to be added to cover the loss during this waiting periods. 180 days is used as a medium waiting period, realistic according to the oilfield experts at BASF and Wintershall (BASF daughter, oil and gas).

As the reasons for loss of GA (see 1-4) vary from well to well, project to project and the respective situation at the oil platform or terminal and different volumes of testing water based on the size of pipeline segments or vessels, tanks or valves submitted to the pressure tests, we can't realistically define and cover all the potential situations on the respective oilfields. The high dosages are only relevant if there is a loss of glutaraldehyde in the respective tests. A customer using relatively clean water for a short pressure testing time and low or no oxygen scavenger will determine much lower glutaraldehyde dosage rates in the pre-tests and won't use the maximum dosage due to economic reasons/disposal permit situations.

Therefore, the applicant proposed to calculate the risk assessments with three exemplary situations to show the safe use with a certain glutaraldehyde concentration left over after all potential degradation situations and with certain additional requirements for the users:

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[24] SPE, Chris Carpenter, Feb. 2017 "Use of Preservation Chemicals Following Hydrostatic Testing of Pipelines", available under https://www.spe.org/en/print-article/?art=2711

a) We recommend in the SPC and on the draft label to run tests to determine the rate and extend of degradation under the real conditions of the project in question in order to avoid using too low or too high concentrations of glutaraldehyde. This is done either way by the users – the rheology modifier test submitted in the efficacy section is part of such a test program. This way the user can check how much glutaraldehyde will be left after the project and if the required discharge concentration of < 0.2 mg/L glutaraldehyde can be achieved merely by degradation or if further treatment before discharge or different modes of disposal (e.g. onshore treatment or re-injection) are necessary.

b) We recommend in the SPC and on the draft label to make sure that the concentration of glutaraldehyde discharged to the sea is < 0.2 mg/L – whatever the starting concentration of glutaraldehyde initially was. This concentration can either be achieved by degradation or by adding bisulfite or by adding sodium hydroxide or by a slow release with a certain release rate (the different scenarios calculated for an exemplary case). This is the central RMM to cover all possible situations depending on the actual project as we can’t influence/determine all the other factors mentioned above as they may vary from project to project.

c) Dependent on the amount of glutaraldehyde left over after the project the applicant proposes several possibilities to reduce the amount of glutaraldehyde if discharged – the slow release (certainly not feasible for large amounts of testing water, but for smaller amounts if a small water volume needs to be disposed, e.g. from testing a valve or smaller tanks/vessels), the addition of bisulfite or sodium hydroxide or the direct discharge if the concentration is low enough. Which method is to be used depends on the amount of glutaraldehyde used and left over at the end of the pressure test and the situation on the platform or terminal etc. The disposal situation is dependent on the permits under OSPAR and covered within these permits.[25] Thus,

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[25] Permit situation/additional legislation, see e.g.: https://www.gov.uk/guidance/oil-and-gas-offshore-environmental-legislation, e.g. The Offshore Chemicals Regulations 2002 (as amended)

“The Offshore Chemicals (Amendment) Regulations 2011 came into force on 29 March 2011, extending certain provisions of the Offshore Chemicals Regulations 2002. The Offshore Chemical Regulations 2002 were introduced to apply the provisions of a decision made by the Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention) to implement a harmonised mandatory control system for the use and discharge of chemicals by the offshore oil and gas industry. Under the regulations offshore operators must apply for permits for the use and/or discharge of chemicals in the course of all offshore oil and gas activities, including oil and gas production operations, well drilling, discharges from pipelines, and discharges during decommissioning activities.

The Offshore Chemicals (Amendment) Regulations 2011 further extend the provisions of the regulations to allow the department to take enforcement action in the event of any unintentional offshore chemical release. They also: extend DECC’s information-gathering powers so information can be obtained from a wider range of persons and in relation to a wider range of incidents/simplify the permitting process for varying permits or transferring them to other operators/more closely align the regulations with the Offshore Petroleum (Oil Pollution Prevention and Control) Regulations (as amended)

Norway discharge permits: see e.g. http://www.offshore-environment.com/norway.html

Danish comment to the Ctgb 2015 ESD paper dating 7.2.2014 (published on the ECHA webpage together with the Ctgb paper) referring to the emission calculation using the more detailed program DREAM under OSPAR. This program takes local current situation and all disposal specifics into account.

it is covered by a different legislation taking the actual situations, local requirements (there are e.g. no-discharge-areas under OSPAR defined) and the full discharge situation from e.g. other process steps into account. In our view, the authorization under the Biocidal Product Regulation can't cover this in detail, but only give the general requirements for the biocidal product in question.

d) To give an indication on how much bisulfite under which conditions (pH, reaction time etc.) is required, we tested an exemplary concentration of glutaraldehyde in water. This has nothing to do with the amount of initially added glutaraldehyde/Protectol® GA 50 but would be one possible GA concentration at the end of the hydrotesting phase. If the treatment is feasible, has to be decided by the operator of the platform/pressure test under the situation of the actual project.

e) Testing of the GA concentration left over after the hydrotest can be done e.g. via a bypass to the pipeline segment used either way e.g. for measuring the residual oxygen concentration to determine the necessary amounts of oxygen scavenger and the scavenger efficacy1 or in lab tests or at the outlet of the tested facility or in hold-up tanks.

The input parameters for calculating the local emissions of glutaraldehyde after application for hydrotesting and for the various options of hydrotesting are presented in following table.

Input parameters for calculating the local emission of glutaraldehyde used for hydrotesting (12.2 – 2)

Input	**Definition**	**Value**	**Unit**	**S/D/O/P**
12.2.2 - 1: Slow release				
In-use concentration of 25 mg/L Protectol® GA 50				
Concentration of a.s. in pipeline	$C_{pipeline}$	12.5	[mg/L]	S
Minimum dilution factor*	F	5×10^4	[-]	S
Maximum daily discharge volume**	D_v	< 180	[m³/d]	S
In-use concentration of 200 mg/L Protectol® GA 50				
Concentration of a.s. in pipeline	$C_{pipeline}$	100	[mg/L]	S
Minimum dilution factor*	F	4×10^5	[-]	S
Maximum daily discharge volume**	Dv	< 22.5	[m³/d]	S
12.2 2 - 2: Disposal/re-use of hydrotesting water				
Concentration of a.s. in pipeline	$C_{pipeline}$	12.5-2000	[mg/L]	S
Release fraction of hydrotesting water in the marine	f_r	Negligible***	[-]	S

Input parameters for calculating the local emission of glutaraldehyde used for hydrotesting (12.2 – 2)				
Input	**Definition**	**Value**	**Unit**	**S/D/O/P**
12.2.2 - 3: Degradation before discharge using bisulfite				
Concentration of a.s. in pipeline	$C_{pipeline}$	50	[mg/L]	S
Fraction of degradation during storage within 180 days	F_{deg}	0.5	[-]	S
Concentration of a.s. in pipeline after storage	$C_{pipeline\_deg}$	25	[mg/L]	O
Concentration of a.s. after adding bisulfite	$C_{release}$	0.15	[mg/L]	S

* F = $C_{pipeline}$ / PNECmarine for GA (0.00025 mg/L)
**Dv of 50 is based on a release of 180,000 m^3/d. Consequently, a Dv of 50,000 is based on 180 m^3/d and a Dv of 400,000 is based on 22.5 m^3/d.
***A quantitative exposure calculation is not conducted since the release to the marine compartment is considered as negligible.

Scenario 12.2 - 3 – Produced water disposal

Protectol® GA50 containing the a.s. glutaraldehyde is used as a slimicide for the oil and gas exploration industry may be added to produced water prior to disposal into seawater to prevent the formation of biofilms in different structures, e.g., hydrocyclones, gas floatation units and filters. Glutaraldehyde is added at concentration of up to 130 ppm. According the AR (2014) and also applied in scenario 12.2 -1 (reservoir injection), the interval between applications needs to be considered in a first dosing option. Therefore, the concentration of the a.s. in the fluid is 5.42 mg/L assuming a dose of 130 mg/L for 1 h per day.

As a second dosing option, the application interval is taken into account as it is described in the AR (2014), i.e., two hours of dosing once a week resulting in a concentration of a.s. in the fluid of 1.55 mg/L.

According to the AR (2014), 85% dissipation of the a.s. is assumed after one day at 55°C as a possible refinement, which is used in the following calculations. In the use-specific instructions for use the minimum retention time of 24 hours is given in order to allow sufficient degradation.

Input parameters for calculate the concentration of glutaraldehyde in produced water before disposal (12.2 – 3)				
Input	**Definition**	**Value**	**Unit**	**S/D/ O/P**
Concentration of chemical in the produced water_Tier 1	C_i	5.42*	[mg/L]	S
Concentration of chemical in the produced water_Tier 2	C_i	1.55**	[mg/L]	S
Dissipation of 85% after one day at 55 °C according to AR (2014)	F_{dis}	0.85	[-]	S
Output				
Concentration of the chemical in the produced water – Dosing option 1	$C_{pw\_dosing1}$	9.21	[µg/L]	O
Concentration of the chemical in the produced water – Dosing option 2	$C_{pw\_dosing2}$	2.64	[µg/L]	O

C_{pw}= $((f_r*C_{inj}*V_{inj})/V_{pw})*(1-F_{dis})$

where:

– C_{pw}	concentration in the produced water (mg/L)	O
– f_r	fraction of biocide released to the open sea (0.01)	D
– C_{inj}	the concentration of the active substance in the injection fluid according to the instructions of use (mg/L)	S
– V_{inj}	volume of the water injected daily (17 000 m³/d)	D
– V_{pw}	volume of the produced water (15 000 m³/d)	

*Shock dose of 130 ppm applied for 1h. Daily average concentration 130 x (1/24) = 5.42 mg/L

** Daily average concentration of 1.55 mg/L covers dosage of 130 mg/L applied for 2 h once a week according to the AR (2014), 130 x 2 / (24 x 7) = 1.55 mg/L

The following concentration in produced water can be calculated.

Resulting concentrations of glutaraldehyde in produced water prior to disposal (12.2 – 3)		
Parameter	**Definition**	**Value [µg/L]**
Concentration of the chemical in the produced water – Dosing option 1	$C_{pw\_dosing1}$	9.21
Concentration of the chemical in the produced water – Dosing option 2	$C_{pw\_dosing2}$	2.64

Justification of using high temperature and 85 % dissipation

During the commenting period one Member State did not accept assumption of 55 °C and subsequent degradation of 85 %. This degradation was accepted during the active substance approval, although it was not needed in the end. According to the applicant produced water coming from the well is hot (temperature at least 60 °C) and it is heated on the platform to 60-70 °C during the oil/water/gas separation process to allow the phase separation by reducing the viscosity of the crude oil.[26] The produced water discarded is still at 50- 70 °C.

The RMM to measure the glutaraldehyde concentration before discharge and only to discharge water with < 0.2 mg/L glutaraldehyde ensure that the required dissipation is achieved. If this is not the case, the water can’t be discharged but has to be treated with either bisulfite or sodium hydroxide or shipped onshore for corresponding treatment or disposal.

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[26] Produced Water Treating Systems - Comparison Between North Sea and Deepwater Gulf Of Mexico, SPE 159713, JM Walsh and WJ Georgie, SPE ATCE, San Antonio 8-10 October 2012; J.M. Walsh, Oil and Gas Facilities, p. 73, April 2015.

Fate and distribution in exposed environmental compartments

The relevant exposed environmental compartments are scenario specific and listed in the following tables.

Product type 6: In-can preservatives

Identification of relevant receiving compartments based on the exposure pathway							
Compartment / Scenario	**Surface water**	**Sediment**	**STP**	**Air**	**Soil**	**Ground water**	**Sea-water**
PT 6.1 – 1	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr
PT 6.2 – 1	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr
PT 6.2 – 2	Yes ++	nr	No	nr	Yes ++	Yes +	nr
PT 6.3.1 – 1	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr
PT 6.3.2 – 1	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr
PT 6.3.3 – 1	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr

++ Direct exposure
+ Indirect exposure
nr: Not relevant

Product type 12: Slimicides (covering the PT 11 use in the offshore oil exploration industry)

Identification of relevant receiving compartments based on the exposure pathway							
Compartment / Scenario	**Surface water**	**Sediment**	**STP**	**Air**	**Soil**	**Ground water**	**Seawater**
PT 12.1 – 1	Yes ++	nr	nr	nr	nr	nr	Yes ++
PT 12.1 – 2	Yes +	nr	Yes ++	nr	Yes +	Yes +	nr
PT 12.2 – 1	nr	nr	nr	nr	nr	nr	Yes ++
PT 12.2 – 2-1/2/3	nr	nr	nr	nr	nr	nr	Yes ++
PT 12.2 - 3	nr	nr	nr	nr	nr	nr	Yes ++

++ Direct exposure
+ Indirect exposure
nr: Not relevant

All input parameters used for calculating the fate and distribution of the a.s. in the environment are taken from the assessment report for glutaraldehyde (2014).

Input parameters (only set values) for calculating the fate and distribution of the a.s. glutaraldehyde in the environment			
Input	Value	Unit	Remarks
Molecular weight	100.1	g/mol	[-]
Melting point	-18	°C	[-]
Boiling point	101.5	°C	[-]
Vapour pressure (at 20°C)	44	Pa	[-]
Water solubility (at 21°C)	51300	mg/L	[-]
Log Octanol/water partition coefficient	-0.36	Log 10	[-]
Organic carbon/water partition coefficient (Koc)	326	L/kg	[-]

Input parameters (only set values) for calculating the fate and distribution of the a.s. glutaraldehyde in the environment			
Input	Value	Unit	Remarks
Henry's Law Constant (at 20°C)	8.6×10^{-3}	Pa/m3/mol	[-]
Biodegradability	Readily biodegradable	[-]	[-]
Rate constant for STP Tier 0	1	h^{-1}	[-]
Rate constant for STP Tier 1-2	2.9	h^{-1}	[-]
Rate constant for biodegradation in surface water	0.56	d^{-1}	at 12ºC
Rate constant for hydrolysis in surface water	6×10^{-4}	d^{-1}	at 12ºC / pH 7
Rate constant for photolysis in surface water	4×10^{-3}	d^{-1}	[-]
DT_{50} for degradation in soil	30	d	Default according to Guidance on BPR IV/B (2015)

The fate and distribution data of glutaraldehyde in the different environmental compartments is in accordance with the AR (2014). There, a tiered approach for the fate in the STP is described considering a default degradation rate constant of 1 h^{-1} for readily biodegradable substances for Tier 0 and an experimentally derived rate constant of 2.9 h^{-1} for Tier 1 and Tier 2. For Tier 2, the concentration in dry sewage sludge C_{sludge} is additionally set to 0 based on results from desorption experiments due to reactions with the organic matter. Here only results for Tier 2 are presented as agreed during the commenting period.

Fate and distribution in the STP according to the assessment report (2014)		
Compartment	Percentage [%]	
Air		0.0015
Water		4.64
Sludge		2.86 (Tier 1) / 0 (Tier 2)
Degraded in STP		92.5

Furthermore, following partitioning coefficients were presented in AR (2014).

Partitioning Coefficients according to the assessment report (2014)	
Soil-water	9.96
Suspended matter-water	9.05
Sediment-water	8.95
Air-water	2.29E-06

Calculated PEC values

PEC values - Product type 6: In-can preservatives

Indirect emissions to environmental compartments – STP route

The distribution of the a.s. glutaraldehyde in the environment after release to the sewer system is calculated according to the Guidance on BPR IV/B (2015).

PEC in STP

The PEC_{STP} is calculated using equation 33 and 38 of the Guidance on BPR IV/B (2015) and using the distribution factors (tiered approach) presented in the table above.

Resulting predicted environmental concentrations of glutaraldehyde in the sewage treatment plant (STP)	
Scenario	**PEC_{STP} [µg/L]**
PT 6.1 – sum	14.85
PT 6.2 – 1 - application	0.93
PT 6.2 – 1 – service life	2.09
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)	101
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)	97.4
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)	0.46
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)**	0.46
PT 6.3.2 – 1- Tier 1 (0% elimination)	70.5
PT 6.3.2 – 1– Tier 2 (99.6% elimination)	0.23
PT 6.3.3 – 1 - Tier 1 (0% elimination)	77.3
PT 6.3.3 – 1 – Tier 2 (99.6% elimination)	0.23

PEC in water

The effluent of the STP is diluted into the surface water. The PEC_{water} is calculated according to equation 45 of the Guidance on BPR IV/B (2015) using a solid-water partition coefficient of 32.6 L/kg and a default dilution factor of 10.

Resulting predicted environmental concentrations of glutaraldehyde in the surface water	
Scenario	**PEC_{water} [µg/L]**
PT 6.1 – sum	1.48
PT 6.2 – 1 - application	0.09
PT 6.2 – 1 – service life	0.22
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)	10.1
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)	9.74
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)	0.05
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)	0.05
PT 6.3.2 – 1 - Tier 1 (0% elimination)	7.05
PT 6.3.2 – 1– Tier 2 (99.6% elimination)	0.02
PT 6.3.3 – 1 - Tier 1 (0% elimination)	7.73
PT 6.3.3 – 1 – Tier 2 (99.6% elimination)	0.02

PEC in sediment

The sediment is not considered, since the a.s. does not fulfil criteria for sediment risk assessment. It’s readily biodegradable and has a log Kow less than three (according to the AR, 2014). Furthermore, the risk characterization for the aquatic will also cover the sediment compartments for chemicals with a log Kow up to 5 (Guidance on BPR IV/B, 2015).

PEC in soils

For the soil compartment, emission of the a.s. occurs due to the indirect release *via* sewage sludge application from a STP. The rate of sewage sludge production is 710 kg/d (default size of a STP). The initial concentrations in soil following 10 sludge applications are used to calculate time weighted average residues in soils (PEC_{soil}) of terrestrial ecosystems assuming 30 days degradation (averaging time) and a first order rate constant for removal from top soil of 0.0231 d^{-1} (calculated from DT_{50} soil of 30 d). The PEC_{soil} is calculated applying equation 55 of the Guidance on BPR IV/B (2015).

Resulting predicted environmental concentrations of glutaraldehyde in soil	
Scenario	**PEC_{soil} [µg/kg ww]**
PT 6.1 – sum	No exposure
PT 6.2 – 1 - application	No exposure
PT 6.2 – 1 – service life	No exposure
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)	No exposure
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)	No exposure
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)	No exposure
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)	No exposure
PT 6.3.2 – 1 - Tier 1 (0% elimination)	No exposure
PT 6.3.2 – 1– Tier 2 (99.6% elimination)	No exposure
PT 6.3.3 – 1 - Tier 1 (0% elimination)	No exposure
PT 6.3.3 – 1 – Tier 2 (99.6% elimination)	No exposure

PEC in groundwater

The soil pore water concentration is assessed using Guidance on BPR IV/B (2015) using default values for the PEC calculation in soil pore water according to equation 20-22 and using the time weighted concentrations in agricultural soil after 180 days. Furthermore, an air-water partitioning coefficient of 2.29×10^{-6}, a partitioning coefficient solid-water in soil of 6.52 L/kg is used to calculate a soil-water partitioning coefficient of 10 m^3/m^3. As result, the soil-water partitioning coefficient is used as input parameter to calculate the local pore water concentration (PEC_{gw}).

Resulting predicted environmental concentrations of glutaraldehyde in groundwater	
Scenario	**PEC_{gw} [µg/L]**
PT 6.1 – sum	No exposure
PT 6.2 – 1 - application	No exposure
PT 6.2 – 1 – service life	No exposure
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)	No exposure
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)	No exposure
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)	No exposure
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)	No exposure
PT 6.3.2 – 1 - Tier 1 (0% elimination)	No exposure
PT 6.3.2 – 1– Tier 2 (99.6% elimination)	No exposure
PT 6.3.3 – 1 - Tier 1 (0% elimination)	No exposure
PT 6.3.3 – 1 – Tier 2 (99.6% elimination)	No exposure

PEC in air

Glutaraldehyde is volatile, but does not easily evaporate from water due to high water solubility. As the substance is subjected to rapid photodegradation in air with a half-life of 8.2 h, a risk for the atmosphere and a long-range transport is therefore not to be expected.

Direct emissions to environmental compartments

Scenario 6.2 – 2 – Countryside – Direct emissions to surface water - PEC_{water}

The treatment of bridges with paints containing glutaraldehyde as preservative in the countryside (Scenario 6.2 – 2 in this document) may result in direct releases to surface water during brush application and during service life. The concentration of glutaraldehyde (no removal in surface water) resulting from brush application is calculated according to the ESD for PT 8 (2013) considering a water volume of 1000 m³.

Resulting local concentrations of glutaraldehyde in surface water for scenario 6.2 -2 (countryside scenario, bridge over pond) due to direct release during application and service life over the initial and longer assessment period assuming no removal in surface water

Parameter	**Assessment period [d]**	**Definition**	**Value [µg/L]**
Local concentration of a.s. resulting from release during brush application	Not relevant	$Clocal_{water,applicr}$	0.17
Local concentration of a.s. resulting from release during leaching in-service	30 and 1825*	$Clocal_{water,leach,time1/2}$	3.43

*concentrations in water are the same for both assessment periods, as 100% leaching and no degradation in water is considered

However, as glutaraldehyde can be considered as rapidly degradable in water/sediment system (AR, 2014), the time dependent concentrations assuming degradation in surface water can be used as a refinement for the assessment, which is in accordance with the calculations described in Table 3.8 of the ESD for PT 8 (2013). A DT_{50} water of 1.25 days (12°C according to AR, 2014) is considered. A water volume V_{water} of 1000 m³ and a leachable area of a bridge of 10 m² are also assumed. $Clocal_{water,applic}$ is defined as the initial concentration in water during application, i.e. after brush application. The duration of the initial assessment period (Time 1) is 30 d and of the longer assessment period 1825 d (Time 2).

The average daily emissions of glutaraldehyde due to leaching over the assessment period are calculated according to equations 3.14 and 3.15 of the ESD for PT 8 (2013). The time weighted concentrations in local water over the two assessment periods are calculated using modified versions of equation 3.16 and 3.17 of the ESD for PT 8 (2013), as the in-situ treatment is not foreseen in the ESD, but should be taken into account for the use in paints and coating.

$$Clocal_{water,time1/2} = \frac{E_{water,leach,Time1/2}}{V_{water} \times k} + \frac{1}{k \times Time_1}\left[Clocal_{water,appplic} - \frac{E_{water,leach,Time1/2}}{V_{water} \times k}\right] \times \left(1 - e^{-Time1 \times k}\right)$$

This results in the following concentration in surface water for the countryside scenario.

Resulting local concentrations of glutaraldehyde in surface water for scenario 6.2 - 2 (countryside scenario) due to release during application and service life over the initial and longer assessment period assuming degradation in surface water

Parameter	**Assessment period [d]**	**Definition**	**Value [µg/L]**
Local concentration of a.s. resulting from release during brush application + leaching in service life – worst case amateur use	30	$Clocal_{water}$	0.25
	1825	$Clocal_{water}$	3.52×10^{-3}

Scenario 6.2 – 2 – Countryside – Direct emissions to soil – PEC_{soil}

The treatment of facades with paints containing glutaraldehyde as preservative in the countryside (Scenario 6.2 – 2 in this document) may result in direct releases to the soil during spray or brush application and during service life. The concentration of glutaraldehyde (no removal in soil) resulting from spray application due to the exposure *via* drift and runoff is calculated according to the ESD for PT 8 (2013) considering a soil volume of 13 m^3 (wind stillness and no soil cover, equation 4.118). The soil volume adjacent to treated surface is assumed to be 13 m^3 for the brush application (equation 4.38) and the service life (equation 4.45-4.46). Furthermore, a default bulk density of wet soil of 1700 kg/m^3 ww is applied.

Resulting local concentrations of glutaraldehyde in soil for scenario 6.2 -2 (countryside scenario) due to release during application and service life over the initial and longer assessment period assuming no removal in soil

Parameter	**Assessment period [d]**		**Definition**	**Value [mg/kg ww]**
Local concentration of a.s. resulting from release during spray application	Not relevant		$Clocal_{soil,tier1}$	0.58
Local concentration of a.s. resulting from release during brush application	Not relevant		$Clocal_{soil,brush}$	0.10
Local concentration of a.s. resulting from release during leaching in-service	30 and 1825**		$Clocal_{soilleach,time1/2}$	1.94

The time dependent concentrations assuming degradation in soil can be used as a refinement for the assessment, which is in accordance with the calculations described in Table 3.6 of the ESD for PT 8 (2013). A default DT_{50} soil of 30 d (according to Table 8, Guidance on BPR IV/B, 2015) is assumed. However, this value is likely to underestimate the degradation in soil, because in the water/sediment system the half-life of 1.25 d at 12 °C was determined ((AR, 2014). A soil volume V_{soil} of 13 m^3 and a leachable area of a façade of 125 m^2 are also assumed. $Clocal_{soil,applic}$ is defined as the initial concentration in soil during application, i.e. after brush or spray application. The duration of the initial assessment period (Time 1) is 30 d and of the longer assessment period 1825 d (Time 2).

The average daily emissions of glutaraldehyde due to leaching over the assessment period are calculated according to equations 3.5 and 3.6 of the ESD for PT 8 (2013).

The time dependent concentrations in local soil over the two assessment periods are calculated using equation 3.11 and 3.12 of the ESD for PT 8 (2013):

$$Clocal_{soil,time\ \ /2} = \frac{E_{soil,leach,time1/2}}{Vsoil\ x\ RHOsoil\ x\ k} - \left[\frac{E_{soil,le\ \ \ \ ,time\ 1/2}}{Vsoil\ x\ RHOsoil\ x\ k} - Clocal_{soil,applic}\right] x\ e^{-ti\ \ \ \ 1/2\ x\ k}$$

This results in the following concentration in soil for the countryside scenario.

Resulting local concentrations of glutaraldehyde in soil for scenario 6.2 - 2 (countryside scenario) over the initial and longer assessment period assuming degradation in soil

Parameter	**Assessment period [d]**	**Definition**	**Value [mg/kg ww]**
Local concentration of a.s. resulting from release during spray application and leaching in service life	30	$Clocal_{soil,time1,spray,tier1,deg}$	1.69
	1825	$Clocal_{soil,time2, spray,tier1,deg}$	0.05
Local concentration of a.s. resulting from release during brush application + leaching in service life – worst case amateur use	30	$Clocal_{soil,time1, brush,tier1,deg}$	1.45
	1825	$Clocal_{soil,time2, brush,tier1,deg}$	0.05

Scenario 6.2 – 2 – Countryside – Direct emissions to soil – PEC_{gw}

The predicted environmental concentration in groundwater for scenario PT 6.2 - 2 is calculated according to the ESD for PT 8 (2013) using a soil-water partitioning coefficient of 10 m^3/m^3 (calculated according to Guidance on BPR IV/B, 2015; equation 24). The groundwater concentrations are calculated with (equations 3.9 and 3.10) and without (equation 3.3) taking removal of the a.s. in soil into account.

Resulting local concentrations of glutaraldehyde in soil pore water for scenario 6.2 - 2 (countryside scenario)		
Parameter	**Assessment period [d]**	**Value [µg/L]**
Local concentration of a.s. resulting from spray application – no degradation in soil	Not relevant	98.6
Local concentration of a.s. resulting from brush application – no degradation in soil	Not relevant	16.5
Local concentration of a.s. resulting from service life - no degradation in soil	30 and 1825	330
Local concentration of a.s. resulting from release during spray application and leaching in service life – degradation in soil	30	287
	1825	8.5
Local concentration of a.s. resulting from release during brush application + leaching in service life – worst case amateur use – degradation in soil	30	247
	1825	8.50

PECs in pore water amount to >0.1 µg/L for the countryside scenario. According to Council Directive 98/83/EC (1993) relating to the quality of water intended for human consumption, the maximum admissible concentration for organic chemicals in drinking water is 0.1 µg/L for substances considered separately. The calculated pore water concentrations for glutaraldehyde (as an indicator of the potential concentrations in groundwater) do not comply with this criterion.

Therefore, an exposure assessment was conducted using FOCUS PEARL 4.4.4. This groundwater simulations are performed according to the PT 08 (2013) scheme and as recommended in TAB, 2017 (ENV84). The original assessment was based on the service life of 5 years of the paint. During commenting one Member State required the assessment based on 30 days, i.e. Time 1 because only 5 % of glutaraldehyde would be left after 30 days due to polymerization in the dry paint (half-life 7 days). The original calculation was based on the same parameter setting apart from the leached amount of 0.014 kg per application event and 10 applications per year. All nine scenarios resulted in PECgw < 0.001 µg/L.

The revised calculations assumed similarly a density of 16 treated houses per ha and a leachable area of 125 m² per house resulting in a total leachable area of 2000 m² per ha. Considering a product application rate of 250 mL/m², a product density of 1.4 kg/L and an a.s. concentration of 0.0979% results in a total amount of 0.34 g a.s./m² treated area. Thus, the assumption is made that the total amount of leached a.s. per ha and per year is 0.680 kg (i.e. 100 % of applied amount is subjected for leaching). The further assumption was made that the 16 houses are all treated at one time point and the total applied amount could all leach at once, i.e. within a time period of one day.

According to the supplement to Appendix 4 of the ESD for PT 8 (2013) the worst-case application events were selected, which are at 24th of March and at 29th of October. Thus, two model calculations were conducted to select the worst-case scenario based on an application rate of 0.68 kg/ha at 24th of March and 0.68 kg/ha at 29th of October, respectively. The latter proved worst-case and was used for the calculations, although it is highly unlikely that exterior objects are painted when rain is expected and thus, it is realistic that the houses are painted in spring to autumn.

The crop type is alfalfa/grass and the application mode is surface application. A default, worst-case DT_{50} soil of 30 d for readily biodegradable substances, a KOM of 189.1 L/kg (K_{oc}/1.724), a Freundlich exponent of 0.9 and no plant uptake is assumed.

The FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of < 0.001 µg/L for all nine groundwater scenarios and therefore no unacceptable risk to groundwater is posed for the use of glutaraldehyde as a preservative in paints.

Summary table on calculated PEC_{GW} values using FOCUS Pearl for scenario 6.2 - 2 (countryside, crop type: alfalfa/gras; date of application October 29)

FOCUS scenario	**PEC_{GW}**
	[µg/L]
Chateaudun	<0.001
Hamburg	<0.001
Jokioinen	<0.001
Kremsmünster	<0.001
Okehampton	<0.001
Piacenza	<0.001
Porto	<0.001
Sevilla	<0.001
Thiva	<0.001

Summary of PEC values – PT 6

The PECs of the a.s. glutaraldehyde in the environment after release to the sewer system are shown for all scenarios in the following table.

Scenario	Summary table on calculated PEC values (indirect emissions *via* STP)			
	PEC_{STP}	PEC_{water}	PEC_{soil}	PEC_{GW}
	[µg/L]	[µg/L]	[µg/kg ww]	[µg/L]
6.1 – sum (detergents)	14.85	0.1.48	No exposure	No exposure
6.2 - 1 (city)- Application (worst case spray)	0.93	0.09	No exposure	No exposure
6.2 - 1 (city)- – Service life	2.09	0.22	No exposure	No exposure
6.3.1 – 1 – newsprint - Tier 1/0% elimination (paper production)	101	10.1	No exposure	No exposure
6.3.1 – 1 – printing and writing paper - Tier 1/0% elimination (paper production)	97.4	9.74	No exposure	No exposure
6.3.1 – 1 – newsprint - Tier 2/99.6% elimination (paper production)	0.46	0.05	No exposure	No exposure
6.3.1 – 1 – printing and writing paper - Tier 2/99.6% elimination (paper production)	0.46	0.05	No exposure	No exposure
6.3.2 – 1 – Tier 1/0% elimination (textile processing)	70.5	7.05	No exposure	No exposure
6.3.2 – 1 – Tier 2/99% elimination (textile processing)	0.23	0.02	No exposure	No exposure
6.3.3 – 1 – Tier 1 (leather production)	77.3	7.73	No exposure	No exposure
6.3.3 – 1 – Tier 2/99% elimination (leather production)	0.23	0.02	No exposure	No exposure

The PECs of the a.s. glutaraldehyde in the environment after direct release to surface water or soil are shown for all scenarios in the following table.

Scenario	Summary table on calculated PEC values (direct emissions)
6.2 – 2 (countryside) water	**PEC_{water} [µg/L]**
Application brush (worst case amateur use)	0.17

Scenario		**Summary table on calculated PEC values (direct emissions)**	
6.2 – 2 (countryside) water		**PEC$_{water}$ [µg/L]**	
Leaching in-service (no degradation in water)		3.43	
	Assessment period [d]		
Brush application + leaching in service life – degradation in water assumed (amateur use)	30	0.25	
	1825	3.52 x 10^{-3}	
6.2 – 2 (countryside)soil		**PEC$_{soil}$ [mg/kg ww]**	**PEC$_{GW}$ [µg/L]**
Application - Spray		0.58	98.6
Application brush (worst case amateur use)		0.10	17
Leaching in-service (no degradation in soil)		1.94	330
	Assessment period [d]		
Spray application + leaching in service life – degradation in soil assumed	30	1.69	287
	1825	0.05	8.5
Brush application + leaching in service life – degradation in soil assumed (amateur use)	30	1.45	247
	1825	0.05	8.50

PEC values – Product type 11: Preservatives for liquid-cooling and processing systems

The in-use concentration and use scenarios in PT 11 (prevention of microbially induced deterioration and corrosion in injections systems, transmission lines, storage systems and pipelines) are identical to those in PT 12. Therefore, exposure assessment for PT 12 covers the assessment for PT 11.

PEC values - Product type 12: Slimicides

12.1: Paper mills

Indirect emissions to environmental compartments – STP route

The distribution of the a.s. glutaraldehyde in the environment after release to the sewer system is calculated according to the Guidance on BPR IV/B (2015). Regarding PT 12, this emission path is relevant for the typical case scenario PT 12.1 - 2.

PEC in STP

The PEC_{STP} is calculated using equation 36 and 41 of the Guidance on BPR IV/B (2015) and using the distribution factors (tiered approach) presented in the table above. Furthermore, for PT 12.1 - 2 (typical case scenario) the STP represents an industrial WWTP with an effluent discharge rate of 5000 m³/d.

Resulting predicted environmental concentrations of glutaraldehyde in the sewage treatment plant (STP)	
Scenario	**PEC_{STP} [µg/L]**
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	1936
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	8.61

PEC in water

The effluent of the STP is diluted into the surface water. The PEC_{water} is calculated according to equation 48 of the Guidance on BPR IV/B (2015) using a solid-water partition coefficient of 32.6 L/kg and a default dilution factor of 10.

Resulting predicted environmental concentrations of glutaraldehyde in the surface water and seawater	
Scenario	**PEC_{water} [µg/L]**
	Surface water
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	194
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	0.86
	Seawater
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	19.4
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	0.09

PEC in sediment

The sediment is not considered, since the a.s. does not fulfil criteria for sediment risk assessment. It’s readily biodegradable and has a log Kow less than three (according to the AR, 2014). Furthermore, the risk characterization for the aquatic environment will also cover the sediment compartments for chemicals with a log Kow up to 5 (Guidance on BPR IV/B, 2015).

PEC in soils

For the soil compartment, emission of the a.s. occurs due to the indirect release *via* sewage sludge application from a STP. The rate of sewage sludge production is 710 kg/d. The initial concentrations in soil following 10 sludge applications are used to calculate time weighted average residues in soils (PEC_{soil}) of terrestrial ecosystems assuming 30 days degradation (averaging time) and a first order rate constant for removal from top soil of 0.023 d^{-1} (calculated from DT_{50} soil of 30 d). The PEC_{soil} is calculated applying equation 55 of the Guidance on BPR IV/B (2015).

Resulting predicted environmental concentrations of glutaraldehyde in soil	
Scenario	**PEC_{soil} [µg/kg ww]**
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	No exposure
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	No exposure

PEC in groundwater

The soil pore water concentration is assessed using Guidance on BPR IV/B (2015) using default values for the PEC calculation in soil pore water according to equation 20-22 and using the time weighted concentrations in agricultural soil after 180 days. Furthermore, an air-water partitioning coefficient of 2.29×10^{-6}, a partitioning coefficient solid-water in soil of 6.52 L/kg is used to calculate a soil-water partitioning coefficient of 10 m^3/m^3. As result, the soil-water partitioning coefficient is used as input parameter to calculate the local pore water concentration (PEC_{gw}).

Resulting predicted environmental concentrations of glutaraldehyde in groundwater	
Scenario	**PEC_{gw} [µg/L]**
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	No exposure
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)**	No exposure

PEC in air

Glutaraldehyde is volatile, but does not easily evaporate from water due to high water solubility. As the substance is subjected to rapid photodegradation in air with a half-life of 8.2 h, a risk for the atmosphere and a long-range transport is therefore not to be expected.

Direct emissions to environmental compartments

Scenario 12.1 – 1 – Reasonable worst case Scenario – Direct emissions to surface water – PEC_{water}

For the reasonable worst case scenario, it is assumed that the paper mill discharges the wastewater directly to surface water. In case of emissions to freshwater, dilution factors of 10 and 1000 are proposed by the AR (2014). For emissions to seawater, the dilution factor is 100, which is also stated in the ESD for PT 12 (2003).
This results in the following local concentrations of glutaraldehyde in freshwater and seawater.

Resulting local concentrations of glutaraldehyde in surface water (PEC_{water}) or seawater (PECmarine) for scenario 12.1 - 1 (Reasonable worst case scenario) due to direct release during application	
Parameter	**Value [µg/L]**
Local concentration in surface water of a.s. – Tier 1 – Dilution factor 10	10752
Local concentration in seawater of a.s. – Tier 1 – Dilution factor 100	1075
Local concentration in surface water of a.s. – Tier 2 – Dilution factor 10**	47.8
Local concentration in seawater of a.s. – Tier 2 – Dilution factor 100**	4.78

12.2: Oil and gas exploration industry

Direct emissions to environmental compartments

Scenario 12.2 – 1 - Direct emissions to seawater – PEC_{marine} - Reservoir injection

According to the offshore oil exploration scenario document (Ctgb, 2015), two PECs need to be considered for the worst-case reservoir injection use: 1) the concentration in the vicinity of a single platform (peak concentrations during or right after discharge) and 2) the background concentration in the open sea. The peak concentration is calculated using the concentration of the a.s. in the produced water ($C_{pw\_dosing1}$: 53.1 µg/L and $C_{pw\_dosing2}$: 18.2) and a dilution factor of 1000.

The background concentration is calculated using the MAMPEC model and the "Default open sea" scenario taking the input parameter presented in the offshore oil exploration scenario document (Ctgb, 2015) and the calculated total emissions ($\text{Elocal}_{\text{MAMPEC}}$) into account.
The resulting concentrations are used to calculate $\text{PEC}_{\text{marine}}$.

Resulting local concentrations of glutaraldehyde in seawater ($\text{PEC}_{\text{marine}}$) for scenario 12.2 - 1 (Reservoir injection)	
Parameter	**Value [µg/L]**
Local concentration in seawater in the vicinity of one oil platform (Dilution factor 1000) – Dosing option 1*	0.05
Local concentration in seawater in the vicinity of one oil platform (Dilution factor 1000) – Dosing option 2**	0.02
Background concentration in the open sea	3.23×10^{-3}
Total predicted environmental concentration in seawater – $\text{PEC}_{\text{marine}}$ – Dosing option 1 (background + local concentration)	0.05
Total predicted environmental concentration in seawater – $\text{PEC}_{\text{marine}}$ – Dosing option 2 (background + local concentration)	0.02

Scenario 12.2 – 2 - Direct emissions to seawater – $\text{PEC}_{\text{marine}}$ – Hydrotesting

As described in section "Scenario 12.2 - 2 – Hydrotesting", the dilution factor increases with lower discharges and larger discharge depths. Furthermore, a higher dilution factor results in a lower local concentration in seawater.

For sub-scenario 12.2.2 - 1 and the minimum in-use concentration of 12.5 mg a.s./L, a minimum dilution factor of 50,000 results in local concentration below 0.25 µg/L (i.e., $\text{PNEC}_{\text{marine}}$ of the a.s.) and for a maximum in-use concentration of 100 mg a.s., local concentrations below 0.25 µg/L can be achieved by applying a minimum dilution factor of 400,000.

In case of disposal or re-use of hydrotesting water, the exposure to seawater is considered as negligible and thus, predicted environmental concentrations were not derived.

For sub-scenario 12.2.2 - 3 (degradation before discharge using bisulfite), the local concentration in seawater is calculated using the concentration of the a.s. in the hydrotesting water after degradation and bisulfite addition (i.e., 0.15 mg/L) and a dilution factor of 1000, which is in accordance to the AR (2014) and equation 22 from CHARM (2005).

Resulting local concentrations of glutaraldehyde in seawater (PEC$_{marine}$) for scenario 12.2.2 - 1/2/3 (Hydrotesting)	
Parameter	**Value [µg/L]**
12.2.2 - 1: Slow release	
Local concentration in seawater – 12.5 mg a.s./L in-use concentration	< 0.25
Local concentration in seawater – 100 mg a.s./L in-use concentration	< 0.25
12.2.2 - 2: Disposal/re-use of hydrotesting water	
Local concentration in seawater	Negligible
12.2.2 - 3: Degradation before discharge using bisulfite	
Local concentration in seawater	0.15

Scenario 12.2 – 3 - Direct emissions to seawater – PEC$_{marine}$ – Produced water disposal

The local peak concentration after disposal of produced water is calculated using the concentration of the a.s. in the produced water (C$_{pw\_dosing1}$: 9.21 µg/L and C$_{pw\_dosing2}$: 2.64 µg/L) and a dilution factor of 1000 according to Ctgb (2015).

Resulting local concentrations of glutaraldehyde in seawater (PEC$_{marine}$) for scenario 12.2 - 3 (Produced water disposal)	
Parameter	**Value [µg/L]**
Local concentration in seawater (Dilution factor 1000) – Dosing option 1+ background	0.012
Local concentration in seawater (Dilution factor 1000) – Dosing option 2 + background	0.006

Summary of PEC values – PT 12

The PECs of the a.s. glutaraldehyde in the environment after release to the sewer system are shown for all scenarios in the following table.

Scenario	**Summary table on calculated PEC values (indirect emissions *via* STP)**				
12.1 – 2: typical case scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{marine}**	**PEC_{soil}**	**PEC_{GW}**
	[µg/L]	[µg/L]	[µg/L]	[µg/kg ww]	[µg/L]
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	1936	194	19.4	No exposure	No exposure
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	8.61	0.86	0.09	No exposure	No exposure

The PECs of the a.s. glutaraldehyde in the environment after direct release to surface water (freshwater and seawater) are shown for all scenarios in the following table.

Scenario	**Summary table on calculated PEC values (direct emissions)**
12.1 – 1 (reasonable worst case scenario)	**PEC$_{water}$**
	[µg/L]
Local concentration in <u>surface water</u> of a.s. – Tier 1 – Dilution factor 10	10752
Local concentration in <u>seawater</u> of a.s. – Tier 1 – Dilution factor 100	1075
Local concentration in <u>surface water</u> of a.s. – Tier 2 – Dilution factor 10	47.8
Local concentration in <u>seawater</u> of a.s. – Tier 2 – Dilution factor 100	4.78
12.2 – 1 (reservoir injection)	
Total predicted environmental concentration in seawater – Dosing option 1	0.05
Total predicted environmental concentration in seawater - Dosing option 2	0.02
12.2 – 2 (hydrotesting)	
12.2.2 - 1 (slow release)	
Local concentration in seawater – 12.5 mg a.s./L in-use concentration	< 0.25
Local concentration in seawater – 100 mg a.s./L in-use concentration	< 0.25
12.2.2 – 2 (disposal/re-use of hydrotesting water)	
Local concentration in seawater	Negligible
12.2.2 – 3 (degradation before discharge using bisulfite)	
Local concentration in seawater	0.15
12.2 – 3 (Produced water disposal)	
Local concentration in seawater – Dosing option 1	0.012
Local concentration in seawater – Dosing option 2	0.006

Primary and secondary poisoning

Primary poisoning

Due to the intended uses of glutaraldehyde, a risk assessment for non-target animals primary exposed to glutaraldehyde is not necessary.

Secondary poisoning

The a.s. is unlike to bioaccumulate in aquatic or terrestrial environment according to the Guidance on BPR IV/B (2015). It has a very low log Kow (-0.36) and a low organic carbon/water partition coefficient of 326 L/kg. Further assessment of secondary exposure *via* the food chain is therefore not deemed reasonable, which is in accordance to the Guidance on BPR IV/B (2015).

2.2.8.3 Risk characterisation

Risk characterisation – Product type 6: In-can preservative

Atmosphere

Conclusion: Glutaraldehyde is volatile, but does not easily evaporate from water due to high water solubility. As the substance is subjected to rapid photodegradation in air with a half-life of 8.2 h, a risk for the atmosphere and a long-range transport is therefore not to be expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values for STP	
Scenario	**PEC/PNEC$_{STP}$**
PT 6.1 – sum	0.03
PT 6.2 -1 – application (spray)	0.002
PT 6.2 – 1 – service life	0.004
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)	0.20
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)	0.19
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)	0.0009
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)	0.0009
PT 6.3.2 – 1 - Tier 1 (0% elimination)	0.14
PT 6.3.2 – 1– Tier 2 (99.6% elimination)	0.0005
PT 6.3.3 – 1 - Tier 1 (0% elimination)	0.15
PT 6.3.3 – 1– Tier 2 (99.6% elimination)	0.0005

Conclusion: Risk ratios for all assessed scenarios are < 1 indicating no unacceptable risk for STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values for surface water		
Scenario		**PEC/PNEC$_{water}$**
Indirect emissions to surface water *via* STP		
PT 6.1 – sum		0.59
PT 6.2 -1 – Application (spray)		0.04
PT 6.2 – 1 – Service life		0.09
PT 6.3.1 – 1- Newsprint - Tier 1 (0% elimination)		**4.04**
PT 6.3.1 – 1- Printing and writing paper- Tier 1 (0% elimination)		**3.90**
PT 6.3.1 – 1 - Newsprint– Tier 2 (99.6% elimination)		0.02
PT 6.3.1 – 1 – Printing and writing paper– Tier 2 (99.6% elimination)		0.02
PT 6.3.2 – 1 - Tier 1 (0% elimination)		**2.82**
PT 6.3.2 – 1– Tier 2 (99.6% elimination)		0.008
PT 6.3.3 – 1 - Tier 1 (0% elimination)		**3.09**
PT 6.3.3 – 1– Tier 2 (99.6% elimination)		0.008
Direct emissions to surface water		
PT 6.2 – 2 – Bridge over pond – brush application (no degradation in water)		0.07
PT 6.2 – 2 – Bridge over pond – service life (no degradation in water)		**1.37**
	Assessment period [d]	
PT 6.2 – 2 – Bridge over pond - brush application + leaching in service life - degradation assumed (amateur use)	30	0.10
	1825	0.001

Bold numbers indicate a possible risk to water organisms

Conclusion:

Risk ratios for surface water due to indirect emissions *via* STP are < 1 indicating no unacceptable risk to water organisms, when considering 99.6% elimination for PT 6.3.1/2/3, i.e. pulp and paper mills, textile and leather production. Because the elimation factor is based on the monitoring studies in paper industry and it is justified on the basis of BAT/BREF documents for the textile and leather industry the following RMM is required: Waste water has to be treated according to industry standards defined in the respective BAT documents.

For the direct emission to surface water, a safe use for the only assessed scenario bridge over pond scenario (countryside) is identified considering degradation in surface water.

Terrestrial compartment

Summary table on calculated PEC/PNEC values for soil		
Scenario		**PEC/PNEC$_{soil}$**
Indirect emissions to soil *via* STP		
PT 6.1 – sum		No exposure
PT 6.2 -1 – application (spray)		No exposure
PT 6.2 – 1 – service life		No exposure
PT 6.3.1 – 1- newsprint - Tier 1 (0% elimination)		No exposure
PT 6.3.1 – 1- printing and writing paper- Tier 1 (0% elimination)		No exposure
PT 6.3.1 – 1 - newsprint– Tier 2 (99.6% elimination)		No exposure
PT 6.3.1 – 1 – printing and writing paper– Tier 2 (99.6% elimination)		No exposure
PT 6.3.2 – 1 - Tier 1 (0% elimination)		No exposure
PT 6.3.2 – 1– Tier 2 (99.6% elimination)		No exposure
PT 6.3.3 – 1 - Tier 1 (0% elimination)		No exposure
PT 6.3.3 – 1– Tier 2 (99.6% elimination)		No exposure
Direct emission to soil		
Scenario 6.2 - 2 (countryside)		
Application – Spray		**3.15**
Application brush (worst case amateur use)		0.54
Leaching in-service (no degradation)		**10.5**
	Assessment period [d]	
Spray application + leaching in service life – degradation assumed	30	**9.18**
	1825	0.27
	30	**7.88**

Summary table on calculated PEC/PNEC values for soil		
Scenario		**PEC/PNEC$_{soil}$**
Brush application + leaching in service life - degradation assumed (amateur use)	1825	0.27

Bold numbers indicate a possible risk for the soil

Conclusion: The risk characterization ratios are below the trigger value of 1 for the indirect emissions to soil *via* STP. It was agreed during the evaluation of glutaraldehyde as an active substance that dry sewage sludge can be set to 0 in Tier 2 which means no emissions to soil via sewage sludge (Doc IIB, 8.3.3).

The use of glutaraldehyde as in-can preservative in paints leads also to direct emissions to soil. For the use in the countryside (scenario 6.2 - 2) unacceptable risks are identified for the spray application (no soil cover and no wind during application, exposed zone 50 cm adjacent to the treated wall) and the leaching during service life taking no degradation in soil into account. Soil cover up to 100 cm is needed as a risk mitigation measure.

The risk assessment for leaching in-service can be refined taking removal processes in soil into account. By considering the degradation of the a.s. in soil, PEC/PNEC-ratios above 1 are calculated for the soil after the initial assessment period of 30 days. However, by increasing the assessment period to 1825 days (i.e. service life of the paint), no unacceptable risks for the soil are identified for all scenarios for service-life plus application due to the degradation in the soil.

Groundwater

Conclusion: For indirect emissions to groundwater *via* STP, the calculated pore water concentrations for glutaraldehyde (as an indicator of the potential concentrations in groundwater) are below the maximum admissible concentration for pesticides in drinking water of 0.1 µg/L. For scenario 6.2 - 2 (countryside), the higher tier FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of <0.001 µg/L for all nine FOCUS scenarios (Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva) and an acceptable risk to the groundwater compartment.

Risk characterisation – Product type 11: Preservatives for liquid-cooling and processing systems

The in-use concentration and use scenarios in PT 11 (prevention of microbially induced deterioration and corrosion in injections systems, transmission lines, storage systems and pipelines) are identical to those in PT 12. Therefore, the risk assessment for PT 12 covers the risks for PT 11.

Risk characterisation – Product type 12: Slimicides

Atmosphere

Conclusion: Glutaraldehyde is volatile, but does not easily evaporate from water due to high water solubility. As the substance is subjected to rapid photodegradation in air with a half-life of 8.2 h, a risk for the atmosphere and a long-range transport is therefore not to be expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values for STP	
Scenario	**PEC/PNEC$_{STP}$**
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	**3.80**
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	0.02

Bold numbers indicate a possible risk for STP microorganisms

Conclusion: Risk ratios are for < 1 considering the Tier 2 refinement, i.e. 99.6% elimination in the dry end of the papermaking machine indicating no unacceptable risk for the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values for surface water and seawater	
Scenario	**PEC/PNEC$_{water}$**
Indirect emissions to surface water *via* STP	
	Surface water

Summary table on calculated PEC/PNEC values for surface water and seawater	
Scenario	**PEC/PNEC$_{water}$**
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	**77.6**
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	0.34
	Seawater
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	**77.6**
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	0.36
Direct emissions to surface water	
PT 12.1 – 1 – Tier 1 (10% elimination in dry end of the papermaking machine) – Dilution factor 10	**4300**
PT 12.1 – 1 – Tier 2 (99.6% elimination in dry end of the papermaking machine) – Dilution factor 10	**19.1**
Direct emissions to seawater	
PT 12.1 – 1 – Tier 1 (10% elimination in dry end of the papermaking machine) – Dilution factor 100	**4300**
PT 12.1 – 1 – Tier 2 (99.6% elimination in dry end of the papermaking machine) – Dilution factor 100	**19.1**
PT 12.2 – 1 – Dosing option 1	0.20
PT 12.2 – 1 – Dosing option 2	0.08
PT 12.2.2 - 1 – 12.5 mg a.s./L in-use concentration	< 1
PT 12.2.2 - 1 – 100 mg a.s./L in-use concentration	< 1
PT 12.2.2 - 2	Not relevant, as emissions to seawater are expected to be negligible
PT 12.2.2 - 3	0.60
PT 12.2 – 3 – Dosing option 1	0.048
PT 12.2 – 3 – Dosign option 2	0.024

Bold numbers indicate a possible risk to water organisms

Conclusion:
For indirect emissions to surface water *via* industrial STP, a safe use can be achieved considering the Tier 2 refinement for paper mills (99.6% elimination, AR 2014).

Regarding direct emissions to fresh surface water and seawater (no industrial STP) unacceptable risks are identified for the Tier 2 refinement and a dilution factors of 10 and 100. Therefore, it is stated at the label as risk mitigation measure (RMM), that is 'Application in the paper industry is only allowed when waste water is purified at least biologically before discharge to surface water'.

Regarding direct emissions to seawater for the use as production chemical in the oil and gas exploration industry, no unacceeptable risks for seawater organisms are identified.

For hydrotesting, no unacceptable risks are expected in case of slow release (12.2.2 – 1), if the maximum daily discharge volume is < 180 m³/d in case of an in-use concentration of 12.5 mg a.s./L and < 22.5 m³/d for 100 mg a.s./L, respectively. In case of storage of 180 days and sodium bisulfite addition to the hydrotesting water (scenario 12.2.2 - 3), the PEC/PNEC-ratio is < 1 indicating no unacceptable risk for the environment. Hydrotesting water with an in-use concentration of up to 2000 mg a.s./L should be disposed accordingly or re-used, as the resulting emissions to the seawater are negligible.

Regarding the use as slimicide for produced water prior to disposal (scenario 12.2 – 3); no unacceptable risk is identified, if a shock dosing of 130 ppm a.s. applied for 1 h is assumed. Furthermore, the use poses no unacceptable risk as well, if the dosage of 130 mg a.s./L which is applied for 2 h once a week (Tier 2) the PEC/PNEC remains below 1 (0.012). For the shock dosing (Tier 1), no unacceptable risk is identified, when the in-use concentration is < 40 ppm a.s. Furthermore, the storage time of produced water prior to disposal to seawater must be at least 24 h and the concentrations of hydrocarbons in the produced water need to be tested according to OSPAR. In that case, the glutaraldehyde concentrations prior to disposal must be < 0.2 ppm ($PNEC_{marine}$ 0.25 mg/L). Therefore, the in-use concentrations and the storage times can be varied.

Terrestrial compartment

Summary table on calculated PEC/PNEC values for soil	
Scenario	**$PEC/PNEC_{soil}$**
Indirect emissions to soil *via* STP	
PT 12.1 – 2 - Tier 1 (10% elimination in dry end of the papermaking machine)	No exposure
PT 12.1 – 2 – Tier 2 (99.6% elimination in dry end of the papermaking machine)	No exposure

Conclusion: The risk characterization ratios are below the trigger value of 1 for the indirect emissions to soil *via* STP and assuming an elimination of 99.6% indicating no unacceptable risk to soil organisms.

Groundwater

Conclusion: For indirect emissions to groundwater *via* STP, the calculated pore water concentrations for glutaraldehyde (as an indicator of the potential concentrations in groundwater) are below the maximum admissible concentration for pesticides in drinking water of 0.1 µg/L.

Primary and secondary poisoning for PT 6, 11 and 12

Primary poisoning

Due to the intended use as an in-can preservative, a risk assessment for non-target animals primary exposed to glutaraldehyde is not necessary.

Secondary poisoning

The a.s. is unlike to bioaccumulate in aquatic or terrestrial environment according to the Guidance on BPR IV/B (2015). It has a very low log Kow (-0.36) and a low organic carbon/water partition coefficient of 326 L/kg. Further assessment of secondary exposure *via* the food chain is therefore not deemed reasonable, which is in accordance to the Guidance on BPR IV/B (2015).

Mixture toxicity for PT 6, 11 and 12

Conclusion: The b.p. only contains glutaraldehyde as a.s. and no substances of concern. Mixture toxicity is therefore not relevant.

Aggregated exposure (combined for relevant emmission sources) for PT 6

According to the TAB (2015), an aggregated exposure assessment should be always performed for PT 6, where a wide-dispersive use may occur. Therefore, the focus should be on uses with release to STP. Only emissions from the PT 6 are considered relevant as the same size of the STP has been used in the calculations (a municipal STP with the effluent discharge rate of 2000 m^3 per day). For PT 12 paper mills, typical case scenario, an industrial waste water treatment plant with the effluent discharge rate of 5000 m^3 per day has been used.

Summary table on calculated PEC/PNEC values for aggregated exposure for STP and surface water (wide-dispersive use; STP route)*		
Scenario	**PEC/PNEC$_{STP}$**	**PEC/PNEC$_{water}$**
PT 6.1 – sum detergents	0.03	0.59
PT 6.2 - 1 (city)- Application of paints (worst case spray)	0.002	0.04
PT 6.2 - 1 (city)- – Service life of paints	0.004	0.09

Summary table on calculated PEC/PNEC values for aggregated exposure for STP and surface water (wide-dispersive use; STP route)*		
Scenario	**PEC/PNEC$_{STP}$**	**PEC/PNEC$_{water}$**
6.3.1 – 1 – newsprint - Tier 2/99.6% elimination (paper production)	0.0009	0.02
6.3.1 – 1 – printing and writing paper - Tier 2/99.6% elimination (paper production)	0.0009	0.02
PT 6.3.2 – 1–textile production Tier 2/99.6% elimination	0.0005	0.008
PT 6.3.3 – 1–leather production Tier 2/99.6% elimination	0.0005	0.008
Aggregated PEC/PNEC	0.04	0.78

*Soil and groundwater are not considered, as there is no exposure in Tier 2 according to the AR for glutaraldehyde (2014, concentration in dry sewage sludge C_{sludge} is set to 0)

Conclusion: No unacceptable risks for STP and surface water can be identified for all wide-dispersive emissions *via* the STP route in PT 6.

Overall conclusion on the risk assessment for the environment of the product

PT 6

- **STP:**

  PEC/PNEC values are below 1 for all uses in the PT 6

- **Surface water:**

  Emissions via STP resulted in the PEC/PNEC values below 1 for all uses in the PT 6 when considering 99.6% removal for preservation of materials in pulp and paper mills, textile and leather production. Because the elimation factor is based on the monitoring studies in paper industry and it is justified on the basis of BAT/BREF documents for the textile and leather industry the following RMM is required: Waste water has to be treated according to industry standards defined in the respective BAT documents.

  Use in paints leads to direct emissions to surface water in the countryside. A safe use for the bridge over pond scenario was identified.

- **Soil:**

  PEC/PNEC values below 1 were identified for all uses in the PT 6 for emissions via STP.

  For direct emissions to soil (PT6.2 - 2), unacceptable risks were identified for the spray application step and thus the RMM is required: The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information: In order to avoid soil contamination during spray application of the treated articles (paints and coatings) cover ground adjacent to the wall with plastic sheet unless the ground is impermeable hardstanding.

  An unacceptable risk was identified for the leaching during service life when no degradation was taken into account. However, considering the polymerization of glutaraldehyde in the dried paint layer the risk becomes acceptable. Glutaraldehyde is stable up to 50 % aqueous solutions, but polymerizes irreversible (in the European weather conditions) at higher

Overall conclusion on the risk assessment for the environment of the product

concentrations and is not any longer available for leaching. Even without considering polymerization the risk would become acceptable during the service life of the paint (1825 days) when degradation of glutaraldehyde in soil is taken into account.

- **Groundwater:**

  Groundwater concentrations below the threshold concentration of 0.1 µg/L have been identified in PT 6 (STP route).

  For scenario 6.2 – 2 (preservation of paints, countryside scenario with direct emissions to soil), higher tier FOCUS PEARL 4.4.4 calculations demonstrate groundwater values of <0.001 µg/L for all nine FOCUS scenarios.

PT 12 (covering uses in offshore oil exploration industry in PT 11)

- **STP:**

  PEC/PNEC values below 1 were identified for PT 12 when considering 99.6% removal in the paper machine.

- **Surface water:**

  PEC/PNEC values below 1 were identified for PT 12 (STP route, 99.6% elimination in the paper mill).

  In case of direct emissions from paper mills to surface water (fresh) or seawater, no safe use could be identified. Therefore, Protectol GA 50 can only be used in pulp and paper mills connected to an on-site or off-site WWTP with the biological purification step.

  Regarding direct emissions to seawater from the oil and gas exploration industry no unacceptable risks for seawater organisms were identified when considering 85% dissipation in the produced water. In order to achieve safe use for hydrotesting the maximum daily discharge must be adjusted for the dilution conditions. Glutaraldehyde concentration must be measured before disposal of any water from the oilfield uses and it must not exceed 0.2 mg/L.

- **Soil:**

  For glutaraldehyde, PEC/PNEC values in soil below 1 have been identified PT 12 (STP route).

- **Groundwater:**

  For glutaraldehyde, groundwater concentrations below the threshold concentration of 0.1 µg/L have been identified in PT 12 (STP route).

2.2.9 Measures to protect man, animals and the environment

To protect man: The exposure of industrials / professionals and the general population to glutaraldehyde in the b.p. does not pose an unacceptable health risk when following the label instructions of the biocidal product for the respective use. Please refer to the conclusion in section 2.2.6. – "Risk characterization for human health".

To protect animals: Livestock exposure can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to animal health is expected and no measures to protect animals are required. Please refer to section 2.2.7. – "Risk assessment for animal health".

To protect the environment: Remains of the product and spillage must be collected and not discharged to sewage system. For specific risk mitigation measures, please refer to the conclusions in section 0 - "Risk characterisation".

2.2.10 Assessment of a combination of biocidal products

This section is not relevant since Protectol GA50 is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

The Finnish Competent Authority (Tukes) has been evaluating an application for a biocidal product (Protectol GA 50) which contains an active substance which meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (528/2012) (glutardehyde). Therefore, in line with Article 23(2) of the Regulation, the Tukes has conducted a comparative assessment for Protectol GA 50 and has produced the following comparative assessment report.

The biocidal product Protectol GA 50 is a preservative containing one active substance, glutardehyde. The product is to be used as a preservative during storage (PT6), preservative in oilfield applications (PT11) and as a slimicide (PT12) in the industrial use and by trained professionals. Preserved end-products (PT6) are to be used by professionals and consumers.

According to the most recent scientific information available on the active substance in the biocidal product, the in-can preservative (PT6) / preservative in oilfield applications (PT11) / slimicide (PT12) glutardehyde does meet the conditions laid down in Article 10(1)(b) of Regulation (EU) No 528/2012 and is therefore a candidate for substitution by being respiratory sensitizer. Glutardehyde is not considered as meeting the exclusion criteria according to Article 5(1).

Under Article 23(1) of Regulation 528/2012 Member States evaluating biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment. Tukes has therefore used the approach in the most recent EU guidance on the comparative assessment of the biocidal product. In line with this Note for Guidance, Tukes began the comparative assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances and mode of action combination in authorised biocidal products is adequate.

2.2.11.1 Screening phase

Intended use pf the biocidal product and the properties of the active substance
Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the comparative assessment has to be product specific.

Table 1. Intended uses of the biocidal product

	Protectol GA 50		
Product Type	**6 (in-can preservative)**	**11 (preservative in oilfield applications)**	**12 (slimicide)**
Where relevant, an exact description of the authorised use	Preservation of detergents and cleaning fluids Preservation of water-based polymer emulsions Preservation of chemicals used in the production of paper Preservation of paints and raw materials for the production of paints, plastic and glues Preservation of auxiliaries used in leather and textile production	To prevent microbially induced deterioration and corrosion in pipelines, vessels, boilers etc. and in (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations.	To prevent biofilm formation in pipelines, vessels, boilers etc. during pressure tests after construction or maintenance and (produced) water (re-) injection systems in water treatment units, in the produced water system, in gas/crude production, transmission and storage systems and during pipeline pigging and scraping operations. For use as paper slimicide for continuous paper production, for slime control/prevention for process water and short-term protection of wet stock during machine shut down. For papermill de-inking use for the control of slime and microbial release of catalase enzyme interfering with the de-inking process during paper recycling.
Target organism (including, where relevant) development stage)	gram-positive and gram-negative bacteria and fungi and yeasts	deterioration and corrosion inducing gram-positive and gram–negative bacteria	biofilm forming gram-positive and gram-negative bacteria fungi
Field(s) of use	indoor outdoor	outdoor	indoor outdoor
Application method(s)	To be incorporated during manufacture	single dose of liquid to the testing water via automated pumps and dosing lines addition to water phases via automated pumps and dosing lines	single dose of liquid to the testing water via automated pumps and dosing lines addition to water phases via automated pumps and dosing lines automatic dosing
Category(ies) of users	industrial use (trained) professionals	industrial use	industrial use

Glutaraldehyde acts by reacting with the free amino groups of some proteins that are located in the cell walls and membranes of micro-organisms. This reaction leads to cross-linking. Cross-linked microbial cells cannot transport nutrients or perform any critical metabolic functions.

Glutaraldehyde also deactivates various membrane-bound enzymes. The kinetics of the cross-linking mechanism is influenced by the pH, the contact time, the glutaraldehyde concentration and the temperature.

In viruses, the main targets for glutaraldehyde are nucleic acid, proteins and envelope constituents. The established reactivity of glutaraldehyde with proteins suggests that the viral capsid or viral-specific enzymes are vulnerable to glutaraldehyde treatment.

Chemical diversity of the active substances

PT6: Authorised products in Finland

The Finnish CA has granted one authorisation for biocidal products under product type 6 (in-can preservative) of the Biocidal Products Regulation (BPR). This product contains 3-iodo-2-propynylbutylcarbamate (IPBC) which has fungicidal mode of action.

PT11: Authorised products in Finland

The Finnish CA has not granted any authorisations for biocidal products under product type 11 (preservative in oilfield applications) of the BPR.

PT12: Authorised products in Finland

The Finnish CA has not granted any authorisations for biocidal products under product type 12 (slimicides) of the BPR.

In the technical guidance note on comparative assessment of biocidal products, it is stated that:

> - A suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection;
> - A general rule states that at least three different and independent "active substance/mode of action" combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

2.2.11.2 Tier II

Non-chemical alternatives to the use of the biocidal product Protectol® GA 50

1 Introduction

Comparative assessment is the mandatory process, foreseen in Article 23 of the BPR that biocidal products undergo as part of the evaluation of product authorization applications, if they contain an active substance that is a candidate for substitution (CfS) under Article 10 of the BPR.

Based on "Opinion on the application for approval of the active substance: Glutaraldehyde ECHA/BPC/022/2014" Glutaraldehyde fulfills the conditions to be a candidate of substitution. Hence a comparative assessment for chemical as well as non-chemical alternatives to Glutaraldehyde has to be conducted. As Glutaraldehyde is the biocidal active substance of the biocidal product Protectol® GA 50 it also needs to undergo comparative assessment.

The following chapter focusses on the second part of the comparative assessment – the non-chemical alternatives.

The eligible non-chemical alternatives should:

1. present a significantly lower overall risk for human health, animal health and for the environment;
2. offer no other significant economic or practical disadvantages; and
3. be sufficiently effective for the use considered.

Protectol® GA 50 shall be approved as bactericide/fungicide for the following product types:

PT 6
PT 11 – Oilfield
PT 12 – Oilfield, Pulp&Paper

2 Conceivable non-chemical alternatives to Protectol® GA 50 for PT 6, 11 and 12

2.1 Irradiation (gamma-irradiation)

2.1.1 Principle

The products or water to be treated are exposed to gamma radiation. Gamma radiation is energy that can be transmitted without direct contact capable of freeing electrons from their chemical bonds (ionization) in the product/water. While breaking chemical bonds the gamma radiation is capable to severely damage vital functions of livings organism including microbes. This process involves damage to DNA. As a result, microorganisms that would normally cause spoilage cannot continue their activities. As gamma irradiation is easily capable to penetrate common materials it is a well-suited method to treat even dense and colored articles.

Usually this technology is applied for the preservation of food, spices and medical equipment.

2.1.2 Equipment

A radioactive material is used as the source for the gamma-rays. gamma irradiation is the standard irradiation applied because the deeper penetration (compared to alpha- or X-rays) of the gamma rays enables administering treatment to entire industrial pallets. Generally cobalt-60 is used as a radioactive source for gamma irradiation. Cobalt-60 is bred from cobalt-59 using neutron irradiation in specifically designed nuclear reactors.

The cost of gamma irradiation is influenced by dose requirements, the material's tolerance of radiation and handling conditions. gamma irradiation is a capital-intensive technology requiring a substantial initial investment. In the case of large irradiation facilities, major capital costs include a radiation source, hardware (irradiator, totes and conveyors, control systems, and other auxiliary equipment), land, radiation shield, and warehouse. Operating costs include energy, salaries, maintenance, taxes/insurance, cobalt-60 replenishment, general utilities, and miscellaneous operating costs.

2.1.3 Nuclear Safety

Interlocks and safeguards are mandated to minimize risk. There have been radiation related accidents, deaths, and injury at gamma-irradiating facilities, many of them caused by operators overriding the safety related interlocks. In a gamma-radiation processing facility, radiation specific concerns need to be supervised by special authorities. Final disposal of radioactive waste is still a huge problem.

2.1.4 Ease of use vs GA biocidal product

The biocidal product Protectol® GA 50 is applied by simple addition to a product or process water to be preserved. Provided the treatment is conducted properly no further action is required. As long as an effective concentration is present in the product/water the preservation remains, protecting against possible recontamination. Already existing dosing points and safety equipment can be used. The application of Protectol® GA 50 is a well-established process applied for many decades already.

The use of Protectol® GA 50 does not require investments in any special equipment, personal safety equipment is not very special and freely available even for small and medium sized companies. Training necessary to instruct people to work with Glutaraldehyde containing products is common practice.

For gamma-irradiation a proper gamma-ray source needs to be installed, personnel to be trained, and safety measurements to be established and maintained. Beside maintenance of the equipment it can be expected that the effort for the actual biocidal treatment when running on a regular basis is on a similar level than treatment with Protectol® GA 50.

2.1.5 Time to achieve the same result compared to Protectol® GA 50

Protectol® GA 50 can be used in small as well as in large scale and the time to obtain a sufficient biocidal effect is limited by mixing the product into the matrix only.

Radiation treatments on the other hand act only at the point of irradiation and for proper treatment a certain amount of energy needs to be transmitted to the product/water. Hence either huge gamma-irradiation facilities are needed or water / product flow must pass through a comparatively small cross section. The first making the investment even more demanding, the latter is significantly slowing down the process.

2.1.6 Limitations

As described in the section "Principle" the biocidal effect of gamma-irradiation is based on the ionization of chemical bonds of the microorganisms. Same holds for any other ingredient in a product or water to be treated. Hence there is a great danger that processing aids in water or components in a formulation to be preserved are losing their intrinsic properties (i. e. stability issues with process aids or ingredients in products to be preserved).

The effect obtained by gamma-radiation is disinfection but not a preservation, immediately after passing the gamma-radiation beam possible recontamination cannot be controlled.

The summary of limitations of gamma-irradiation is presented in the Table 1.

Table 1. Disadvantages and problems of gamma-irradiation

	Pulp & Paper	Oilfield	
PT6	PT12	PT11	PT12
Disintegration of product, short term effect, high investment, extremely high demands on safety, no social or legal acceptance for large scale application	Disintegration of production liquids, slurries, short term effect, high investment, extremely high demands on safety, no social or legal acceptance for large scale application	Short term effect, high investment, extremely high demands on safety, no social or legal acceptance for large scale application	Short term effect, high investment, extremely high demands on safety, no social or legal acceptance for large scale application no social or legal acceptance for large scale application

Others: Risk for fatal accidents of personnel (all PTs); Legal restriction: Application and approval for equipment and its use needed, inspections by authorities, in Germany gamma-irradiation is only allowed for treatment of spices, other countries have different restrictions, cost for maintenance of equipment (functionality and safety) are very high.

2.1.7 Literature used

1. Food Irradiation – A technique for preserving and improving the safety of food, WHO, Geneva, 1991
2. Gamma Irradiators for Radiation Processing, IAEA, Vienna, 2005
3. *"The Use of Irradiation for Post-Harvest and Quarantine Commodity Control | Ozone Depletion – Regulatory Programs | U.S. EPA". Wayback.archive.org. Archived from the original on April 21, 2006.* Retrieved March 19, 2014
4. The Radiological Accident in Soreq, IAEA, Vienna, 1993, STI/PUB/925.

2.2 Irradiation (UV-Light)

2.2.1 Principle

UV radiation is energy that can be transmitted without direct contact. UV light of specific wavelength is absorbed by chemical compounds and biological mass. This absorbed energy excites chemical bonds which might break or enter into (photo)-chemical reactions changing the chemical composition of the DNA or compound. As a result, microorganisms that would normally cause spoilage cannot continue their activities. UV is easily absorbed by particles and organic matter dissolved in the water. Also low concentrations of iron and manganese significantly absorb UV light. Hence only comparatively clean water can efficiently be treated with UV radiation.

2.2.2 Equipment

UV disinfection is used for drinking water and waste water treatment in industrial scale already. Appropriate equipment is freely available. In principle, a UV (drinking/waste) water treatment unit looks like exhibited in Figure 1. In a flocculation and filtration unit particles are removed from the water which than is UV treated. After storage in the clearwell drinking water can be distributed or treated waste water is released. In drinking water purification or waste water treatment plants all equipment except the UV-Lamp-unit is already installed.

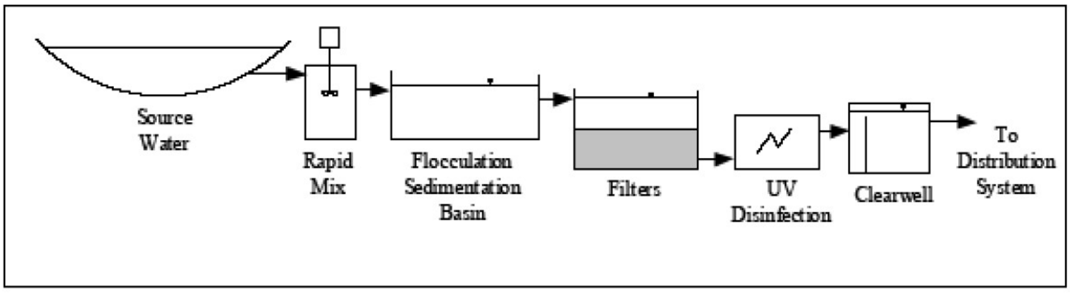

Figure 1. Water disinfection by UV light, equipment

The cost of UV irradiation is influenced by dose requirements, water UV-transmittance and handling conditions. UV irradiation is a capital-intensive technology requiring a substantial initial investment. Workers in the plant need to be trained with the new technology, safety measures need to be installed since UV is harmful to skin and eyes.

2.2.3 Ease of use vs GA biocidal product

The biocidal product Protectol® GA 50 is applied by simple addition to a product or process water to be preserved. Provided the treatment is conducted properly no further action is required. As long as an effective concentration is present in the product/water the preservation remains, protecting against possible recontamination. Already existing dosing points and safety equipment can be used. The application of Protectol® GA 50 is a well-established process applied for many decades already.

As explained above UV treatment needs comparatively clean water to obtain sufficient reduction of microbes. Hence costly installation of equipment as given in Figure 1 would be necessary at facilities that change from chemical to non-chemical treatment. Efforts for maintenance of such installations and energy consumption will be significant.

Beside maintenance of the equipment it can be expected that the effort for the actual biocidal treatment when running on a regular basis is on a similar level than treatment with Protectol® GA 50.

2.2.4 Time to achieve the same result compared to Protectol® GA 50

Protectol® GA 50 can be used in small as well as in large scale and the time to obtain a sufficient biocidal effect is limited by mixing the product into the matrix only.

Radiation treatments on the other hand act only at the point of irradiation and for proper treatment a certain amount of energy needs to be transmitted to the product/water. Hence either huge UV irradiation facilities are needed or water / product flow have to pass through a comparatively small cross section. The first making the investment even more demanding, the latter is significantly slowing down the process.

The use of Protectol® GA 50 does not require investments in any special equipment, personal safety equipment is not very special and freely available even for small and medium sized companies. Training necessary to instruct people to work with Glutaraldehyde containing products is common practice.

2.2.5 Limitations

Ultraviolet (UV) sanitizing units are used in water purification systems / waste water treatment to control bacteria and have certain applications in animal drinking water systems. UV units can be effective water treatment tools, but it is important to recognize what UV can do, what its limitations are, and what maintenance is required. Usual UV sanitizing units do not effectively disinfect some organisms (most fungi, protozoa, and cysts of *Giardia lamblia* and Cryptosporidium) since they require an outstandingly high UV dose.

Any contaminants in water reduce the transmission of UV light through the water, which reduces the UV dose that reaches the bacteria. Suspended particles are a severe problem because microorganisms buried within particles are shielded from the UV light and pass through the unit unaffected.

UV units only kill bacteria at one point in a watering system and do not provide any residual germicidal effect downstream. There is nothing to inhibit microbial growth or prevent microbes from attaching to downstream piping surfaces and proliferating. There is an upper limit of bacterial load that can successfully be treated with UV. This is in the order of a couple of 1000cfu/ml hence UV treatment of highly contaminated waters will be ineffective.

Due to low penetration depth of UV radiation this method is suitable for thin layers only (not suitable for bulk materials, PT6).

UV lamps do not burn out as normal fluorescent lamps do. Instead, the UV lamps will solarize, reducing their intensity to about 60% of a new lamp after about one year of continuous use. Lamps usually need replacement after one year of use. Lamp life will be shortened significantly if the lamp is turned on and off more frequently than once every eight hours.

As water passes through the UV unit, minerals, debris and other material in the water will deposit significantly absorbing UV before it reaches the water to be treated. To maintain high clarity, the glass around the lamp must be cleaned regularly.

UV-irradiation might in principle work for PT11 (with the limitations explained) but is not feasible for PT12 and PT6. Irradiation of a biofilm is almost not possible as it is attached to surfaces deep inside a plant/machine/well which hardly can be reached by light sources. UV-radiation is not just capable to kill microbes, it is also capable to break chemical bonds of materials absorbing UV, which is the case for more or less every material. Hence, UV irradiation of formulations like paints, slurries, emulsions etc. results in decomposition of formulation ingredients and alteration of the formulation characteristics, phase separation and in the destruction of the whole formulation.

First attempts to equip cooling towers with UV units for water treatment appear on the market. Such treatments are capable to reduce the use of chemical biocides but the chemicals are still necessary. As already described the UV light is not capable to exhibit any effect downstream, consequently chemicals are still needed to avoid microbial growth and biofilm formation in the cooling tower.

The summary of limitations of UV irradiation is presented in the Table 2.

Table 2. Disadvantages and problems with UV irradiation

	Pulp & Paper	Oilfield	
PT6	PT12	PT11	PT12
Not effective, low penetration depth, instability issues with product, high UV-Absorption of products, not suitable	Biofilm treatment not possible	High UV-Absorption of ingredients, high investment, local effect only	Biofilm treatment not possible

2.2.6 Literature

1. C.C.E. Meulemanns, The Basic Principles of UV-Disinfection of Water, Ozone: Science and engineering, Volume 9, 1987 - Issue 4.
2. Edstrom Industries, How does UV work?
3. EPA, Waste Water Technology Fact Sheet, Ultraviolet Disinfection, EPA 832-F-99-064, September 1999
4. Evaluation of ultraviolet (UV) radiation disinfection technologies for wastewater treatment plant effluent, New York State Energy Research and Development Authority, Report 04-07, NYSERDA 4818, December 2004

2.3 Membrane Technology (ultrafiltration, reverse osmosis)

2.3.1 Principle

Ultrafiltration or reverse osmosis is a high-pressure filtration through a medium (a semipermeable capillary wall) which allows small molecules (water) to pass but holds back larger ones. Holding back particles with a diameter <0.45 µm guarantees the absence of microbes in the water passing the membrane. Hence ultrafiltration etc. are separation technologies, dividing the water into a sterile fraction and a water fraction which is enriched with microbes. The relationship between pore size, particles removed and pressure is represented in the Figure 2.

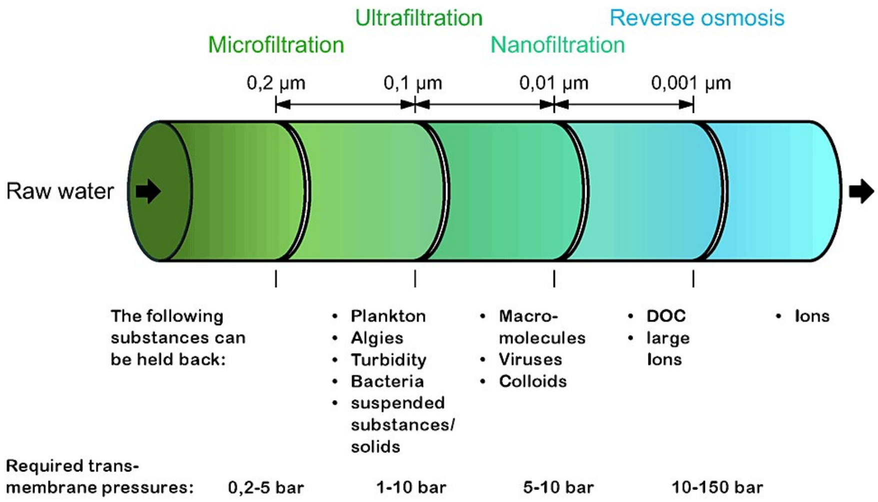

Figure 2 Relationship between pore sizes, particles removed and pressure
Source: http://www.hydrogroup.biz/

2.3.2 Equipment

Large scale ultrafiltration is always a cross-flow (X-flow) process, as illustrated in Figure 3 below. The raw water to be treated is the "Feed". The X-flow process splits this water into two parts:

1. The "Permeate" which is the decontaminated water and the "Retentate" which is still (as it is concentrated even more) contaminated waste water.
2. The "Feed" needs to be a comparatively clean source as particles tend to damage the pumps and membranes and facilitate membrane fouling which significantly limits the flow rate of the filtration unit.

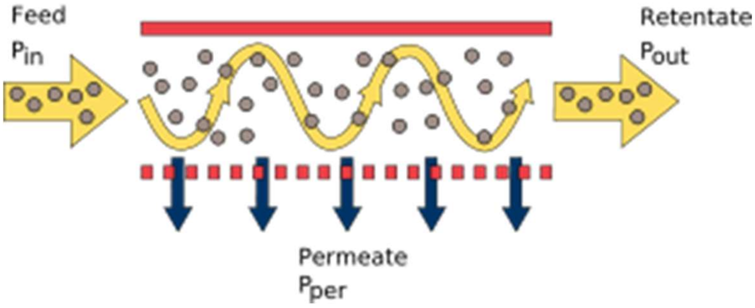

Figure 3. Principle of X-flow-filtration
Source: https://de.wikipedia.org/wiki/Cross-Flow-Filtration

Disinfection by ultrafiltration is used for drinking water and waste water treatment in industrial scale already. Appropriate equipment is freely available. In principle, an ultrafiltration (drinking/waste) water treatment unit looks like exhibited in Figure 4. In a sedimentation and filtration unit particles are removed from the water which than passes through the ultrafiltration system.

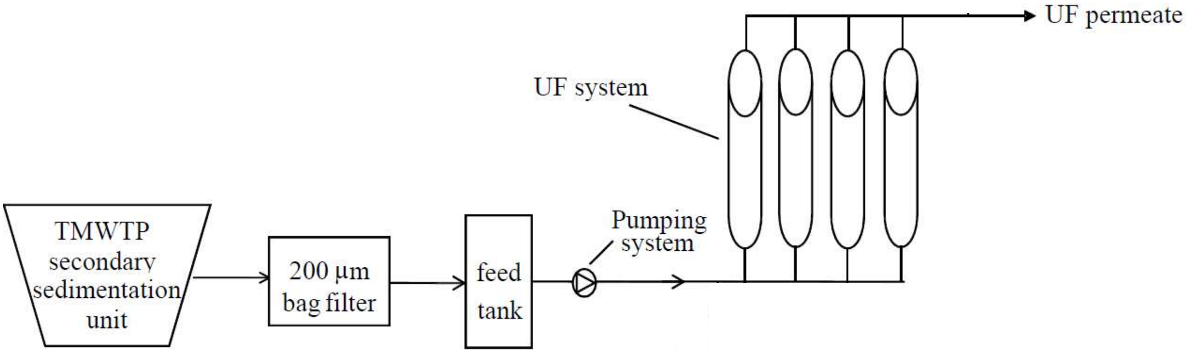

Figure 4. Disinfection by Ultrafiltration, equipment

2.3.3 Ease of use vs GA biocidal product:

The biocidal product Protectol® GA 50 is applied by simple addition to a product or process water to be preserved. Provided the treatment is conducted properly no further action is required. As long as an effective concentration is present in the product/water the preservation remains, protecting it against possible recontamination. Already existing dosing points and safety equipment can be used. The application of Protectol® GA 50 is a well-established process applied for many decades already.
The use of Protectol® GA 50 does not require investments in any special equipment, personal safety equipment is not very special and freely available even for small and medium sized companies. Training necessary to instruct people to work with Glutaraldehyde containing products is common practice.

As explained above ultrafiltration needs comparatively clean water for a stable running process. Hence installation of equipment as given in Figure 4 would be necessary at facilities that change from chemical to non-chemical treatment. Costs for installations, efforts for maintenance of such installations and energy consumption will be significant.

Beside maintenance of the equipment, waste management of the "Retentate" and replenishment of process additives lost with the "Retentate" it can be expected that the effort for the actual biocidal treatment when running on a regular basis is on a similar level than treatment with Protectol® GA 50.

2.3.4 Time to achieve the same result compared to Protectol® GA 50

Protectol® GA 50 can be used in small as well as in large scale and the time to obtain a sufficient biocidal effect is limited by mixing the product into the matrix only.

Filtration on the other hand acts only at the point of filtration and treats only a part of the whole water stream. Hence either huge filtration facilities are needed or water / product flow have to pass over a comparatively small filtration area. The first making the investment even more demanding, the latter is significantly slowing down the process.

2.3.5 Limitations

As pore size of the membrane needs to be <= 0.45µm, it is not only microbes that are removed from the water. Many process chemicals are removed partly (e. g. surfactants) or completely (e. g. polymers) from the process water which immediately changes the product or water characteristics. If possible at all the chemicals lost into the "Retentate" need to be substituted in the "Permeate", additionally the water lost with the "Retentate" needs to be substituted with all process aids necessary. The "Retentate" (typically 10-30% of the "Feed") needs to be properly treated as waste water. On the "Retentate"-side of the process microbes are still active and do form biofilms on the filtration membrane which needs biocidal treatment in order to maintain the process.

Filtration units remove microbes at one point in a watering system and do not provide any antimicrobial effect downstream. Recontamination may occur just after the filtration process.

Filtration might in principle work for PT11 (with the limitations explained) but is not feasible for PT12 and PT6. Filtration of a biofilm is not possible as it is attached to surfaces. Filtration of formulations like paints, slurries, emulsions etc. results in phase separation and in the destruction of the formulation. Filtration of homogeneous solutions of very low viscosity and very low molecular weight ingredients might be possible to be disinfected by membrane filtration.

Filtration is not capable exhibiting any lasting effect, consequently chemicals are still needed to avoid microbial growth and biofilm formation in machine parts downstream the filtration unit.

Damage of filtration membranes results in total failure of the technology (spontaneous damage which is difficult to prevent or to foresee and thus results in high losses with damages product or process water.

The limitations with ultrafiltration are represented in the Table 3.

Table 3. Disadvantages and problems with ultrafiltration

	Pulp & Paper	Oilfield	
PT6	PT12	PT11	PT12
Does only work with non-viscous and homogeneous formulations, which is rarely the case. Actually not feasible	Biofilms are not accessible to filtration because they are fixed on surfaces	Huge investment, local effect, poor water quality	Biofilms are not accessible to filtration because they are fixed on surfaces

2.3.6 Literature used

1. D. Falsanisi et al., Ultrafiltration (UF) Pilot Plant for Municipial Wastewater Reuse in Agriculture: Impact of the Operation Mode on Process Performance, Water, 2009, 1, 872-885.
2. R. Ramil et al., Review on the factors affecting ultrafiltration hollow fiber membrane operational performance in water treatment, 10th Seminar Sains and Teknologi 2012, S&T 2012.

2.4 Thermal Treatment (boiling, pasteurization, sterilization)

2.4.1 Principle

Three different methods can be used for biocidal heat treatment:

Sterilization	Heating above boiling point under pressure for some minutes
Boiling	Heating to the boil at atmospheric pressure for some minutes
Pasteurization	Heating to increased temperatures up to temperatures above the boiling point for a few seconds to minutes

All treatments target at reducing the present microbes. Sterilization is capable to kill all microbes and is more or less exclusively used in medicine and microbiological laboratories for the decontamination of equipment and devices.

Pasteurization is widely used in order to extend storage life of milk, beverage and ice cream (before freezing of course) in closed containers. By fast heating and cooling microbes are killed and inactivated. Pasteurization does not result in a complete removal of microbes.

Simple boiling treatments are not common. If boiling is used at all it is applied as a cleaning operation rather than as biocidal treatment.

2.4.2 Equipment

Sterilization needs an autoclave. An autoclave is a pressure chamber used to carry out processes requiring elevated temperature and pressure higher than ambient air pressure. By construction it is possible to run batch wise processes only.

In principle pasteurization process unit looks like shown in Figure 5.

The liquid to be pasteurized passes a couple of heat exchangers in order to quickly heat and cool down the heated product. The product to be pasteurized needs to have considerably low viscosity in order to secure fast heating and cooling.

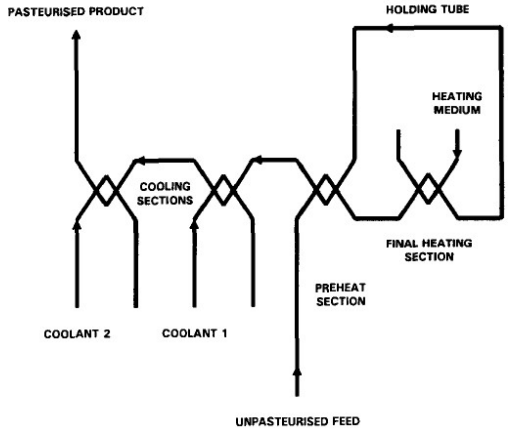

Figure 5. Simplified flow diagram of a pasteurization process

Of the three thermal treatments, pasteurization seems to fit best into industrial applications since it can be run continuously.

2.4.3 Ease of use vs GA biocidal product

The biocidal product Protectol® GA 50 is applied by simple addition to a product or process water to be preserved. Provided the treatment is conducted properly no further action is required. As long as an effective concentration is present in the product/water the preservation remains, protecting it against possible recontamination. Already existing dosing points and safety equipment can be used. The application of Protectol® GA 50 is a well-established process applied for many decades already. The use of Protectol® GA 50 does not require investments in any special equipment, personal safety equipment is not very special and freely available even for small and medium sized companies. Training necessary to instruct people to work with Glutaraldehyde containing products is common practice.

As explained above pasteurization needs comparatively free flowing products for a stable running process. Installation costs, efforts for maintenance of such installations and energy consumption will be significant.

Beside maintenance of the equipment it can be expected that the effort for the actual biocidal treatment when running on a regular basis is on a similar level than treatment with Protectol® GA 50.

2.4.4 Time to achieve the same result compared to Protectol® GA 50

Protectol® GA 50 can be used in small as well as in large scale and the time to obtain a sufficient biocidal effect is limited by mixing the product into the matrix only.

Pasteurization on the other hand acts only at the point of pasteurization and treats only a part of the whole water stream. Hence either huge pasteurization facilities are needed or water / product flow have to pass over a comparatively small heat exchanging area. The first making the investment even more demanding, the latter is significantly slowing down the process.

2.4.5 Limitations

As many processing aids (e. g. nonionic surfactants, polyoxyethylen containing polymers) are sensitive to thermal stress (segregation above cloud point, thermal decomposition of polymers especially at pH different from neutral, different phase behaviours upon heating and cooling cycles) thermal treatment can only be applied for waters that are more or less free from other ingredients which might be necessary for maintaining the process or stabilizing a formulation.

The biggest issue is the formation of lime scale which always takes place when water hardness precipitates due to removal of CO_2 (by heating the water) transferring the $Ca(HCO_3)_2$ into $CaCO_3$ which is much less soluble in water. Especially the treatment of large water volumes causes tremendous problems with lime scale formation resulting in a much lower heat exchange rate, clogging of tubes, piping and heat exchangers.

Heating kills the microbes only at one point, except the whole process runs close to the boil. Recontamination at lower temperatures will occur.

A simple natural law the heat capacity of water rules another limitation. The following calculation gives an idea about the amounts of energy involved just for heating large an amount of water.

4.18 KJ = energy needed to heat up 1Kg of water by 1K
4.18 KJ = 4.18Ws = 4.18Ws/3600s/h = 0.001611 KWh per Kg per K
= 1.611 KWh per t per K

Example: Paper Mill

Water needs to be heated from 20°C to 100°C for proper decontamination, a temperature difference of 80K
Heating of 1t water from 20°C to 100°C water needs:
1.611 KWh/K x 80K = 129KWh
The production of 1t paper uses (depending on paper quality) 5-20t of water, hence

129KWh/t x 5t/t = 645KWh/t paper
129Kwh/t x 20t/t = 2580KWh/t paper

A paper mill produces between 100.000 and 500.000 tons of paper per year

Table 4. Virtual energy consumption in a paper mill, non-chemical alternative: heating/boiling

		100.000t/a	500.000t/a
Low quality	645 KWh/t	645000 MWh	3225000 MWh
High quality	2580 KWh/t	2580000 MWh	12900000 MWh

Whereas the use in PT 11 and PT 12 seems to be theoretically feasible heating or pasteurization is not applicable for PT6. Application of heat will inevitably result in some losses of water by evaporation which will cause changes in the composition and disintegration of the formulation. Just replacing the water lost by evaporation mostly does not work properly since proper formulation usually is not obtained by simply mixing the ingredients at any conditions. Furthermore, many ingredients of today’s formulations lose function when severely heated resulting in e.g. precipitation, breaking of emulsions or solidification of dispersions.

Summary of the limitations on thermal treatment is represented in the Table 5.

Table 5. Disadvantages and problems with thermal treatment

	Pulp & Paper	Oilfield	
PT6	PT12	PT11	PT12
Disintegration of product, short term effect; pasteurization may be suitable for some selected products, high energy consumption, high investment	Biofilms are not accessible to thermal treatment because they are fixed on surfaces inside the machine using the water to be treated	Short term effect, local effect, pasteurization may be suitable for some selected applications, high energy consumption, high investment	Biofilms are not accessible to thermal treatment because they are fixed on surfaces inside the equipment using the water to be treated

2.4.6 Literature used

A.P.M. Hasting, Practical considerations in the design, operation and control of food pasteurization processes, Food Control, 1992, 3(1), 27-33.

OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 23
ESD ON PULP, PAPER AND BOARD INDUSTRY, ENV/JM/MONO(2009)25

Thermodynamics and an Introduction to Thermostatistics. Wiley & Sons. ISBN 978-0-471-86256-7

3 Hazard Analysis and Critical Control Points (good housekeeping, mechanical cleaning, boilouts)

Hazard Analysis and Critical Control Points (HACCP), mechanical cleaning, good housekeeping and boilouts are the most effective complementary processes to chemical treatment. Such operations and measures can help to significantly reduce the amount of biocide needed for maintaining processes and preservation. On the other hand good housekeeping and the proper use of HACCP measures are no capable to completely substitute biocidal treatment in industry. Actually, where ever possible chemical treatment follows mechanical cleaning. It has to be taken into account that mechanical cleaning does not provide for the absence of microbes. Cleaning of paper machines and pipelines (pigging) is an established procedure in industry. Back in service, microbial growth will proceed right away. As cleaning is a costly and time-consuming procedure the intervals need to have a certain length. Between two cleaning operations, the use of biocides protects machines and pipelines form exaggerated microbial growth.

Not applicable for PT6 (in-can preservation). Method is helpful as a complementary hygiene measure to reduce soil prior to a chemical step but in most cases not sufficient to reduce microbial contamination to an extent necessary for the application or running the operation (PT11 / 12).

The limitations of the mechanical cleaning are summarised in the Table 6.

Table 6. Disadvantages and problems with mechanical cleaning

	Pulp & Paper	Oilfield	
PT6	PT12	PT11	PT12
Not feasible	Common practice, complementary measure only and not a replacement for chemical treatment, service intervals need to be shortened to non-profitable operation of the paper machine	Not feasible since microbes are in the cooling and process water only	Common practice for pipelines, service intervals need to be shortened to non-profitable operation of the pipeline; usually complementary measure and not a replacement for chemical treatments

3.1 Literature

1. P. Bajpai, Pulp and Paper Industry, Elsevier, ISBN: 987-0-12-803409-5

4 Conclusion

Finally, yet importantly all methods described (heating, ultrafiltration, UV, gamma irradiation) might in principle be suitable to reduce microbial contamination in certain products or applications in order to extend product life times but do not provide protection against re-growth of residual microorganisms after treatment. Especially in cases of microbial contamination after the treatment, there is no preservation effect.

Also, many products are sensitive to heat, gamma-radiation or UV radiation. Significant investments and extensive maintenance measures are necessary which might be inhibitive for small to medium sized companies at least.

Optimum preservation as achieved with chemical treatments is characterized by a lasting effect providing for at least some preservation in the following production steps (PT11/12) or product life cycle (PT6).

Additionally, all the described alternative methods provide for local effects only. They are just effective at the point of application. Microbes sitting in niches, sumps and corners that are not reached by heat, UV-radiation etc. will survive and immediately re-contaminate the process waters or products without any further control.

Especially the control of biofilms is problematic to achieve with physical means and thus would need alternative treatment on every surface, which can be colonized by microbes. This is technically not feasible yet.

Control of planktonic microbes in long piping systems will at least need repeated alternative treatment. Also, the already described problem with niches, corners and sumps will significantly limit the performance in microbial control of such systems. In many cases, it is simply not possible to place such appliances at the places where the biocidal effect is needed e.g. inside oilfields, (offshore) pipelines, wells, paper machines.

5 Uses applied for the biocidal product Protectol® GA 50 vs applicability of non-chemical alternatives

	Non-chemical alternative			
Uses/ objects to be protected	**gamma-irradiation**	**UV-irradiation**	**Filtration**	**Thermal Treatment**
Preservatives of detergents (e.g. laundry softeners, liquid detergent, raw materials thereof)- **Use #1**	Disinfection only, no lasting effect, possibility of product damage	Disinfection only, no lasting effect, high UV absorption of products; low penetration depth of UV radiation; stability issues with UV-sensitive ingredients	Separation of product by process	Disinfection only, no lasting effect disintegration of formulation; thermal instability of ingredients
Preservation of wax and polymer emulsions and raw materials thereof (e.g. car polish) - **Use #2**	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry- **Use #3** *(in inorganic particle dispersions - $CaCO_3$ slurries)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry - **Use #3** *(in inorganic particle dispersions – kaolin slurries)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry - **Use #3** *(in organic dispersions – cellulose)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry - **Use #3** *(in organic solutes – Starch)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry - **Use #3** *(in aqueous polymer dispersion)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of water based products used in the paper industry - **Use #3** *(In pigment dispersions used in paper)*	See Use #1	See Use #1	See Use #1	See Use #1

	Non-chemical alternative			
Uses/ objects to be protected	**gamma-irradiation**	**UV-irradiation**	**Filtration**	**Thermal Treatment**
Preservation of paints and raw materials thereof - **Use #4** *(wall paint)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of paints and raw materials thereof - **Use #4** *(in pigment dispersions)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of paints and raw materials thereof - **Use #4** (polymer dispersions used for paints)	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of auxiliaries used in leather and textile - **use #5** *(pigment dispersions used in plastic, textile etc.)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of auxiliaries used in leather and textile - **use #5** *(auxiliaries used in leather and textile industry)*	See Use #1	See Use #1	See Use #1	See Use #1
Preservation of hydrotesting fluids in oil field applications - **use #6**	Disinfection only, no lasting effect,	Disinfection only, no lasting effect,	Disinfection only, no lasting effect	Disinfection only, no lasting effect
Preservation of production and injection water in oilfield applications - **use #7**	See Use #6	See Use #6	See Use #6	See Use #6
Slimicide for hydrotesting fluids in oilfield applications- **use #8**	Treatment of biofilms not possible	Treatment of biofilms not possible	Treatment of biofilms not possible	Treatment of biofilms not possible
Slimicide for production and injection water in oilfield applications - **use #9**	See Use #8	See Use #8	See Use #8	See Use #8
Slimicide for paper industry, wet end - **use #10**	See Use #8	See Use #8	See Use #8	See Use #8
Slimicide for paper industry, de-inking - **use #11**	See Use #8	See Use #8	See Use #8	See Use #8

2.2.11.3 Overall conclusion

Taking into account that there is only one biocidal product authorized for the PT 6 use and no products authorised for the PT11 or PT12 use, Tukes concludes that there is no adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since glutaraldehyde does not meet the exclusion criteria as outlined in Article 5(1), Tukes considers it valid to not conduct further assessment at this point.

The comparative assessment for Protectol GA 50 can be finalised at the screening stage and the product can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

3 ANNEXES[27]

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[27] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.1 List of studies for the biocidal product (family)

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Achhammer, G.	2015	Differential Scanning Calorimetry (DSC)	BASF SE, Ludwigshafen, Germany	SIK-Nr. 15/2089	No	No	Yes	BASF SE	3.4.2.1
Ayliffe GAJ & Deverill	1979	Decontamination of gastroscopes, Health and Social Service J.,538-541	-	-	-	Yes	No	Data published	-
BASF AG	1970a	Relugan GT/M, Ergebnis der Gewerbetoxikologischen Vorpruefung.	BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany	XX/117	No	No	Yes	BASF SE	8.1 8.2 8.5.1 8.5.2
BASF AG	1970b	Relugan GT/M, Ergebnis der Gewerbetoxikologischen Vorpruefung.	BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany	XX/118	No	No	Yes	BASF SE	8.1 8.2 8.5.1 8.5.2

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
BASF AG	1975	Bericht ueber die Pruefung von Methoxidihydropyran im Vergleich zu Methoxidihydropyran, roh und Relugan GT auf etwaige hautsensibilisierende Wirkung.	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	XXIII/115	No	No	Yes	BASF SE	8.3
BASF AG	1994a	Study on the irritation to the intact dorsal skin of the albino rabbit (short-term test).	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.1
BASF AG	1994b	Report on the study of the irritation to the eye of white rabbits based on Draize.	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.2
BASF AG	1994c	Report on the study of the acute oral toxicity 80/265; rat/oral. English translation of the German report dated 1981	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.5.1 Key study

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
BASF AG	1994d	Acute inhalation toxicity LC50 4 hours (rat) of "glutaraldehyde, approx. 50% solution, poor in methanol", liquid aerosol study (test substance No. 80/265).	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.5.2
BASF AG	1994e	Study of the acute inhalation toxicity in rats in the inhalation hazard test	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.5.2
BASF AG	1994f	Report on the study of the acute dermal toxicity of "Glutaraldehyde" in the rat	BASF AG, Department of Toxicology, BASF, Ludwigshafen/Rhein, Germany	80/265	No	No	Yes	BASF SE	8.5.3
BASF AG	2001	Acute inhalation toxicity LC50 4 hours (rat) of "glutaraldehyde, 50% solution" (test substance No. 83/59), liquid aerosol study.	BASF AG, Department of Product Safety, Ludwigshafen/Rhein, Germany	83/59	No	No	Yes	BASF SE	8.5.2

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
BASF Grenzach GmbH	2016a	Determination of the efficacy of Protectol GA 50 (50% Glutaraldehyde solution in water) in preservation of organic solutes - cleaning formulation for laundry, dish wash or hard surfaces - mixed bacterial inoculum	BASF Grenzach GmbH, Grenzach-Wyhlen, Germany	BIO16-028	No	No	Yes	BASF SE	6.7 Key study
BASF Grenzach GmbH	2016b	Determination of the efficacy of Protectol GA 50 (50% Glutaraldehyde solution in water) in preservation of an anorganic dispersion (Kaolin) – two inoculations, single and mixed bacterial inoculum	BASF Grenzach GmbH, Grenzach-Wyhlen, Germany	BIO16-018b	No	No	Yes	BASF SE	6.7 Key study

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
BASF Grenzach GmbH	2016c	Determination of the efficacy of various Glutalradehyde (Protectol® GA 50) concentrations in preservation of organic polymer (Cellulose) dispersion as used in pulp and paper industry	BASF Grenzach GmbH, Grenzach-Wyhlen, Germany	BIO16-049	No	No	Yes	BASF SE	6.7 Key study
BASF Grenzach GmbH	2016d	Determination of the efficacy of Protectol® GA 50 (50% Glutaraldehyde solution in water) in preservation of organic solutes – Starch solution as used in paper industry or wall paper paste – fungal (yeast) and mixed bacterial inoculum	BASF Grenzach GmbH, Grenzach-Wyhlen, Germany	BIO16-026a	No	No	Yes	BASF SE	6.7 Key study

Author(s)	**Year**	**Title**	**Testing Company**	**Report No.**	**GLP Study (Yes/No)**	**Published (Yes/No)**	**Data Protection Claimed (Yes/No)**	**Data Owner**	**Section No. in IUCLID / Non-key study/ Published**
BASF Grenzach GmbH	2016e	Determination of the efficacy of various Glutaraldehyde (Protectol® GA 50) concentrations in preservation of a wall paint	BASF Grenzach GmbH, Grenzach-Wyhlen, Germany	BIO16-004	No	No	Yes	BASF SE	6.7 Key study
BASF SE		Efficacy of an aqueous solution of 24% Glutaraldehyde in protecting a rheology modifier for oilfield reservoir water from biodegradation	Group Microbiology, Department White Biotechnology, BASF SE, Ludwigshafen, Germany		No	No	Yes	BASF SE	6.7 Supporting study

Author(s)	**Year**	**Title**	**Testing Company**	**Report No.**	**GLP Study (Yes/No)**	**Published (Yes/No)**	**Data Protection Claimed (Yes/No)**	**Data Owner**	**Section No. in IUCLID / Non-key study/ Published**
BAV Institut GmbH	2016	Determination of the efficacy of Protectol® GA 50 (a 50% solution of Glutaraldehyde in water) in preservation of an inorganic dispersion – used as filler in paper, paint, plastic industry; here a CaCO2$_3$ Slurry – Low concentrations	BAV Institut für Hygiene und Qualitäts-sicherung GmbH, Offenburg, Germany	EXBIO16-003	No	No	Yes	BASF SE	6.7 Key study
BiSN	2016	Protectol® GA 50 Qualification for Biocide Regulations (UK)	BiSN Laboratory Services Ltd, Runcorn, United Kingdom	2016-119	No	No	Yes	BASF SE	6.7 Key study
Carson LA, Petersen NJ, Favero MS, Aguero SM	1978	Growth characteristics of atypical mycobacteria in water and their comparative resistance to disinfectants, Appl Environ Microbiol., 36(6), 839-846	-	-	-	Yes	No	Data published	-

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Carstens-Roth D.	2016	Deactivation study of Protectol® GA 50 in substitute ocean water and Rhine river filtrate water	Competence Center Analytics, BASF SE	-	No	No	Yes	BASF SE	10.2
Corrado OJ, Osman J, Davies RJ	1986	Asthma and rhinits after exposure to glutaraldeyhde in endoscopy units	-	-	No	Yes	No	Data published	8.4
Curran AD, Burge PS, Wiley K	1996	Clinical and immunologic evaluation of workers exposed to glutaraldehyde	-	-	No	Yes	No	Data published	8.4
Deva AK	1998	Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastro-intestinal endoscopes, J. Hosp. Inf., 39, 149-157	-	-	-	Yes	No	Data published	-

Author(s)	**Year**	**Title**	**Testing Company**	**Report No.**	**GLP Study (Yes/No)**	**Published (Yes/No)**	**Data Protection Claimed (Yes/No)**	**Data Owner**	**Section No. in IUCLID / Non-key study/ Published**
Di Stefano F, Siriuttanapruk S, McCoach J, Sherwood Burge P	1999	Glutaraldehyde: an occupational hazard in the hospital setting.	-	-	No	Yes	No	Data published	8.4
DOW	2004	Glutaraldehyde: pharmacokinetics in Fischer 344 rats following oral gavage or dermal application.	The Dow Chemical Company, Department of toxicology and environmental research and consulting, Midland, Michigan 48674, USA	021134	Yes	No	Yes	DOW/BASF	8.6
DOW	2012	Primary Skin Irritation	Product Safety Labs, 2394 US Highway 130, Dayton, NJ 08810, USA	33561	Yes	No	Yes	DOW/BASF	8.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Duarte RS, Lourenço MC, Fonseca Lde S, Leão SC, Amorim Ede L, Rocha IL, Coelho FS, Viana-Niero C, Gomes KM, da Silva MG, Lorena NS, Pitombo MB, Ferreira RM, Garcia MH, de Oliveira GP, Lupi O, Vilaça BR, Serradas LR, Chebabo A, Marques EA, Teixeira LM, Dalcolmo M, Senna SG, Sampaio JL	2009	Epidemic of postsurgical infections caused by Mycobacterium massiliense, J Clin Microb., 2149-2155	-	-	-	Yes	No	Data published	-
Ferruzzi, A.B.	2015	HPLC Determination of Glutaraldehyde in Glutaraldehyde Biocide Products	Impact Analytical 1940 N. Stark Road Midland, Michigan 48642, USA	R150228	Yes	Yes	No	DOW/BASF	5

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Fisher CW, Fiorello A, Shaffer D, Jackson M, McDonnell GE	2012	Aldehyde-resistant mycobacteria bacteria associated with the use of endoscope reprocessing systems, Am J Infect Control., 40(9), 880-882.	-	-	-	Yes	No	Data published	-
Gannon PF, Bright P, Campbell M, O'Hickey SP, Burge PS	1995	Occupational asthma due to glutaraldehyde and formaldehyde in endoscopy and x ray departments.	-	-	No	Yes	No	Data published	8.4
Griffiths PA, Babb JR, Bradley CR, Fraise AP	1997	Glutaraldehyde-resistant Mycobacterium chelonae from endoscope washer disinfectors, J Appl Microbiol., 82(4), 519-26	-	-	-	Yes	No	Data published	-

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Gröhl, O.	2015	Laboratory Corrosion Test of Protectol GA 50% (Glutardialdehyd 50%) According to REACH and the Regulation for the Transportation of Dangerous Goods	BASF - Materials Engineering, Germany	215.1153T B01	No	No	Yes	BASF SE	4.17
Hewitt PJ	1993	Occupational health problems in processing of X-rays photographic films.	-	-	No	Yes	No	Data published	8.4
Hygiene Nord GmbH	2016	Determination of the bactericidal efficacy of Protectol® GA 50 (50% Glutaraldehyde) as slimicide in the paper industry	Hygiene Nord GmbH, Greifswald, Germany	EX15/025	No	No	Yes	BASF SE	6.7 Key study
Jachuck SJ, Bound CL, Steel J, Blain PG	1989	Occupational hazard in hospital staff exposed to 2 per cent glutaraldeyhde in an endoscopy unit.	-	-	No	Yes	No	Data published	8.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Kampf G, Ostermeyer C, Tschudin-Sutter S, Widmer AF	2013	Resistance or adaptation? How susceptible is a 'glutaraldehyde-resistant' Pseudomonas aeruginosa isolate in the absence of selection pressure?, J Hosp Infect., 84(4), 316-318	-	-	-	Yes	No	Data published	-
Labor L+S AG	2016a	Determination of the efficacy of a 50% Glutaraldehyde solution in water (Protectol® GA 50) in preservation of organic solutes - cleaning formulation for laundry or heard surfaces	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	BP11/056_ c1	No	No	Yes	BASF SE	6.7 Key study

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Labor L+S AG	2016b	Determination of the efficacy of a 50% Glutaraldehyde solution in water (Protectol® GA 50) in preservation of a polymer emulsion - car Polish	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	EX15/028	No	No	Yes	BASF SE	6.7 Key study
Labor L+S AG	2016c	Determination of the efficacy of Protectol® GA 50 (a 50% solution of Glutaraldehyde in water) in preservation of an inorganic dispersion – used as filler in paper, paint, plastic industry; here $CaCO_3$ Slurry	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	EX15/023	No	No	Yes	BASF SE	6.7 Key study

Author(s)	**Year**	**Title**	**Testing Company**	**Report No.**	**GLP Study (Yes/No)**	**Published (Yes/No)**	**Data Protection Claimed (Yes/No)**	**Data Owner**	**Section No. in IUCLID / Non-key study/ Published**
Labor L+S AG	2016d	Determination of the efficacy of Protectol® GA 50 (a 50% solution of Glutaraldehyde in water) in preservation of an organic dispersion – used as pigment/dye or filler in paper, paint, plastic industry, pigment slurry – high Protectol® GA 50 concentrations	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	EX15/024	No	No	Yes	BASF SE	6.7 Key study

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Labor L+S AG	2016e	Determination of the efficacy of Protectol® GA 50 (a 50% solution of Glutaraldehyde in water) in preservation of an organic dispersion – used as pigment/dye or filler in paper, paint, plastic industry, here pigment slurry – low concentrations of Protectol® GA 50	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	BIO16_002	No	No	Yes	BASF SE	6.7 Key study
Labor L+S AG	2016f	Determination of the efficacy of Protectol® GA 50 (a 50% solution of Glutaraldehyde in water) in preservation of polymer dispersion as used in production for sealants and glues	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	EX13/006A	No	No	Yes	BASF SE	6.7 Key study

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Labor L+S AG	2016g	Determination of the efficacy of Protectol® GA 50 in preservation of an organic emulsion; here re-fattening agent used in leather industry	Labor L+S AG, Bad Bocklet-Großenbrach, Germany	EX15/015	No	No	Yes	BASF SE	6.7 Key study
Lorena NS, Pitombo MB, Côrtes PB, Maya MC, Silva MG, Carvalho AC, Coelho FS, Miyazaki NH, Marques EA, Chebabo A, Freitas AD, Lupi O, Duarte RS.	2010	Mycobacterium massiliense BRA100 strain recovered from postsurgical infections: resistance to high concentrations of glutaraldehyde and alternative solutions for high level disinfection, Acta Cir Bras., 25(5), 455-459	-	-	-	Yes	No	Data published	-
McDonald JC, Keynes HL, Meredith SK	2000	Reported incidence of occupational asthma in the United Kingdom, 1989-97.	-	-	No	Yes	No	Data published	8.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
McDonnell G & Burke P	2011	Disinfection: is it time to reconsider Spaulding?, J Hosp Inf. 78, 163-170	-	-	-	Yes	No	Data published	-
Nicewicz JT, Murphy DMF, Welsh JP, Sirolli H	1986	Occupational asthma caused by glutaraldehyde exposure.	-	-	No	Yes	No	Data published	8.4
Ong TH, Tan KL, Lee HS, Eng P	2004	A case report of occupational asthma due to glutaraldehyde exposure	-	-	No	Yes	No	Data published	8.4
Oosterik LH, Peeters L, Mutuku I, Goddeeris BM, Butaye P	2014	Susceptibility of avian pathogenic Escherichia coli from laying hens in Belgium to antibiotics and disinfectants and integron prevalence.Avian Dis., 58, 271-278	-	-	-	Yes	No	Data published	-

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Otter JA, Vickery K, Walker JT, deLancey Pulcini E, Stoodley P, Goldenberg SD, Salkeld JA, Chewins J, Yezli S, Edgeworth JD	2015	Surface-attached cells, biofilms and biocide susceptibility: implications for hospital cleaning and disinfection, J. Hosp. Infect. 89, 16-27	-	-	-	Yes	No	Data published	-
Palczynski C, Walusiak J, Ruta U, Gorski P	2001	Occupational asthma and rhinitis due to glutaraldeyhde: changes in nasal lavage fluid after specific inhalatory test.	-	-	No	Yes	No	Data published	8.4
Pechter E, Davis LK, Tumpowsky C, Flattery J, Harrison R, Reinisch F, Reilly MJ, Rosenman KD, Schill D P, Valiante D, Filios M	2005	Work-related asthma among health care workers: surveillance data from California, Massachusetts, Michigan, and New Jersey, 1993-1997	-	-	No	Yes	No	Data published	8.4

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Pisaniello DL, Gun RT, Tkaczuk MN, Nitshcke M, Crea J	1997	Glutaraldehyde exposures and symptoms among endoscopy nurses in South Australia.	-	-	No	Yes	No	Data published	8.4
Quirce S, Gomez M, Bombin C, Sastre J	1999	Glutaraldehyde-induced asthma.	-	-	No	Yes	No	Data published	8.4
Reifenrath WG, Prystowsky SD, Nonomura JH, Robinson PB	1985	Topical glutaraldehyde-percutaneous penetration and skin irritation.	-	-	No	Yes	No	Data published	8.6
Rohwer, H.	2016a	Decomposition in wall paints	Competence Center Analytics, BASF SE	-	No	No	Yes	BASF SE	10.2
Rohwer, H.	2016b	Determination of Glutaraldehyde in vapor phase over a paint	Competence Center Analytics, BASF SE	-	No	No	Yes	BASF SE	10.2

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Sagripanti JL, Eklund CA, Trost PA, Jinneman KC, Abeyta C Jr, Kaysner CA, Hill WE	1997	Comparative sensitivity of 13 species of pathogenic bacteria to seven chemical germicides, Am J Infect Control., 25(4), 335-339.	-	-	-	Yes	No	Data published	-
Stenton SC, Beach JR, Dennis JH, Keaney NP, Hendrick DJ	1994	Glutaraldehyde, asthma and work - a cautionary tale.	-	-	No	Yes	No	Data published	8.4
Svetlikova Z, Skovierova H, Niederweis M, Gaillard J, McDonnell G, Jackson M	2009	Role of Porins in the Susceptibility of Mycobacterium smegmatis and Mycobacterium chelonae to Aldehyde-Based Disinfectants and Drugs, Antim. Agents Chemoth. 53 (09), 4015-4018	-	-	-	Yes	No	Data published	-

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Tey S L, Lafuente Cerdá O	2016	Protectol GA® 50 BPR registration in Europe – Application in Oilfied Uses	-	2016ST01	-	No	Yes	BASF SE	13
Tschudin-Sutter S, Frei R, Kampf G, Tamm M, Pflimlin E, Battegay M, Widmer AF	2011	Emergence of glutaraldehyde-resistant Pseudomonas aeruginosa, Inf Control Hosp Epidem. 32, 1173-1178	-	-	-	Yes	No	Data published	-
Ulrich P, Homey B, Vohr HW	1998	A modified murine local lymph node assay for the differentiation of contact photoallergy from phototoxicity by analysis of cytokine expression in skin-draining lymph node cells.	-	-	No	Yes	No	Data published	8.3

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Vikram A, Bomberger JM, Bibby KJ	2015	Efflux as a glutaraldehyde resistance mechanism in Pseudomonas fluorescens and Pseudomonas aeruginosa biofilms, Antim. Ag and Chemoth., 59 (4), 3433-3440	-	-	-	Yes	No	Data published	-
Vikram A, Lipus D, Bibby K	2014	Produced water exposure alters bacterial response to biocides, Environ Sci Technol., 4; 48(21), 13001-13009	-	-	-	Yes	No	Data published	-

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Vyas A, Pickering CAC, Oldham LA, Francis HC, Fletcher AM, Merrett T, McL Niven R	2000	Survey of symptoms, respiratory function, and immunology and their relation to glutaraldehyde and other occupational exposures among endoscopy nursing staff.	-	-	No	Yes	No	Data published	8.4
Walter, D.	2015	Physico-chemical Properties of Protectol GA 50 before and after Accelerated Storage at 40 °C for 8 Weeks	Eurofins Agroscience Services EcoChem GmbH	S15-04190	Yes	No	Yes	BASF SE	3.4.1
Walter, D.	2015	Physico-chemical Properties of Protectol GA 50 after Storage at 0 °C for 7 days	Eurofins Agroscience Services EcoChem GmbH	S15-04192	Yes	No	Yes	BASF SE	3.4.2.1
Walter, D.	2016	Physico-chemical Properties of Protectol GA 50 over 2 Years at 20 °C	Eurofins Agroscience Services EcoChem GmbH	S15-04191	Yes	No	Yes	BASF SE	5

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Werley MS, Burleigh-Flayer HD, Ballantyne B	1995	Respiratory peripheral sensory irritation and hypersensitivity studies with glutaraldehyde vapor.	-	-	No	Yes	No	Data published	8.4
WIL Research Laboratories Inc.	1995	Acute dermal toxicity study of glutaraldehyde in albino rabbits.	WIL Research Laboratories Inc., Ashland, OH	WIL-234002	Yes	No	Yes	BASF SE	8.5.3
Willinghan EM, Sander JE, Thayer SG, Wilson JL	1996	Investigation of bacterial resistance to hatchery disinfectants, Avian Dis., 40(3), 510-515	-	-	-	Yes	No	Data published	-

3.2 Output tables from exposure assessment tools

Product type 6

Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums or intermediate bulk containers (IBCs))

Scenario [1a] PT 6 - Professional users loading Protectol® GA 50 (Connecting/Disconnecting drums)

Model 7-Mixing and Loading (pump liquid)	**Glutaraldehyde** **Tier 1**	 **Tier 2**	 **Tier 3**
active substance % (w/w)	50%	50%	50%
Exposure by inhalation			
Indicative value mg/m³	22	22	22
Duration min	10	10	10
Inhalation rate m³/h	1.25	1.25	1.25
Mitigation by RPE (PF)	1	10	40 (2.5% penetration)
Inhaled [product] mg	4.58	0.458	0.115
Systemic exposure *via* inhalation route a.s. mg	2.29	0.229	0.057
Systemic exposure mg kg^{-1} day^{-1}	**0.038**	**0.0038**	**0.00096**
Systemic exposure			
Total systemic exposure a.s. mg	2.29	0.229	0.057
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0.038**	**0.0038**	**0.00096**

Professional users applying detergents preserved with Protectol® GA 50

Scenario [2] PT 6 – Professional users mixing and loading liquid dish washing detergent

Frequency	3650 per year
Body weight	60 kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	0.75 minute
Product amount	500 g
Weight fraction substance	0.0979 %
Room volume	1 m³
Ventilation rate	2.5 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	44 Pa

Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	20 cm^2
Emission duration	0.3 minute
Product in pure form	No
Molecular weight matrix	36 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Instant application
Exposed area	205 cm^2
Weight fraction substance	0.0979 %
Product amount	0.01 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario 2. Mixing & Loading

Inhalation

Mean event concentration	1.6×10^{-5} mg/m^3
Mean concentration on day of exposure	8.1×10^{-8} mg/m^3
Year average concentration	8.1×10^{-8} mg/m^3
External event dose	4.1×10^{-9} mg/kg bw
External dose on day of exposure	4.1×10^{-8} mg/kg bw
Internal event dose	4.1×10^{-9} mg/kg bw
Internal dose on day of exposure	4.1×10^{-8} mg/kg bw/day
Internal year average dose	4.1×10^{-8} mg/kg bw/day

Dermal

Dermal load	4.6×10^{-5} mg/cm^2
External event dose	1.6×10^{-4} mg/kg bw
External dose on day of exposure	1.6×10^{-3} mg/kg bw
Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Integrated

Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Scenario [3]: PT 6 – Professional users applying liquid dish washing detergent

Frequency	3650 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	15000 g
Weight fraction substance	0.000137 %
Room volume	15 m^3
Ventilation rate	2.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	1500 cm^2
Emission duration	16 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Instant application
Exposed area	820 cm^2
Weight fraction substance	0.000137 %
Product amount	8.2 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario 3. Application

Inhalation

Mean event concentration	1.3×10^{-6} mg/m^3
Mean concentration on day of exposure	5.4×10^{-7} mg/m^3
Year average concentration	5.4×10^{-7} mg/m^3
External event dose	2.7×10^{-8} mg/kg bw
External dose on day of exposure	2.7×10^{-7} mg/kg bw

Dermal

Dermal load	1.4×10^{-5} mg/cm^2
External event dose	1.9×10^{-4} mg/kg bw
External dose on day of exposure	1.9×10^{-3} mg/kg bw
Internal event dose	1.9×10^{-5} mg/kg bw
Internal dose on day of exposure	1.9×10^{-4} mg/kg bw/day
Internal year average dose	1.9×10^{-4} mg/kg bw/day

Integrated

Internal event dose	1.9×10^{-5} mg/kg bw
Internal dose on day of exposure	1.9×10^{-4} mg/kg bw/day
Internal year average dose	1.9×10^{-4} mg/kg bw/day

Scenario [4]: Professional users loading liquid detergent for hand washing

Frequency	3650 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	0.75 minute
Product amount	500 g
Weight fraction substance	0.0979 %
Room volume	1 m^3
Ventilation rate	2 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	20 cm^2
Emission duration	0.3 minute
Product in pure form	No
Molecular weight matrix	90 g/mol
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Instant application
Exposed area	215 cm^2
Weight fraction substance	0.0979 %
Product amount	0.01 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario 4. Loading

Inhalation

Mean event concentration	3.9×10^{-5} mg/m^3
Mean concentration on day of exposure	2.0×10^{-7} mg/m^3
Year average concentration	2.0×10^{-7} mg/m^3
External event dose	1.0×10^{-8} mg/kg bw
External dose on day of exposure	1.0×10^{-7} mg/kg bw

Dermal

Dermal load	4.6×10^{-5} mg/cm^2
External event dose	1.6×10^{-4} mg/kg bw
External dose on day of exposure	1.6×10^{-3} mg/kg bw
Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Integrated

Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Scenario [5]: PT 6 – Professional users applying liquid hand washing detergent

Frequency	3650 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	15000 g
Weight fraction substance	0.1 %
Room volume	15 m^3
Ventilation rate	2.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	22 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	1500 cm^2
Emission duration	16 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Instant application
Exposed area	1950 cm^2
Weight fraction substance	0.000979 %
Product amount	19.5 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario 5. Application

Inhalation

Mean event concentration	9.4×10^{-4} mg/m^3
Mean concentration on day of exposure	3.9×10^{-4} mg/m^3
Year average concentration	3.9×10^{-4} mg/m^3
External event dose	2.0×10^{-5} mg/kg bw
External dose on day of exposure	2.0×10^{-4} mg/kg bw
Internal event dose	2.0×10^{-5} mg/kg bw
Internal dose on day of exposure	2.0×10^{-4} mg/kg bw/day
Internal year average dose	2.0×10^{-4} mg/kg bw/day

Dermal

Dermal load	9.8×10^{-5} mg/cm^2

External event dose	3.2×10^{-3} mg/kg bw
External dose on day of exposure	3.2×10^{-2} mg/kg bw
Internal event dose	3.2×10^{-4} mg/kg bw
Internal dose on day of exposure	3.2×10^{-3} mg/kg bw/day
Internal year average dose	3.2×10^{-3} mg/kg bw/day

Integrated

Internal event dose	3.4×10^{-4} mg/kg bw
Internal dose on day of exposure	3.4×10^{-3} mg/kg bw/day
Internal year average dose	3.4×10^{-3} mg/kg bw/day

Scenario [6]: PT 6 – Professional users loading laundry softener

Frequency	3650 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	0.75 minute
Product amount	500 g
Weight fraction substance	0.0979 %
Room volume	1 m^3
Ventilation rate	2 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	20 cm^2
Emission duration	0.3 minute
Product in pure form	No
Molecular weight matrix	90 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Instant application
Exposed area	205 cm^2
Weight fraction substance	0.0979 %
Product amount	0.01 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario 6. Laundry softener

Inhalation

Mean event concentration	3.9×10^{-5} mg/m^3
Mean concentration on day of exposure	2.0×10^{-7} mg/m^3
Year average concentration	2.0×10^{-7} mg/m^3

External event dose	1.0×10^{-8} mg/kg bw
External dose on day of exposure	1.0×10^{-7} mg/kg bw
Internal event dose	1.0×10^{-8} mg/kg bw
Internal dose on day of exposure	1.0×10^{-7} mg/kg bw/day
Internal year average dose	1.0×10^{-7} mg/kg bw/day

Dermal

Dermal load	4.6×10^{-5} mg/cm^2
External event dose	1.6×10^{-4} mg/kg bw
External dose on day of exposure	1.6×10^{-3} mg/kg bw
Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Integrated

Internal event dose	1.6×10^{-5} mg/kg bw
Internal dose on day of exposure	1.6×10^{-4} mg/kg bw/day
Internal year average dose	1.6×10^{-4} mg/kg bw/day

Professional users applying wax emulsion

Scenario [7a]: PT 6 – Professional users applying undiluted wax emulsion

Frequency	365 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	550 g
Weight fraction substance	0.0979 %
Room volume	58 m^3
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Increasing
Release area	220000 cm^2
Application duration	60 minute
Product in pure form	No
Molecular weight matrix	22 g/mol
Absorption model	Fixed fraction
Absorption fraction	100%

Dermal

Exposure model	Direct contact - Instant application
Exposed area	430 cm^2
Weight fraction substance	0.0979 %
Product amount	5.5 g
Absorption model	Fixed fraction

Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for Scenario [7a]: PT 6 – Professional users applying undiluted wax emulsion

Inhalation

Mean event concentration	5.8×10^{-2} mg/m^3
Mean concentration on day of exposure	2.4×10^{-3} mg/m^3
Year average concentration	2.4×10^{-3} mg/m^3
External event dose	1.2×10^{-3} mg/kg bw
External dose on day of exposure	1.2×10^{-3} mg/kg bw

Dermal

Dermal load	1.3×10^{-2} mg/cm^2
External event dose	9.0×10^{-2} mg/kg bw
External dose on day of exposure	9.0×10^{-2} mg/kg bw
Internal event dose	9.0×10^{-3} mg/kg bw
Internal dose on day of exposure	9.0×10^{-3} mg/kg bw/day
Internal year average dose	9.0×10^{-3} mg/kg bw/day

Integrated

Internal event dose	1.0×10^{-2} mg/kg bw
Internal dose on day of exposure	1.0×10^{-2} mg/kg bw/day
Internal year average dose	1.0×10^{-2} mg/kg bw/day

Scenario [7b]: PT 6 – Professional users applying diluted wax emulsion

Frequency	1460 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	240 minute
Product amount	550 g
Weight fraction substance	0.0049 %
Room volume	58 m^3
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Increasing
Release area	220000 cm^2
Application duration	60 minute
Product in pure form	No
Molecular weight matrix	22 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Instant application
Exposed area	430 cm^2
Weight fraction substance	0.0049 %
Product amount	5.5 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for Scenario [7b]: PT 6 – Professional users applying diluted wax emulsion

Inhalation

Mean event concentration	9.7×10^{-3} mg/m^3
Mean concentration on day of exposure	6.4×10^{-3} mg/m^3
Year average concentration	6.4×10^{-3} mg/m^3
External event dose	8.1×10^{-4} mg/kg bw
External dose on day of exposure	3.2×10^{-3} mg/kg bw
Internal event dose	8.1×10^{-4} mg/kg bw
Internal dose on day of exposure	3.2×10^{-3} mg/kg bw/day
Internal year average dose	3.2×10^{-3} mg/kg bw/day

Dermal

Dermal load	6.3×10^{-4} mg/cm^2
External event dose	4.5×10^{-3} mg/kg bw
External dose on day of exposure	1.8×10^{-2} mg/kg bw
Internal event dose	4.5×10^{-4} mg/kg bw
Internal dose on day of exposure	1.8×10^{-3} mg/kg bw/day
Internal year average dose	1.8×10^{-3} mg/kg bw/day

Integrated

Internal event dose	1.3×10^{-3} mg/kg bw
Internal dose on day of exposure	5.0×10^{-3} mg/kg bw/day
Internal year average dose	5.0×10^{-3} mg/kg bw/day

Scenario [8]: PT 6 – Professional users applying car polish

Frequency	2 per day
Body weight	60kg

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product amount	59 g
Weight fraction substance	0.0979 %
Room volume	34 m^3
Ventilation rate	1.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min

Release area mode	Increasing
Release area	11 m^2
Application duration	60 minute
Product in pure form	No
Molecular weight matrix	22 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Instant application
Exposed area	410 cm^2
Weight fraction substance	0.0979 %
Product amount	0.6 g
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [8]: PT 6 – Professional users applying car polish

Inhalation

Mean event concentration	3.9×10^{-2} mg/m^3
Mean concentration on day of exposure	3.3×10^{-3} mg/m^3
Year average concentration	3.3×10^{-3} mg/m^3
External event dose	8.2×10^{-4} mg/kg bw
External dose on day of exposure	1.6×10^{-3} mg/kg bw
Internal event dose	8.2×10^{-4} mg/kg bw
Internal dose on day of exposure	1.6×10^{-3} mg/kg bw/day
Internal year average dose	1.6×10^{-3} mg/kg bw/day

Dermal

Dermal load	1.4×10^{-3} mg/cm^2
External event dose	9.8×10^{-3} mg/kg bw
External dose on day of exposure	2.0×10^{-2} mg/kg bw
Internal event dose	9.8×10^{-4} mg/kg bw
Internal dose on day of exposure	2.0×10^{-3} mg/kg bw/day
Internal year average dose	2.0×10^{-3} mg/kg bw/day

Integrated

Internal event dose	1.8×10^{-3} mg/kg bw
Internal dose on day of exposure	3.6×10^{-3} mg/kg bw/day
Internal year average dose	3.6×10^{-3} mg/kg bw/day

__Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals__

__Scenario [9]: PT 6 – Professional users applying organic emulsions preserved with Protectol GA® 50 e.g. leather re-fattening agent and preservation of other leather, textile treatment chemicals__

	Solvent-based double vacuum timber pre-treatment	
Product	**Tier 1**	**Tier 2**
active substance % (w/v)	0.0979 %	0.0979 %
Potential body exposure		
Indicative value µL/min	4	4
Duration min	360	360
Potential dermal deposit µL	1,440	1,440
Clothing type	No protective clothing	Coated coveralls, 5% penetration
Clothing penetration	100%	5%
Actual dermal deposit [*product*] µL	1440	72
Hand exposure		
Indicative value µL/min (actual)	1.18	1.18
Duration min	360	360
Hand deposit µL	424.8	424.8
Actual hand deposit [*product*] µL	424.8	424.8
Total dermal exposure		
Total dermal deposit [*product] µL*	1864.8	496.8
Active substance mg	1.826	0.486
Dermal absorption %	10%	10%
Systemic exposure *via* dermal route mg	0.1826	0.0486
Systemic exposure mg kg^{-1} day^{-1}	0.00304	0.000811
Exposure by inhalation		
Indicative value µL/m^3	0.55	0.55
Duration	360	360
Inhalation rate m^3/h	1.25	1.25
Mitigation by RPE (PF)	1	1
Inhaled [*product*] µL	4.13	4.13
Systemic exposure *via* inhalation route mg	0.0040	0.0040
Density g cm^{-3}	1	1
Systemic exposure mg kg^{-1} day^{-1}	$6.73E_{-5}$	$6.73E^{-5}$
Systemic exposure		
Total systemic exposure a.s. mg	0.1866	0.0527
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0.00311**	**0.00088**

75th percentiles of fitted log normal distributions to solvent based timber pre-treatment data set

Professional users applying organic particle dispersions e.g. pigment and polymer dispersions preserved with Protectol® GA 50 used in paints and plastics

Scenario [10a]: PT 6 – Professional users spraying paints

Indoor decorative painting							
Product	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Tier 6**	**Tier 7**
	NO PPE	**gloves**	**gloves, coated coverall**	**gloves, coated coverall, RPE**	**gloves, coated coverall, dagradation**	**gloves, coated coverall, RPE dagradation**	**gloves, impermeable coverall, dagradation**
active substance % (w/v)	0.0979	0.0979	0.0979	0.0979	**0.04895[1]**	**0.04895[1]**	**0.04895[1]**
Potential body exposure							
Indicative value µL/min	261	261	261	261	261	261	261
Duration min	360	360	360	360	360	360	360
Potential dermal deposit µL	93960	93960	93960	93960	93960	93960	93960
Clothing type	-	-	Coated coveralls, 10% penetration	Coated coveralls, 10% penetration	Coated coveralls, 10% penetration	Coated coveralls, 10% penetration	Impermeable coveralls, 5% penetration
Clothing penetration %	-	-	10	10	10	10	5
Actual dermal deposit [*product*] µL	93960	93960	9396	9396	9396	9396	4698
Hand exposure							
Indicative value µL/min (potential)	238						
Indicative value µL/min (actual)	-	9.4	9.4	9.4	9.4	9.4	9.4
Duration min	360	360	360	360	360	360	360
Hand deposit µL	85680	3384	3384	3384	3384	3384	3384
Mitigation by gloves	1	1	1	1	1	1	1
Actual hand deposit [*product*] µL	85680	3384	3384	3384	3384	3384	3384
Total dermal exposure							
Total dermal deposit [*product]* µL	179640	97344	12780	12780	12780	12780	8082
Density g cm^{-3}	1	1	1	1	1	1	1
Active substance mg	175.87	95.30	12.51	12.51	6.26	6.26	3.9561
Dermal absorption %	10	10	10	10	10	10	10
Systemic exposure *via* dermal route mg	17.59	9.53	1.251	1.251	0.626	0.626	0.3956
Systemic exposure mg kg^{-1} day^{-1}	0.293	0.159	0.0209	0.0209	0.0104	0.0104	0.00659
Exposure by inhalation							
Indicative value µL/m^3	97.5	97.5	97.5	97.5	97.5	97.5	97.5
Duration (min)	360	360	360	360	360	360	360
Inhalation rate m^3 h^{-1}	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Mitigation by RPE (PF)	1	1	1	0.1	1	0.1	1
Inhaled [*product*] µL	731.25	731.25	731.25	73.125	731.25	73.125	731.25
Systemic exposure *via* inhalation route mg	0.7159	0.7159	0.7159	0.07159	0.3579	0.0358	0.3579

Systemic exposure mg kg^{-1} day^{-1}	0.0119	0.0119	0.0119	0.00119	0.00597	0.000597	0.00597
Systemic exposure							
Total systemic exposure a.s. mg	18.306	10.2459	1.967	1.3226	0.9839	0.6618	0.7535
Body weight kg	60	60	60	60	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0.3051**	**0.1708**	**0.0328**	**0.0220**	**0.0164**	**0.0110**	**0.0126**

Scenario [10b]: PT 6 – Professional users rolling/brushing paints

PT8 professional brush treatment model, 240 min (indicative values normalised to 1% active substance) **Product**	**Tier 1**	
active substance % (w/v)	0.0979%	
Potential body exposure		
Indicative value mg/m^2	0.2382	
Application area / day m^2	31.6	
Potential dermal deposit mg	7.527	
Clothing type	No protective clothing	
Clothing penetration %	100	
Actual dermal deposit [*product*] mg	7.527	
Hand exposure		
Indicative value mg/m^2	70.5417	
Application area / day m^2	31.6	
Hand deposit mg	17.118	
Glove penetration %	100	
Actual hand deposit [*product*] mg	17.118	
Total dermal exposure		
Total dermal deposit [*product] mg*	24.644	
Active substance mg	2.41	
Dermal absorption %	10	
Systemic exposure *via* dermal route mg	0.241	
Systemic exposure mg kg^{-1} day^{-1}	4.02E^{-3}	
Exposure by inhalation		
Indicative value mg/m^2	0.0016	
Application area / day m^2	31.6	
Potential inhalation exposure	0.05056	
RPE penetration %	100	
Inhaled [*product*] mg	0.05056	
Active substance mg	4.95E^{-3}	
Systemic exposure *via* inhalation route mg kg^{-1} day^{-1}	8.25E^{-5}	
Systemic exposure		
Total systemic exposure a.s. mg	0.246	
Body weight kg	60	
Systemic exposure mg kg^{-1} day^{-1}	**4.10E^{-3}.**	

<u>Professional use as preservative for paper wet-end additives and paper coatings</u>

Scenario [11a]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings preservation – fully preserved pulp (cellulose and additives)

Dermal exposure calculation:

Paper Wet-end additives	**Tier 1**	**Tier 2**
active substance % (w/v)	0.0979	0.0979
Potential body exposure		
Indicative value mg/min	2.02	2.02
Duration min	120	120
Potential dermal deposit mg	242.4	242.4
Clothing type	No protective clothing	Coated coveralls, 10% penetration
Clothing penetration	100	10
Actual dermal deposit [product] mg	242.4	24.24
Hand exposure		
Indicative value mg/min (potential)	101	101
Duration min	120	120
Hand deposit mg	12,120	12,120
Mitigation by gloves	No	0.1
Actual hand deposit [product] mg	12,120	1,212
Total dermal exposure		
Total dermal deposit [product] mg	12,362.4	1,236.24
Active substance mg	12.103	1.2103
Dermal absorption %	10	10
Systemic exposure *via* dermal route mg	1.2103	0.1210
Systemic exposure mg kg^{-1} day^{-1}	0.0202	0.0020

Scenario [11b]: PT 6 – Professional use as preservative for paper wet-end additives and paper coatings – preserved paper additive(s) only

Mixing & loading	**Glutaraldehyde Tier 1**
active substance % (w/w)	0.0979
Hand exposure	
Indicative value mg/min	0.92
Duration min	120
Mitigation by gloves	No
Actual hand deposit [product] mg	110.4
Total dermal exposure	
Total dermal deposit [product] mg	110.4

Mixing & loading	**Glutaraldehyde Tier 1**
Active substance mg	0.108
Dermal absorption %	10
Systemic exposure *via* dermal route mg	0.0108
Systemic exposure mg kg^{-1} day^{-1}	0.00018
Exposure by inhalation	
Indicative value mg/m³	1.91
Duration (min)	120
Inhalation rate m³/h	1.25
Mitigation by RPE (PF)	1
Inhaled [product] mg	4.775
Systemic exposure *via* inhalation route mg	0.00467
Systemic exposure mg kg^{-1} day^{-1}	0.0000779
Systemic exposure	
Total systemic exposure a.s. mg	0.0154
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	0.000258

Professional use as preservative for polymer dispersions e.g. glues and raw material thereof

Scenario [12]: PT 6 – Professional use as preservative for polymer dispersions e.g. glues and raw material thereof

Frequency 260 per year

Body weight 60kg

Tier 1

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	75 minute
Product amount	9000 g
Weight fraction substance	0.0979 %
Room volume	58 m³
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	40000 cm²
Emission duration	75 minute
Product in pure form	No
Molecular weight matrix	45 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Constant rate
Exposed area	110 cm^2
Weight fraction substance	0.0979 %
Contact rate	30 mg/min
Release duration	4500 second
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [12]
Tier 1
Inhalation

Mean event concentration	8.1×10^{-2} mg/m^3
Mean concentration on day of exposure	4.2×10^{-3} mg/m^3
Year average concentration	3.0×10^{-3} mg/m^3
External event dose	2.1×10^{-3} mg/kg bw
External dose on day of exposure	2.1×10^{-3} mg/kg bw
Internal event dose	2.1×10^{-3} mg/kg bw
Internal dose on day of exposure	2.1×10^{-3} mg/kg bw/day
Internal year average dose	1.5×10^{-3} mg/kg bw/day

Dermal

Dermal load	2.0×10^{-2} mg/cm^2
External event dose	3.7×10^{-2} mg/kg bw
External dose on day of exposure	3.7×10^{-2} mg/kg bw
Internal event dose	3.7×10^{-3} mg/kg bw
Internal dose on day of exposure	3.7×10^{-3} mg/kg bw/day
Internal year average dose	2.6×10^{-3} mg/kg bw/day

Integrated

Internal event dose	5.8×10^{-3} mg/kg bw
Internal dose on day of exposure	5.8×10^{-3} mg/kg bw/day
Internal year average dose	4.1×10^{-3} mg/kg bw/day

Tier 2
Scenario 12. Glue
Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	75 minute
Product amount	9000 g
Weight fraction substance	0.0979 %
Room volume	58 m^3
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	40000 cm^2

Emission duration	75 minute
Product in pure form	No
Molecular weight matrix	45 g/mol
Absorption model	Fixed fraction
Absorption fraction	10 %

Dermal

Exposure model	Direct contact - Constant rate
Exposed area	110 cm^2
Weight fraction substance	0.0979 %
Contact rate	30 mg/min
Release duration	4500 second
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [12]
Tier 2
Inhalation

Mean event concentration	8.1×10^{-2} mg/m^3
Mean concentration on day of exposure	4.2×10^{-3} mg/m^3
Year average concentration	3.0×10^{-3} mg/m^3
External event dose	2.1×10^{-3} mg/kg bw
External dose on day of exposure	2.1×10^{-3} mg/kg bw
Internal event dose	2.1×10^{-4} mg/kg bw
Internal dose on day of exposure	2.1×10^{-4} mg/kg bw/day
Internal year average dose	1.5×10^{-4} mg/kg bw/day

Dermal

Dermal load	2.0×10^{-2} mg/cm^2
External event dose	3.7×10^{-2} mg/kg bw
External dose on day of exposure	3.7×10^{-2} mg/kg bw
Internal event dose	3.7×10^{-3} mg/kg bw
Internal dose on day of exposure	3.7×10^{-3} mg/kg bw/day
Internal year average dose	2.6×10^{-3} mg/kg bw/day

Integrated

Internal event dose	3.9×10^{-3} mg/kg bw
Internal dose on day of exposure	3.9×10^{-3} mg/kg bw/day
Internal year average dose	2.8×10^{-3} mg/kg bw/day

Tier 3
Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	75 minute
Product amount	9000 g
Weight fraction substance	0.04895 %
Room volume	58 m^3
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	20 °C

Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coefficient	0.052 m/min
Release area mode	Constant
Release area	40000 cm^2
Emission duration	75 minute
Product in pure form	No
Molecular weight matrix	45 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	Direct contact - Constant rate
Exposed area	110 cm^2
Weight fraction substance	0.04895 %
Contact rate	30 mg/min
Release duration	4500 second
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [12]
Tier 3

Inhalation

Mean event concentration	4.1×10^{-3} mg/m^3
Mean concentration on day of exposure	2.1×10^{-4} mg/m^3
Year average concentration	1.5×10^{-4} mg/m^3
External event dose	1.1×10^{-4} mg/kg bw
External dose on day of exposure	1.1×10^{-4} mg/kg bw
Internal event dose	1.1×10^{-4} mg/kg bw
Internal dose on day of exposure	1.1×10^{-4} mg/kg bw/day
Internal year average dose	8.2×10^{-5} mg/kg bw/day

Dermal

Dermal load	1.0×10^{-2} mg/cm^2
External event dose	1.8×10^{-2} mg/kg bw
External dose on day of exposure	1.8×10^{-2} mg/kg bw
Internal event dose	1.8×10^{-3} mg/kg bw
Internal dose on day of exposure	1.8×10^{-3} mg/kg bw/day
Internal year average dose	1.3×10^{-3} mg/kg bw/day

Integrated

Internal event dose	3.0×10^{-3} mg/kg bw
Internal dose on day of exposure	3.0×10^{-3} mg/kg bw/day
Internal year average dose	2.1×10^{-3} mg/kg bw/day

Scenario [19]: PT6– Non-professional users applying car polish

Frequency	6 per year
Body weight	60kg

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Instant application
Exposed area	410 cm^2
Weight fraction substance	0.0979 %
Product amount	1362 mg
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [19]

Dermal

Dermal load	3.3×10^{-3} mg/cm^2
External event dose	2.2×10^{-2} mg/kg bw
External dose on day of exposure	2.2×10^{-2} mg/kg bw
Internal event dose	2.2×10^{-3} mg/kg bw
Internal dose on day of exposure	2.2×10^{-3} mg/kg bw/day
Internal year average dose	3.7×10^{-5} mg/kg bw/day

Integrated

Internal event dose	2.2×10^{-3} mg/kg bw
Internal dose on day of exposure	2.2×10^{-3} mg/kg bw/day
Internal year average dose	3.7×10^{-5} mg/kg bw/day

Non-professional users applying organic particle dispersions preserved with Protectol GA® 50 e.g. pigment and polymer dispersions used in paints and plastics

Scenario [20] PT 6 – Non-professional users applying spray paints

Frequency	2 per year
Body weight	60kg

Inhalation

Exposure model	Exposure to spray - Spraying
Spray duration	13.3 minute
Exposure duration	25 minute
Weight fraction substance	0.0979 %
Room volume	34 m^3
Room height	2.25 m
Ventilation rate	1.5 per hour
Inhalation rate	1.25 m^3/hr
Spraying towards person	No
Mass generation rate	0.5 g/s
Airborne fraction	0.14
Density non-volatile	1.5 g/cm^3
Inhalation cut off diameter	15 µm
Aerosol diameter distribution	Log normal LogNormal
Median diameter	15.1 µm
Arithmic coefficient of variation	1.2
Maximum diameter	50 µm
Include oral non-respirable material exposure	Yes
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Constant rate

Exposed area	9520 cm^2
Weight fraction substance	0.0979 %
Contact rate	110 mg/min
Release duration	798 second
Absorption model	Fixed fraction
Absorption fraction	10 %

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	40 %

Results for scenario [20]

Inhalation

Mean event concentration	2.8×10^{-1} mg/m^3
Mean concentration on day of exposure	4.9×10^{-3} mg/m^3
Year average concentration	2.7×10^{-5} mg/m^3
External event dose	2.4×10^{-3} mg/kg bw
External dose on day of exposure	2.4×10^{-3} mg/kg bw

Dermal

Dermal load	1.5×10^{-4} mg/cm^2
External event dose	2.4×10^{-2} mg/kg bw
External dose on day of exposure	2.4×10^{-2} mg/kg bw
Internal event dose	2.4×10^{-3} mg/kg bw
Internal dose on day of exposure	2.4×10^{-3} mg/kg bw/day
Internal year average dose	1.3×10^{-5} mg/kg bw/day

Oral

External event dose	3.7×10^{-4} mg/kg bw
External dose on day of exposure	3.7×10^{-4} mg/kg bw
Internal event dose	1.5×10^{-4} mg/kg bw
Internal dose on day of exposure	1.5×10^{-4} mg/kg bw/day
Internal year average dose	8.0×10^{-7} mg/kg bw/day

Integrated

Internal event dose	2.5×10^{-3} mg/kg bw
Internal dose on day of exposure	2.5×10^{-3} mg/kg bw/day
Internal year average dose	1.4×10^{-5} mg/kg bw/day

Secondary (Indirect) exposure of the general public

Scenario [21] PT 6 – Secondary (Indirect) exposure of the general public from detergent or fabric softener residues from textiles/clothes

Frequency	365 per year
Body weight	60kg

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Migration
Exposed area	9550 cm^2
Product amount	1000 g
Leachable fraction	3.33E-06
Skin contact factor	0.8
Absorption model	Fixed fraction

Absorption fraction	10 %

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario [21]

Dermal

Dermal load	2.8×10^{-4} mg/cm^2
External event dose	4.4×10^{-2} mg/kg bw
External dose on day of exposure	4.4×10^{-2} mg/kg bw
Internal event dose	4.4×10^{-3} mg/kg bw
Internal dose on day of exposure	4.4×10^{-3} mg/kg bw/day
Internal year average dose	4.4×10^{-3} mg/kg bw/day

Integrated

Internal event dose	4.4×10^{-3} mg/kg bw
Internal dose on day of exposure	4.4×10^{-3} mg/kg bw/day
Internal year average dose	4.4×10^{-3} mg/kg bw/day

Scenario [22] PT 6 – Secondary (Indirect) exposure of the general public to liquid dish washing detergent

Frequency	365 per year
Body weight	60kg

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Direct product contact - Direct oral intake
Weight fraction substance	0.0979 %
Amount ingested	0.00042 g
Absorption model	Fixed fraction
Absorption fraction	40 %

Results for scenario [22]

Oral

External event dose	6.9×10^{-6} mg/kg bw
External dose on day of exposure	6.9×10^{-6} mg/kg bw
Internal event dose	2.7×10^{-6} mg/kg bw
Internal dose on day of exposure	2.7×10^{-6} mg/kg bw/day
Internal year average dose	2.7×10^{-6} mg/kg bw/day

Integrated

Internal event dose	2.7×10^{-6} mg/kg bw
Internal dose on day of exposure	2.7×10^{-6} mg/kg bw/day
Internal year average dose	2.7×10^{-6} mg/kg bw/day

Product type 12

Slimicides for paper pulp: wet-end slimicides

Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water

Scenario [25]: PT 12 - Exposure of professional users during cleaning/maintaining of pulp tanks and exposure to paper mill white water

Spraying model 2	**Tier 1**	**Tier 2**
active substance % (w/v)	0.013%	0.013%
Potential body exposure		
Indicative value mg/min	222	222
Duration min	240	240
Potential dermal deposit mg	53,280	53,280
Clothing type	No protective clothes	Coated coveralls, 10% penetration
Clothing penetration	100%	10%
Actual dermal deposit [*product*] mg	53,280	5,328
Hand exposure		
Indicative value mg/min	273	7.8 (inside gloves)
Duration min	240	240
Hand deposit mg	65,520	1,872
Mitigation by gloves	No	Not applicable
Actual hand deposit [*product*] mg	65,520	1,872
Total dermal exposure		
Total dermal deposit [*product]* mg	118,800	7,200
Active substance mg	15.444	0.936
Dermal absorption %	10.00%	10.00%
Systemic exposure *via* dermal route mg	1.5444	0.0936
Systemic exposure mg kg^{-1} day^{-1}	0.02574	0.00156
Exposure by inhalation		
Indicative value mg/m^3	76	76
Duration	240	240

Spraying model 2	**Tier 1**	**Tier 2**
Inhalation rate m^3/h	1.25	1.25
Mitigation by RPE (PF)	1	1
Inhaled [*product*] mg	380.00	380.00
Systemic exposure *via* inhalation route mg	0.049	0.049
Systemic exposure mg kg^{-1} day^{-1}	0.00082	0.00082
Systemic exposure		
Total systemic exposure a.s. mg	1.593	0.1426
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0.02656**	**0.00238**

Secondary (Indirect) exposure of professional users

Scenario [26]: PT 12 - Secondary (Indirect) exposure of professional users to vapours and aerosols of glutaraldehyde used as a slimicide in the paper mill industry

ART REPORT – PT 12 Secondary exposure of professionals to vapours and aerosols
Secondary exposure of professionals to vapours and aerosols during paper production is calculated.

Chemical details	
Chemical	Glutaraldehyde
CAS No.	111-30-8
Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	0
Metadaten	
ART version	1.5
Details for Activity Exposure to vapours and aerosols	
Emission sources	Far-field exposure
Operational Conditions	
Substance emission potential	
Substance product type	Liquids
Process temperature	20C
Vapour pressure	62 Pa
Liquid mole fraction	$1.8E^{-05}$
Activity coefficient	1
Activity emission potential	
Activity class	Spraying of liquids in a space
Situation	

	Small scale space spraying
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Large workrooms only
Risk Management Measures	
Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00% reduction)
Segregation	No segregation (0.00% reduction)
Personal enclosure	No personal enclosure (0.00% reduction)
Dispersion	
Ventilation rate	Only good natural ventilation
Predicted exposure levels	
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.	
Mechanistic model results	
The predicted 90th percentile full-shift exposure is 0.0036 mg/m^3.	
The inter-quartile confidence interval is 0.0018 mg/m^3 to 0.0075 mg/m^3.	

3.3 New information on the active substance

Not available

3.4 Residue behaviour

Not relevant

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[28]

Not applicable. IUCLID file is available.

3.6 Confidential annex

See in a separate document.

3.7 Other

Not applicable

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[28] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.