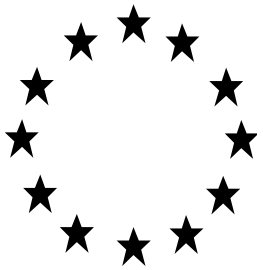
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Peracetic acid

Product-types 1-6

PT 1: Human hygiene
PT 2: Disinfectants and algaecides not intended for direct application to humans or animals
PT 3: Veterinary hygiene
PT 4: Food and feed area
PT 5: Drinking water
PT 6: Preservatives for products during storage

November 2015

Finland

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance Peracetic acid as product-types 1-6 (PT 1: Human hygiene, PT 2: Disinfectants and algaecides not intended for direct application to humans or animals, PT 3: Veterinary hygiene, PT 4: Food and feed area, PT 5: Drinking water, PT 6: Preservatives for products during storage), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Peracetic acid (CAS no. 79-21-0) was notified as an existing active substance, by CEFIC Peracetic Acid Registration Group (PAR), hereafter referred to as the applicant, in product-types 1-6.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Finland was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Peracetic acid as an active substance in Product Types 1-6 was 31 July 2007, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 23 July 2007, Finland competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 23 October 2007.

On 16 January 2013, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings (and Biocides Technical Meeting TMIV2013) and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of Peracetic acid for product-types 1-6, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

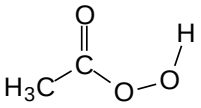
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identification of the active substance

CAS-No.	79-21-0
CAS name	Ethaneperoxoic acid
EINECS-No.	201-186-8
Other No. (CIPAC, ELINCS)	Not available
IUPAC Name	Peroxyethanoic acid
Common name, synonyms	Common name: Peracetic acid Synonyms: Acetyl hydroperoxide, Ethaneperoxoic acid, Peroxyacetic acid
Molecular formula	$C_2H_4O_3$
Structural formula	
Molecular weight (g/mol)	76.05 g/mol

The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water. This evaluation does not cover peracetic acid generated *in situ*.

Peracetic acid is produced by reacting hydrogen peroxide with acetic acid in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. Often the manufacturing process leads into products with characteristics of a chemical equilibrium. The peracetic acid content in existing aqueous equilibrium solutions (products) can be as low as < 0.1% or as high as > 15% (w/w). The equilibrium solution is the typical biocidal product, which is placed on the market. Two representative equilibrium solutions (theoretical products 1 and 2) containing 5% and 15% peracetic acid (PAA) have been defined for this dossier. In addition, ready-to-use antiseptic foam is included in PT1 as a theoretical product 3 with a very low concentration of peracetic acid. For product data collected by the applicant, see Doc IIB and the Confidential Annex. The confidential product data includes typical concentration ranges of hydrogen peroxide and acetic acid, information on ratios of concentrations, and information on other constituents.

Specifications: The pure active substance cannot be isolated, and the impurities are not applicable for the active substance peracetic acid itself. The specification is based on the minimum purity of the starting materials hydrogen peroxide (as in Regulation (EU) 2015/1730) and acetic acid (as in Regulation (EU) No 231/2012).

Purity and impurities: The minimum purity of the starting material acetic acid is $\geq$ 99.8% (w/w) in accordance to Regulation 231/2012 which also states maximum amounts of impurities. See DocIIA in more detail.

For the other starting material hydrogen peroxide the purity (concentration) in its aqueous solution is 35% – 69.9%, and the maximum impurities are as in the Hydrogen peroxide CAR in PTs 1-6, including maximum concentrations for heavy metals Hg, Cd, As, and Pb.

In solutions of peracetic acid, levels of impurities are below their levels in the starting materials acetic acid and hydrogen peroxide, due to mixing and dilution in manufacturing process.

Stabilizers and catalyser in peracetic acid equilibrium solutions are considered as part of the substance. The technical active substance peracetic acid may contain also added sulphuric acid (max 10 g/kg), as a catalyser, and 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (max 14 g/kg) and dipicolinic acid (DPA, PDC) (max 1.6 g/kg) in aqueous solution, as stabilizers.

Water. Manufacturing often includes addition of purified water. However, it was not considered necessary to set a requirement for the quality of water.

Additional aspects

Some products for special uses may contain additional co-formulants. Those should be evaluated at product authorization.

A concentrated solution of peracetic acid (with minor amounts of acetic acid and hydrogen peroxide) can be produced by vacuum distillation from aqueous solutions of peracetic acid. Such concentrated solutions (with 25–40% peracetic acid), with no equilibrium characteristics, intended for industrial uses in PT 2 and PT 6 have not been assessed in this CAR for PTs 1-6.

The hazard as well as the risk assessment in this CAR is only covering products containing peracetic acid concentrations up to 15% as the exposure assessments have not been performed with higher peracetic acid concentrations. For products containing peracetic acid in concentrations > 15%, further assessment shall be required for toxicological and physico-chemical risks.

Companies of the CEFIC Peracetic Acid Registration Group (PAR) for which compliance with the set specification was not demonstrated must provide quality control data to the evaluating Competent Authority (Finland) to demonstrate compliance no later than 6 months before the date of approval of the active substance.

Physico-Chemical Properties

Due to the explosiveness of pure (100%) peracetic acid it is technically impossible to perform experimental studies according to the guidelines to determine the physico-chemical properties of pure peracetic acid. Thus, tested or calculated literature data is given whenever meaningful and possible in Table 2-1.

All peracetic acid solutions are clear, colourless liquids with a pungent vinegar-like odour and are soluble in polar solvents, aromatics and acetates (Swern, 1970). The physical and chemical properties of the aqueous solutions of peracetic acid are specific to the concentration ratio of the individual components in the formulations.

Peracetic acid solutions have oxidising and explosive properties. Peracetic acid must be classified as oxidizing following the criteria defined in Commission Directive 2001/59/EC, paragraph 2.2.2.1, (remarks concerning peroxides). Consequently, no test is required. In CLP the classification procedure and criteria for oxidizing substances is not applicable for organic peroxides. According to the criteria of CLP, Annex I, 2.15.1.1, peracetic acid is an organic peroxide. This term covers formulations. Under CLP, organic peroxides are comprised in a separate hazard class (CLP Annex I, 2.15). The explosive properties, detonation, deflagration and thermal explosion, are described in the decision logic Figure 2.15.1 of CLP. Therefore, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides. For peracetic acid, the information submitted is not sufficient to follow the decision logic in Figure 2.15.1 of CLP, and therefore the Category D of organic peroxides could not be confirmed.

According to information, which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60°C suggesting that pure peracetic acid should be classified in Category 3, in line with the harmonized classification of peracetic acid in CLP.

In product authorisation test data on products should be presented.

Due to the presence of hydrogen peroxide in the aqueous solution of peracetic acid, Regulation (EU) No 98/2013 on the marketing and use of Explosive Precursors has to be considered for applications for authorisation for non-professional use.

Table 2-1. Physico-chemical properties of pure (100%*) peracetic acid (CAS 79-21-0)

Subsection	Results	Reference
Physical state	Clear, colourless liquid	
Melting point	0°C	Swern (1970)
Boiling point	105-110 °C	Mücke & Sprössig (1969)
Bulk density/ relative density	1.22 g/cm^3 liquid at 20°C	(OVA 2009)
Vapour pressure	1.3 - 2.6 kPa, at 20°C (293 K) variable sources 1.9 kPa, at 25°C (298 K) 1.41 kPa, at 20°C (293K)	(OVA 2009, CIS 2009) (EPIWIN 3.20 experimental database) Swern (1970)
Solubility in water	Miscible in water in all proportions	Swern (1970)
Henry´s Law Constant H	0.217 Pa·m^3/mol at 25°C	Lind & Kok (1986)
Dissociation constant	pKa= 8.24 at 25°C	Mekelburger (2007), Doc. No. 115-002, A3.6/01
Surface tension	54.0 mN/m at 20°C for the neat solution (5%) 47.7 mN/m at 20°C (ring method) for the neat solution (15 %)	Mekelburger (2007), Doc. No. 216-002 Mekelburger (2007), Doc. No. 216-003
Partition coefficient n-octanol/ water	log Kow = -0.46 at pH 5 log Kow = - 0.60 at pH 7 log Kow = - 0.66 at pH 9 -0.23 (calc. neutral form)	Byers (1998) Brachhold (2007)
Flammability	15% equilibrium product "PEROXYACETIC ACID 15%": Auto-ignition temperature: 280 °C 5% equilibrium product "PEROXYACETIC ACID 5%": Auto-ignition temperature: 435 °C	Mekelburger (2007), Doc.242-005, B3.4/02 Mekelburger (2007), Doc.242-004, B3.4/01
Flash-point	According to information which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60 °C suggesting that pure peracetic acid should be classified in Category 3, in line with the harmonized classification of peracetic acid in CLP.	Safety Data Sheet (combined)
Explosive properties	The liquid itself can be made to explode. Vapour/air explosive limit: Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5°C. Detailed explosive limits are unknown in the literature.	CIS (2009)
Oxidizing properties	Oxidizing	

*) in most cases the concentration value 100% represents extrapolated concentration, for technical reasons the actual testing has been carried out in lower than 100% concentration. For concentrations in testing see the DocIIB.

Methods of Analysis

Analysis of biocidal product and formulation elements, peracetic acid, hydrogen peroxide, acetic acid, sulphuric acid and 1-hydroxyethane-1,1-diphosphonic (HEDP), can be performed by reactive titration, titration, potentiometric titration, ion chromatography conductivity and ion chromatography UV-VIS, respectively. Their analytical methods and validation data are acceptable for the purpose of the CAR. At WG V 2014 it was agreed that validated methods for determination for stabilizers and acetic acid will be required at product authorisation.

The analytical methods for detection and identification of peracetic acid in air or water or in animal and human body fluids and tissues by HPLC-UV are acceptable.
Applicant's justification for non-submission of data for analytical method for soil is acceptable, because absorption to sediment is not likely to occur due to the physico-chemical properties of peracetic acid and rapid degradation in contact with organic material.
Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) i.e. bacteria, fungi, and viruses, and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

Peracetic acid has been evaluated for several uses in PT 1 - 6: in PT1 for hand disinfection, in PT2 for laundry disinfection, disinfection of sewage/waste water, disinfection of surfaces in industrial, public and health care areas, CIP (Clean-in-Place) in pharmaceutical and cosmetic industry, in PT3 for disinfection of animal houses, in PT4 for disinfection in food and feed industry (CIP, dipping of equipment, automated spraying, and manual spraying, foaming), in PT5 for disinfection of animal drinking water and in PT6 for in-can preservation in the paper production.

Peracetic acid exerts toxic (bactericidal, fungicidal, etc.) rather than bacteriostatic, fungistatic effects on target organisms. Peracetic acid products show evidence of bactericidal activity in PT1, 2, 3, 4, 5 and 6, fungicidal and sporicidal activity in PT2 and 4, and virucidal activity in PT2, 3, 4 and 5. Indications of potential activity against amoebae and algae have also been reported in literature.

The lowest concentrations showing efficacy are 12.5 mg/l against bacteria (E.coli, standard hygienic hand rub assay) and 175/250 mg/l against fungi (C. albicans, clean/dirty conditions) and 250 mg/l against virus (NDV and Vaccinia virus). These concentrations are usually lower than the likely concentrations reported for different uses. The doses should be adjusted to the intended uses at product authorisation stage.

For PT2 disinfection of sewage/waste water, the calculated concentration in the treated water is reported as low as 1.5 mg/l and therefore, the efficacy has to be shown at product authorisation. When showing the effectiveness, however, it should be acknowledged that the main purpose of disinfection of sewage/waste water is the reduction of faecal bacteria counts to adequate level in waste waters leaving a sewage treatment plant (STP) before entering surface water. The adequate level e.g. for total coliforms, intestinal enterococci or *Escherichia coli* in discharged waste water is determined according to national legislation,

since there are no microbial quality standards in the Urban Waste Water Directive (91/271/EEC).

Peracetic acid contributes most to the biocidal efficacy of the application solutions. The results of tests clearly show that peracetic acid has a significantly higher biocidal activity than hydrogen peroxide. However, the synergistic effects cannot be excluded. Acetic acid at the concentrations present in the application solutions will not contribute to the efficacy as the pH is way above the one required for biocidal activity of an acid.

As the mode of action of peracetic acid is very unspecific, it is very unlikely that resistance to peracetic acid can develop. The development of specific resistance management strategies for the use of peracetic acid does not seem to be an urgent task. Nevertheless, the general principle of alternating use of disinfectants with different modes of action is recommended.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Peracetic acid is included in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) (peracetic acid…%, Index number 607-094-00-8). The classification, as presented in the table below, is the translation of the harmonised classification made for the substance under Directive 67/548/EEC.

In accordance with Regulation (EC) No 1272/2008, Annex VI Table 3.1, peracetic acid is classified and labelled as follows:

Hazard Class and Category Code(s)	Flam. Liq. 3 H226 Org. Perox. D **** H242 Acute Tox. 4 * H332 Acute Tox. 4 * H312 Acute Tox. 4 * H302 Skin Corr. 1A H314 Aquatic Acute 1 H400			
Hazard Statement Code(s)	H226 Flammable liquid and vapour. H242 Heating may cause a fire. H332 Harmful if inhaled. H312 Harmful in contact with skin. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life.			
Supplemental Hazard Statement Code(s)	-			
Pictogram(s) and Code(s)	GHS02 	GHS05 	GHS07 	GHS09 
Signal Word (Code)	Danger (Dgr)			
Specific Concentration Limits M Factors	* STOT SE 3; H335: C ≥ 1 %			
Notes	B D			

In accordance with Directive 67/548/EEC, Annex VI Table 3.2, peracetic acid is classified and labelled as follows:

Class of danger	O Oxidising C Corrosive N Dangerous for the environment
R phrases	R7 May cause fire R10 Flammable R20/21/22 Harmful by inhalation, in contact with skin and if swallowed R35 Causes severe burns R50 Very toxic to aquatic organisms
S phrases	S1/2 Keep locked up and out of the reach of children S3/7 Keep container tightly closed in a cool place S14 Keep away from ... (incompatible materials to be indicated by the manufacturer) S36/37/39 Wear suitable protective clothing and gloves S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S61 Avoid release to the environment. Refer to special instructions / safety data sheets
Concentration Limits	Xn; R20/21/22: C ≥ 10 % C; R35: C ≥ 10 % C; R34: 5 % ≤ C < 10 % Xi; R36/37/38: 1 % ≤ C < 5 %
Notes	B D

The evaluating Competent Authority (Finland) (eCA) is of the opinion that based on the data evaluated there is a need to update the harmonised classification. Regarding the acute toxicity the concentration limits according to the DPD (Xn; R20/21/22: C ≥ 10 %) and the presently evaluated data should be reflected in the classification. In order to derive a correct classification/ATE (Acute Toxicity Estimate) value for a mixture containing peracetic acid, a 100% substance should be classified even if the substance cannot exist in such a high concentration. Aquatic Chronic 1 (H410, M-factor 10) classification should be applied according to the 2nd ATP to CLP Regulation (Regulation (EC) No 286/2011).

A CLH dossier will be submitted by the eCA (Finland) to ECHA during 2016 at the earliest.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, distribution, metabolism and excretion

Peracetic acid is reactive and it degrades rapidly in contact with organic material. The rapid degradation upon contact with skin explains the absence of systemic effects from exposure to peracetic acid. However, damage to skin may result in some systemic dose for a very short period of time. In vitro studies showed a rapid degradation of peracetic acid in rat blood. In rat blood diluted 1000 times, the half-life of peracetic acid was less than 5 minutes. For this reason the distribution of peracetic acid in the body is expected to be very limited after exposure to peracetic acid solutions. Hydrogen peroxide is also presumed to

degrade rapidly into oxygen and water. Eventually, the degradation products, i.e. acetic acid, oxygen, and water are processed via the physiological metabolic pathways.
No standard dermal penetration studies with equilibrium peracetic acid have been successfully conducted. Based on the physico-chemical properties of PAA, 100% dermal penetration should be used in the absence of more accurate information. However, in this particular case, in the absence of clear systemic effects, no dermal penetration parameter was needed in order to conclude on human health risks from the presented uses of peracetic acid. In conclusion, it was acceptable to "waive" the dermal penetration study.

Acute toxicity

The results of acute oral toxicity studies performed in rats with formulations containing peracetic acid at concentrations from 5 % to 15 % demonstrated acute oral LD_{50} values in the range of 1020.5-1922 mg/kg bw indicating that equilibrium peracetic acid, at the tested concentrations, is moderately toxic by the oral route (85-153 mg PAA/kg). The acute dermal LD_{50} of formulations containing 5 – 15 % peracetic acid was between 1147 and 1957 mg/kg bw in the rabbit indicating that equilibrium peracetic acid, at the tested concentrations, is moderately toxic by the dermal route (56.1-229 mg PAA/kg). The acute inhalation LC_{50} value for the test substance containing 5% peracetic acid was 4.08 mg/l/4 h (0.204 mg PAA/l).

Irritation, corrosivity and sensitization

5% peracetic acid causes burns. Higher concentrations result in even more severe skin damage and such concentrations warrant classification in the highest subcategory, i.e. Skin Corr. 1A.
Peracetic acid causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. Whereas, very diluted formulations exert only mild and completely reversible irritating effects.
Both animal data and human experience indicate that peracetic acid causes respiratory tract irritation. Two different mechanisms are possible depending on the concentration of PAA. Based on animal data the irritation at lower concentrations is sensory in nature, the reaction being mediated by stimulation of the trigeminal nerve and manifested as depression of the respiration rate in the test animals. At higher concentrations, also the corrosive nature of the substance is manifested as irritation of the airways. In animal studies an RD_{50} value for peracetic acid of approx. 15 mg/m^3 (5 ppm) in mice vs. clinical signs of irritation in an acute toxicity study at 87 mg/m^3 (28 ppm) have been observed.
Peracetic acid is not considered to be a potential skin sensitiser.

Repeated dose toxicity

Repeated dose toxicity of peracetic acid has been studied via, oral, dermal and inhalation route. Following sub-chronic exposure to peracetic acid by gavage, no systemic effects were evident in rat. Apart from local reactions at the site of first contact (stomach and GIT) related to the known irritating/corrosive properties of peracetic acid and its high reactivity, no other observations were made which would be indicative of systemic distribution resulting in specific systemic effects. Based on the results from functional observation battery (FOB) and motor activity (MA) tests there was no indication of neurotoxic potential of PAA either. The NOAEL is set at the mid dose level which was 15 mg/kg bw/d (test substance, 0.75 mg/kg PAA) (at the lowest) from day 23 onwards. There was no mortality or other significant treatment related effects during dosing at that level. In this study, the only observed effects were local effects that are concentration related. It is therefore reasonable to define a NOAEC for local effects at 0.055 % peracetic acid from the oral gavage study in rats.
The experiments via dermal and inhalation route do not provide additional information with regard to toxicity profile of PAA following repeated exposure.

Reproductive toxicity

For peracetic acid, no multi-generation study in rats is available. The subchronic study in rats showed that 5% peracetic acid solution at doses up to 50 mg/kg bw/day (nominal) did not have any effect on the reproductive organs of both sexes to the extent macroscopically and microscopically examined in the study. However, due to the rapid degradation of peracetic acid and the obvious limitation of toxic effects at the site of first contact, a new two generation reproductive toxicity study is not justified.
The developmental toxicity and teratogenicity of peracetic acid has been investigated in rats with a formulation containing 32 – 38 % (w/w) peracetic acid and 10 –14 % (w/w) hydrogen peroxide. In this study, the dams were given 100, 300 or 700 mg peracetic acid/l, (corresponding to 12.5, 30.4 and 48.1 mg peracetic acid/kg bw/day) via drinking water from day 5 to 20 of gestation. Based on the effects on water consumption and body weight gain the NOAEL for maternal toxicity is considered to be 100 mg/L (12.5 mg/kg bw/day). With regard to the foetuses, at and from the mid dose upwards disturbed ossification was observed. The NOAEL for foetal (developmental) effects is therefore 100 mg/L (12.5 mg/kg bw/day).
Performance of a developmental toxicity / teratogenicity study in a second species (rabbit) is not considered necessary based on the known mode of action and lack of systemic effects which equally applies to all mammalian (test) species.

Genotoxicity

The results of mutagenicity and genotoxicity tests, show one single positive result (*in vitro* chromosome aberration assay with human lymphocytes), which is not confirmed in an independent second study (i*n vitro* chromosome aberration assay with Chinese hamster lung fibroblasts). All *in vivo* studies, i.e. *in vivo* MNT and *in vivo* UDS show negative/equivocal results. The biological meaning of any result from the *in vivo* studies is questionable in view of uncertainty of the availability of the test substance in the target organ. On the Weight of Evidence basis it can also be concluded that studies on germ cell effects are not relevant. Based on the overall results it can be concluded that peracetic acid is not of concern regarding mutagenicity or genotoxicity for humans after possible internal dose, whereas the possibility of genotoxic insult in cells which are in direct contact with peracetic acid cannot be excluded. However, TM IV 2013 agreed that further in vivo genotoxicity testing is not required as the site of contact genotoxicity can be anticipated. Due to the corrosive and irritating properties of peracetic acid, the risk mitigation measures include the use of personal protective equipment. The eCA considers the protection sufficient, and does not consider the local genotoxicity as a relevant endpoint for a risk assessment.

Chronic toxicity/ carcinogenicity

No guideline chronic toxicity /carcinogenicity studies with peracetic acid are available, but no new studies are considered necessary. The available studies and the absence of a systemic availability support the conclusion that the toxicity of peracetic acid is mediated mainly by local irritation at the site of first contact. The possibility of systemic effects cannot be completely ruled out.
The available studies related to possible carcinogenicity of peracetic acid show that the substance has a tumour promoting activity and weak carcinogenic potential (slight increase of non-cancerous skin tumours) was also shown.These effects are believed to be secondary to local irritation. No new carcinogenicity studies are considered necessary due to the known mode of action and the lack of structural alerts for carcinogenicity.

Neurotoxicity
There is no need to conduct specific neurotoxicity tests. There are no structural alerts for neurotoxicity and the available acute and repeated dose toxicity studies did not reveal clinical signs related to neurotoxicity.

Human data

Use of washing solutions of 0.2-0.5 % PAA to disinfect hands has been reported to cause irritation or desquamation of skin. A Patch test with 87 persons (48h, occlusive) showed that up to 0.25 % PAA solution was non-irritating and approx. 0.33 % solution was a mild irritant. A dilution containing 0.2 % peracetic acid was well tolerated by the 20 volunteers of an operating team when disinfecting hands after having washed them with soap. In the same study, occasional burning was reported in case of small wounds in the skin.
Humans exposed for a few minutes to air concentrations of 0.5 ppm (total peroxygens, as H_2O_2) from fogging did not experience discomfort, whereas, levels of 0.5 to 1.0 ppm caused some mild discomfort. 1.0 ppm caused tolerable discomfort and 2 ppm extreme discomfort in the same study. Occupational observations also imply that approximately 0.3-0.4 ppm (total peroxygens, vapour) levels is not immediately irritating but would be unpleasant for an extended period of time, whereas, 0.13-0.17 ppm are considered tolerable and not unpleasant.
In conclusion, the primary human health hazard associated with exposure to peracetic acid is irritation of the skin, eyes and respiratory tract (i.e. sites of first contact). Local effects may arise both after short-term and repeated / long-term exposure.

2.2.1.2. Effects assessment

Peracetic acid in aqueous solution is composed of peracetic acid, hydrogen peroxide, acetic acid and water. After application of equilibrium peracetic acid in the intended uses, all three ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. The toxicity tests have been performed with the aqueous solution. Hence, the results also inherently contain the effects of each ingredient. In practice, both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material. Acetic acid is also metabolised relatively quickly. Based on the evaluated information, peracetic acid is the most critical ingredient of solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on peracetic acid itself and the exposure estimates for each intended use.

The adverse effects of peracetic acid in humans are limited to local effects at the site of first contact with the body. No clear systemic effects from equilibrium PAA were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation of peracetic acid. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.

Besides the direct chemical reactivity underlying the irritation and corrosion related lesions, peracetic acid causes sensory irritation. This phenomenon is also clearly concentration dependent and the symptoms manifest soon after start of exposure.

Dermal reference values for peracetic acid

Corrosive effects: According to the available animal data peracetic acid is corrosive at concentrations 5% and above. Concentrations between 1% and 5% could be corrosive if exposure time is longer than one hour. The animal and human data support each other. **Consequently, in short-term, acute (or accidental) exposure situations exposure to peracetic acid concentrations higher than 1% should be avoided in order to exclude the possibility of irreversible damage to human skin.**

Skin irritation: The available information on skin irritation in humans (incl. healthy and "sensitive" individuals) and the test results from animal studies support each other: Based on the "acute" animal studies a LOAEC of approx. 5% can be set and approx. 0.2% PAA

concentration seems to be non-irritating in human volunteers. It is considered that the human evidence comes from a sufficiently large number of people to be used as a starting point for risk characterisation. Instead, in the absence of adequate information from human use for longer periods, data from animals is chosen as the starting point for the dose descriptor for long-term exposure scenarios. Based on animal data from the dermal one-year study (LOAEC 0.2%) with an uncertainty factor of 2 is proposed to be used for risk characterisation. This study was considered as a supplementary information due to its shortcomings as a chronic study but that did not compromise the dermal effects observed. **In conclusion, based on the effects in humans 0.2% peracetic acid is proposed to be used as a dermal NOAEC for short-term and medium-term exposure scenarios and 0.1% for long-term exposure scenarios.**

Serious eye damage/eye irritation: As a corrosive substance peracetic acid is considered to cause also serious eye damage at the higher concentrations. This is indicated in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). In addition, the general concentration limit for corrosion is 5% and for eye irritation 1% in the CLP. In the absence of more accurate data, potential exposure in the different use scenarios should be compared to dermal NOAECs.

Inhalation reference values for peracetic acid

Corrosive effects: Based on the observed corrosive effects on the skin following dermal exposure to the more concentrated solutions of peracetic acid, it is assumed that at least similar concentrations can cause irreversible damage also at the respiratory tract. In addition, the difference of the defensive strength between mucous membranes and intact skin should be taken into account. Thus, an additional assessment factor of 2 is used to extrapolate from the approximated lower range of non-corrosive concentration on the skin to a non-corrosive concentration on the eye. **Hence, it is concluded that in short-term, acute (or accidental) exposure situations peracetic acid concentrations less than 0.5% should not cause irreversible damage to the mucous membranes of exposed persons *via* direct chemical reactivity.**

Respiratory irritation: Peracetic acid triggers respiratory tract irritation *via* two different mechanisms, i.e. direct chemical reactivity leading to reversible tissue damage and sensory irritation mediated by trigeminal nerve stimulation. RD_{50} values from 3.8 ppm to 5.4 ppm (approx. mean 4.6 ppm) have been determined in mice. The data allows extrapolation of an RD_{10} of approximately 0.6 ppm. There is no human data available specifically on sensory irritation. Humans exposed to peracetic acid have reported "non-irritating" or "no-discomfort" around the concentration levels of 0.15 ppm and 0.5 ppm respectively and at least slight discomfort at higher concentrations. Human data is taken as point of departure to derive the inhalation AEC value. The human NOAEC of 0.5 ppm is divided by an intraspecies dynamic factor of 3.16. In conclusion, **an inhalation AEC value is set at 0.16 ppm (0.5 mg/m^3).** This figure is considered appropriate also for medium- and long-term exposure because the sensory irritation symptoms, once produced at a certain concentration, are not enhanced with additional exposure time.

Reference values for hydrogen peroxide

In view of the absence of systemic effects after exposure to hydrogen peroxide, only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide. Since in the intended use(s) the in-use concentration of hydrogen peroxide is below a skin irritating threshold (concentration limit for classification as skin irritating is 35%), only the inhalation route of exposure has been identified to be relevant in the exposure and risk assessment of hydrogen peroxide.

The following **AEC for inhalation exposure** has been set for hydrogen peroxide:

for short-term, medium-term and long-term exposure: **1.25 mg/m^3** based on the NOAEC in 90-day inhalation rat study with the overall assessment factor of 8 (2.5x3.2).

For more details please refer to the CAR of hydrogen peroxide as a biocidal active substance.

2.2.1.3. Exposure assessment

Peracetic acid is mainly used in industrial/professional applications. Hand disinfection (PT1) applies primarily to professionals, but application of general public cannot be excluded.

Description of uses

PT1 Hand disinfection: Hands are disinfected by rubbing the product on hands.

PT2a) Disinfection of sewage/ waste water (including municipal waste water): The product is automatically and continuously dosed into the effluent of an STP.

PT2b) Disinfection of surfaces in industrial, public and health care areas: The product is applied by wiping of hard surfaces with flat mops or cleaning cloths.

PT2c) CIP (cleaning-in-place) in the pharmaceutical and cosmetic industry: The treatment solution is circulated through the pipework and tanks of the installations.

PT2d) Laundry disinfection in closed washing machines: The product is automatically dosed into the washing machine.

PT3a) Disinfection of animal houses by low-pressure manual spraying: Floors and walls of animal houses are disinfected by low pressure spraying with a hand held spray wand. After contact time of circa 30 min, a rinse with water is applied.

PT3b) Disinfection of animal houses by foaming: The product is applied by foaming onto surfaces to be disinfected. After contact times of ½-1 hour, a rinse with water is applied.

PT3c) Disinfection of animal houses by fogging: Tightly sealed animal houses are fogged in the absence of personnel.

PT3d) Disinfection of boots in footbaths in animal production: Footbaths filled with PAA solution are placed at strategic points around the farm (at the entrance of the animal houses, in the interior of the buildings) so that personnel must step through vats when entering or leaving the building.

PT3e) Disinfection of animal feet (hoof disinfection): Cows walk through vats (hoof baths) filled with PAA solution. Hoofs are not rinsed with water.

PT3f) Disinfection of equipment by dipping: Equipment is dipped into a bath with contains the treatment solution.

PT4a) Automated spraying in closed system (aseptic filling of PET (polyethylene terephthalate) bottles, sterilisation of crown corks, cheese moulds and food crates in the beverage/ food industry): The product is diluted in an automated process and applied in a closed system (i.e. in aseptic filling machines) by automated spraying or rinsing to bottles, food crates, cheese moulds, crown corks, etc.

PT4b) Disinfection of equipment in the food and beverage industry by dipping and immersion: Equipment in the food and beverage industry (including milking equipment) is disinfected by dipping.

PT4c) CIP and disinfection of ion-exchangers in the food and beverage industry: The treatment solution is circulated through the pipework and tanks of the installations.

PT4d) Disinfection of surfaces and equipment by low pressure manual spraying and wiping: Floor and walls of buildings, machines and equipment (e.g. milking equipment) is disinfected by low pressure spraying with a hand-held spray wand or by wiping with flat mops and cleaning cloths.

PT4e) Disinfection of surfaces by foaming: Surfaces in animal houses are disinfected by foaming with a hand-held application wand.

PT4f) Disinfection of milking parlours: The pipe work and tanks of the milking installation are disinfected by circulating the treatment solution through the system.

PT5 Disinfection of animal drinking water: Animal drinking water is disinfected by

automated dosing of the product into the water stream.

PT6 In-can preservation in the paper industry: PAA products are used for in-can preservation of coating products used in the production of paper by off-site addition (outside the paper mill) of peracetic acid to gypsum slurry before transport of the gypsum slurry from the slurry-production facility to the paper mill, on-site addition (addition within the paper mill) of peracetic acid to ultra-filtrated pigment (UF) used in the dry-end of a paper mill for coating and on-site addition (addition within the paper mill) of peracetic acid to coating colour used in the dry-end of a paper mill for coating.

For dermal and inhalation exposure values in different scenarios, please refer to the tables in Appendix IV.

In the absence of systemic adverse effects, the risk characterisation of peracetic acid is focused on local effects and no systemic doses are estimated. For the inhalation route the airborne exposure concentration is compared with the AEC for inhalation (0.5 mg/m^3). For dermal exposure route, the concentrations in the products and in-use solutions are compared with the dermal NOAEC values to account for the potential local effects of peracetic acid (0.2 % for short/medium-term exposure and 0.1 % for long-term exposure).

Since hydrogen peroxide has been demonstrated not to exert systemic effects, the local risk characterisation approach applies also to hydrogen peroxide. Thus, for the inhalation exposure a comparison with the external exposure limit value (AEC for inhalation 1.25 mg/m^3) and for dermal exposure a comparison with the skin irritation limit (35%) have been considered to account for the potential local effects of hydrogen peroxide.

2.2.1.4. Risk characterisation

It is concluded that in the absence of (primary) systemic adverse effects the risk characterisation is focused on local effects. The systemic effects, e.g. mortality are considered to be secondary to the local irritation/corrosion. Although some NOAEL/LOAEL values have been set based on the study results, there is, however, no need to compare these internal values to any external dose descriptors in order to decide on the most critical effects.
Tables of risk characterisation for human health are presented in Appendix IV.
The exposure models primarily used for the estimation of inhalation exposure (TNsG models) do not take into account the volatility of the substance. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation. Sufficient ventilation and other organisational risk mitigation measures should be in use to avoid vapour formation and exposure to values higher than the AEC for inhalation.

Equilibrium peracetic acid used in a variety of different product types for disinfection purposes is composed of acetic acid, peracetic acid, hydrogen peroxide (25% in both concentrated theoretical products) and water. After application of equilibrium peracetic acid in the intended uses within PT1 through PT6, peracetic acid and hydrogen peroxide are the relevant substances which have to be considered in the human health exposure assessment and risk characterisation. For this reason, the risk characterisation was performed for both peracetic acid and hydrogen peroxide, respectively. Since both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material, assumptions made in the exposure assessment for the intended uses within PT1 through PT6 were identical for both substances. Only if the reference value for hydrogen peroxide is exceeded that is noted in the conclusion texts.

Conclusion for industrial and professional uses

The exposure and accompanying risk assessments performed for industrial and professional uses of peracetic acid as a disinfectant demonstrated that eye protection and protective clothing is needed to protect against dermal exposure when handling concentrated products

in mixing/loading and diluted formulations in concentrations over 0.1 % in the long-term use.

For industrial uses, these exposure scenarios are relevant in disinfection of sewage/waste waters (PT2), cleaning-in-place (CIP) in the pharmaceutical industry (PT2) and in the food and beverage industry (PT4), automated spraying in closed systems in the food and beverage industry (PT4), disinfection of equipment in the food and beverage industry by dipping and immersion (PT4), disinfection of surfaces in industrial, public and health care areas (PT2), disinfection of surfaces and equipment in food and feed areas by spraying and foaming (PT4) and in-can preservation in the paper industry (PT6).

For professional uses, these exposure scenarios are relevant in hand disinfection in hospitals, health and animal care areas and the food industry (PT1), laundry disinfection (PT2), disinfection of equipment by dipping (PT3), disinfection of animal houses by spraying/foaming/fogging (PT3), disinfection of boots and animal feet (i.e. hooves) in footbaths (PT3), disinfection of milking parlours (PT4) and disinfection of animal drinking water (PT5).

In hand disinfection (PT1), the application of 0.2 % solutions is not considered acceptable in the long-term use due to potential local irritating effects, whereas the use of the more diluted antiseptic foam (0.017%) is at acceptable level also in the long-term use. At product authorisation, the concerns from the long-term use of in-use solutions above 0.1% should be re-evaluated taking into account more recent or formulation specific data.

For inhalation exposure, there is a need for respiratory protection in mixing/loading steps in all product types where concentrated products are handled, if vapour and aerosol formation above AEC is not prevented by other organisational RMM. The same applies for spraying/foaming and dipping scenarios (PT3, 4). The disinfected premises have to be well-ventilated before re-entry. In other applications, sufficient ventilation and local exhaust ventilation (LEV) should be used to avoid exposure over AEC.

Conclusion for non-professional users

Although peracetic acid solutions are not intended to be intentionally used by amateurs and/or non-professionals within PT1 for hand disinfection, the application of the diluted peracetic acid solution by this population cannot be excluded. Non-professionals/amateurs would be exposed to identical in-use concentrations compared to professional users and would, thus, experience the same dermal and inhalation exposure during application. Consequently, the same models and assessment is used. Furthermore, it can be assumed that use of the product by the general public will occur less frequently.

No mixing/loading is considered for non-professionals. As the peracetic acid concentration of the application solution is at maximum 0.2 % it equals the dermal NOAEC value for short and medium-term exposure and the dermal exposure can be considered to be at acceptable level in non-regular use. For inhalation, the estimated exposure is lower than the AEC value for peracetic acid. As a conclusion, non-professional exposure is considered to be at acceptable level.

Conclusion for secondary exposure

After application of aqueous peracetic acid solutions, secondary exposure of humans upon dermal or oral contact with treated surfaces or equipment is considered to be non-relevant. The range of in-use dilutions is below the level of dermally irritating concentrations and therefore no skin damage is possible. Secondly both peracetic acid and hydrogen peroxide are highly unstable and will rapidly degrade at the site of first contact which effectively reduces the possibility of any residual concentrations. Additionally, in applications of peracetic acid solutions as a disinfectant in veterinary hygiene (PT3) and food and feeding areas (PT4), treated equipment, pipework or installations are rinsed with water or left to dry prior to further operations. Therefore, secondary human exposure to peracetic acid and

hydrogen peroxide via food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide degrade rapidly following application and no residues are expected in foodstuffs. Subsequently, no MRL setting is required as peracetic acid is not persistent, no systemic effects are observed and because of its high reactivity.

Inhalation is therefore considered the only relevant route of secondary exposure. Exposure of bystanders/non-users present during cleaning and disinfection of hard surfaces by wiping with flat mops or cleaning cloths (PT2) *via* the inhalation was demonstrated to be at acceptable level and not to exceed the AEC of peracetic acid.

The secondary exposure of bystanders/non-users inadvertently entering sprayed or foamed animal houses (PT3) *via* the inhalation route of exposure was demonstrated to be at acceptable level. Instead, when entering animal houses disinfected by fogging and re-opened for ventilation the acceptable inhalation exposure level may be exceeded (hydrogen peroxide 152% of AEC; exposure to peracetic acid was acceptable, 76% of AEC). However, this represents a worst-case scenario, as bystanders/non-users are not assumed to be present during these operations which are to be performed by professionals and as the residence time in this scenario is assumed to be of short duration only. Furthermore, the importance of the ventilation, safe re-entry time and no-entry of bystanders is underlined in the use instructions.

During the use of peracetic acid solutions for the disinfection of coating-colour and ultra-filtrated pigment slurries (PT6) for the coating of papers in the dry end of a paper-mill, degradation of peracetic acid in the slurries was demonstrated by measurements performed in the slurry. Therefore, dermal exposure towards peracetic acid *via* treated/coated paper is considered to be negligible.

In the application of peracetic acid as a disinfectant of animal drinking water, chronic exposure of farm animals *via* treated water is possible. Based on the comparison of the concentrations of peracetic acid administered to experimental animals *via* the drinking water at concentrations ranging from 0.02 – 0.03 % peracetic acid (200 – 300 ppm or 200 – 300 mg peracetic acid/L) with the concentration in disinfected drinking water within PT5 (0.0025 %), no health risk for farm animals including their offspring is expected as concentrations applied for the disinfection of animal drinking water within PT5 are well below the no-adverse effect levels derived from available animal studies and the margin of safety for farm animals is considered to be sufficient. Similarly, drinking water studies performed with hydrogen peroxide in rats identified a NOAEL ranging from 0.1% to 0.6% in drinking water which provides also a sufficient margin of safety with respect to the hydrogen peroxide concentrations of 0.0042% applied for the disinfection of drinking water of farm animals. Council Dir 2011/84/EU allows use of hydrogen peroxide in oral products sold directly to consumers up to a maximum concentration of 0.1%. Products containing greater than 0.1% and up to 6% hydrogen peroxide must be applied under the supervision of a dental practitioner. Most importantly, the concentration of peracetic acid and hydrogen peroxide in drinking water causing no adverse effects in the offspring of a rat teratology study is also much higher than the concentration in drinking water for the intended use within PT5 thereby substantiating a sufficient margin of safety for a more sensitive segment of the animal population as well. In addition, the residual concentrations in the drinking water are much lower than the applied concentrations as rapid degradation happens.

Conclusion for combined exposure

Based on the absence of systemic effects after exposure towards peracetic acid, it is important to note in this context that the inhalation AEC values are not time-dependent and relate to the concentrations of peracetic acid in the air, which do not cause sensory irritation or corrosive effects. For this reason, only the highest inhalation exposure level is relevant and the addition of exposure levels and the calculation of a combined inhalation exposure during the different tasks are not relevant.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Abiotic decomposition is a significant degradation route for peracetic acid. Depending on environmental conditions, the abiotic decomposition can follow three different reactions: spontaneous decomposition, metal catalysed decomposition and hydrolysis. Spontaneous decomposition results in the formation of acetic acid and oxygen, while hydrolysis results in acetic acid and hydrogen peroxide. Abiotic decomposition rate increases with increasing pH and the role of hydrolysis become significant, when pH increases above 10.5. Phototransformation in water is not a significant degradation route for peracetic acid. The data for the phototransformation in air show that peracetic acid is not expected to persist in the atmosphere.

Peracetic acid degrades rapidly under conditions, where organic matter and microbial activity are present and it can be considered as readily biodegradable substance. DT50 for biodegradation of peracetic acid in the sewage sludge is 3 minutes (at 20°C) and in effluent water from a sewage treatment plant << 5 minutes. No reliable DT50 has been determined for surface waters or soil. Peracetic acid is not expected to be persistent, because organic substances and metal ions promoting the decomposition of peracetic acid are usually available in natural environments.

The adsorption of peracetic acid to aerosol particles, the volatilisation from water into air and the adsorption of peracetic acid to soil can be considered to be very low. Thus, peracetic acid mainly distributes in the aqueous phase if released into the environment.

The measured log Kow of −0.60 (at pH 7) indicates negligible potential of bioconcentration of peracetic acid in biota. Thus, peracetic acid is not expected to accumulate in organisms.

2.2.2.2. Effects assessment

In the acute aquatic tests, algae were found to be the most sensitive species with 72-h EC50 of 0.16 mg PAA/L. Fish with the lowest 96-h LC50 of 1.1 mg PAA/L and daphnia with the lowest 48-h EC50 of 0.73 mg PAA/L were less susceptible. The lowest available NOEC of 0.00069 mg PAA/L is for Zebra fish (*Danio rerio*) based on initial test concentrations, NOEC for daphnia is 0.0121 mg PAA/L. PNECaquatic is 0.069 µg PAA/L and PNECmarine 0.0069 µg PAA/L based on NOEC for fish. The assessment factors for PNECaquatic and PNECmarine are 10 and 100, respectively.

The PNEC for sewage treatment plant micro-organisms is 0.051 mg/l based on an assessment factor of 100. Acute terrestrial toxicity tests are available for earthworm, non-target plants and soil micro-organisms. PNECterrestrial is 0.282 mg PAA/kg_{wwt} based on the seedling emergence test with non-target plants (Brassica napus) with an assessment factor of 1000. Birds and mammals are not anticipated to be directly exposed to peracetic acid, thus risk assessment for bird and mammals is not considered necessary.

Aqueous products

Peracetic acid ($CH_3CO(O_2)H$) can be produced by reacting hydrogen peroxide (H_2O_2) with acetic acid (CH_3COOH) in aqueous solution. In this process, peracetic acid is not obtained as a pure substance but typically in the form of aqueous equilibrium solutions containing peracetic acid, acetic acid, hydrogen peroxide and water:

$$CH_3COOH + H_2O_2 \rightleftharpoons CH_3CO(O_2)H + H_2O$$

The amount of peracetic acid in the equilibrium solution can range from 0.4%, or even lower to 15 %, or higher. The equilibrium solution is the biocidal product which is placed on the market.

Hydrogen peroxide is part of the aqueous product and as such can be regarded as a potential second active substance in theoretical products 1 and 2 at a concentration of 25%

and in antiseptic foam at a concentration of 1.24%. In the environmental exposure and risk assessment the amount of hydrogen peroxide already present in the products is considered. The environmental hazard assessment of hydrogen peroxide is presented in the hydrogen peroxide CAR.

Acetic acid is equilibrium partner of peracetic acid and also a degradation product of peracetic acid. Acetic acid is regarded to be a substance of no concern, because its presence in the products does not trigger classification and labelling for the environment. In addition, when tested as a separate substance acetic acid is less toxic than solution of peracetic acid. Thus no separate exposure and risk assessment have been performed for acetic acid (see DocIIIB7.3).

2.2.2.3. PBT and POP assessment

Peracetic acid shows a very rapid biodegradation in sewage sludge with a DT50 of 3 minutes (at 20°C). Therefore, peracetic acid does not fulfil the criteria for a persistent compound. The measured log Kow of peracetic acid is −0.60 (at pH 7) indicating negligible potential of bioconcentration in biota, thus the bioaccumulation criterion is not fulfilled. The toxic endpoint is below the trigger of < 0.01 mg/L and thus the toxic criterion is fulfilled. Peracetic is not a PBT substance, as it fulfils only one of the three criteria.

Peracetic acid does not fulfil criteria for being persistent organic pollutant (POP). In addition, peracetic does not have potential for long-range transboundary atmospheric transport. The vapour pressure of peracetic acid is above 1000 Pa (14.1 hPa, 20 °C) even though the estimated atmospheric half-life (3.9 days) is more than two days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

2.2.2.4. Exposure assessment

Production

Emissions of peracetic acid into water are very limited, because any waste water is collected and reconditioned in a neutralising facility. Also releases into the air are negligible as nearly the whole production process is run in closed system.

Intended uses and emission routes in different PTs

PT 1: Hand disinfection in hospitals, health and animal care areas and food industry using products which are not washed off the skin. A hospital was used as a representative facility. The environmental emission evaluation is based on the assumption that the whole amount consumed is released to the facility drain of the hospital.

PT 2a: Disinfection of sewage/ waste water (including municipal waste water) by continuous dosing into the effluent stream of the STP.

PT 2b: Disinfection of surfaces in industrial premises, institutional and health care areas. Emission estimation is based on the consumption and the release is to the sewage system.

PT 2c: CIP (Clean In Place) in the pharmaceutical and cosmetic industry similarly to PT4c.

PT 2e: Laundry disinfection in closed washing machines by professionals. Emissions to the sewage system based on consumption are evaluated from the 'washing streets' use in medical sector. The emissions are to the waste water and via sewage treatment plant to surface water and further with sewage sludge application to soil.

PT 3a: Animal house disinfection by spraying. The application rates were used as a basis for the emission estimation via application of liquid manure/ slurry to agricultural land.

PT 3b/c: Animal house disinfection by foaming/fogging. The application rates were used as a basis for the emission estimation via application of liquid manure/ slurry to agricultural land.

PT 3d: Disinfection of boots in footbaths in animal production. Emission estimation is based on daily consumption and exposure is via STP or manure/ slurry.

PT 3e: Disinfection of animal's feet. The emission is to the slurry/manure storage tank and via application of manure/slurry to agricultural land or to STP.

PT 3f: Disinfection of equipment by dipping. Emission was assumed to be similar to PT3d, as in both uses similar sized vats are used and the content is assumed to be emptied into to the STP or manure/slurry storage tank.

PT 4a: Automated spraying in closed systems (aseptic filling of PET bottles, sterilisation of crown corks, cheese moulds and food crates in the beverage/ food industry).
PT 4b: Disinfection of equipment in the food and beverage industry by dipping and immersion .
PT 4c: CIP and disinfection of ion-exchangers in food and beverage industry.

For *PT 4a/b/c* processes the release from industrial uses of disinfectants in food and feed areas is calculated on the basis of the annual use of disinfectants and the annual amount of waste water in the standard sewage treatment plant, based on the fact that disinfection measures using different application techniques such as CIP, automated spraying, foaming, bottle rinsing, etc. take place on the same day. The residues from these different disinfection measures end up in the same waste water collecting tank before release to the sewer system.

PT 4d/e: *Disinfection of surfaces and equipment by low pressure manual spraying/manual application of foam* in industrial kitchens and meat processing industry. Emission estimation is based on consumption and the assumption that disinfectants are released to the facility drain with rinsing water.

PT 4f: Disinfection of milking parlour system. Emission estimation is based on consumption and the assumption that emission is to waste water and STP.

PT 5: Disinfection of animal drinking water evaluation is covered by PT3a.

PT 6: In-can preservation in the paper industry; disinfection of coating-colours and pigments for the coating of papers in the dry end of a paper mill.

PEC in STP and aquatic compartment

Assessment of potential routes of entry into the environment shows that emission to sewage system is the relevant route for the intended biocidal uses in PT1, PT2, PT4 and PT6. Direct emissions of peracetic acid to surface water do not occur in any of the biocidal uses evaluated.

Aqueous products: predicted environmental concentrations (PEC) in STP effluents ranged from 0.0003 µg/L to 0.13 µg/L for peracetic acid and 0.07 µg/L to 26.7 µg/L for hydrogen peroxide. After degradation in the STP, residual peracetic acid and hydrogen peroxide may reach surface water. Consequently, PECs in surface water (river) were assumed to be diluted 10-fold when entering the river. Peracetic acid and hydrogen peroxide in surface water do not partition to suspended matter or sediment to any relevant extent, calculated PECs in sediment ranged in general from 2.3×10^{-8} to 0.003 mg/kg and from 5.5×10^{-6} to 0.166 mg/kg, respectively.

PEC in air

Peracetic acid and hydrogen peroxide might enter the atmosphere duet to volatilisation from the STP and from disinfection of animal feet. The highest PEC in air was calculated to be 1.07 x 10^{-5} mg/m³ for peracetic acid and 5.3 x 10^{-5} mg/m^3 for hydrogen peroxide.

PEC in soil

No direct emissions to soil are expected following the biocidal uses of evaluated theoretical peracetic acid products. Indirect emissions are in principle possible from disinfection in animal housing (PT 3) and disinfection of animal drinking water (PT5), where residual peracetic acid and hydrogen peroxide might be spread to soil with manure. However, low amounts of peracetic acid and hydrogen peroxide are expected to remain in manure when spread to soil, due to the very rapid degradation in manure with high microbial populations and organic-matter content and the long storage times of manure before spreading to soil. Indirect emissions to soil are also possible from uses in PT1-4 and PT6 via the application of sewage sludge from the STP. Calculated PECs in soil ranged from 3.5 x 10^{-10} to 2.06 x 10^{-6} mg/kg for peracetic acid and from 9.4 x 10^{-8} to 9.39 x 10^{-5} mg/kg for hydrogen peroxide.

2.2.2.5. Risk characterisation

Aqueous peracetic acid

Peracetic acid products contain in addition to peracetic acid also hydrogen peroxide as a second active substance. The risks of two substances were evaluated separately and the risk of the product according to the TNsG on Product Evaluation using PEC/PNEC summation of active ingredients and substances of concern ($(PEC/PNEC)_{product} = \Sigma(PEC/PNEC)_{components}$).

STP

In the STP all the individual PEC/PNEC ratios for peracetic acid and hydrogen peroxide and also $\Sigma(PEC/PNEC)_{components}$ are below 0.01 indicating that there are no unacceptable risks to micro-organisms involved in the biological processes of the sewage treatment plants from the proposed uses of peracetic acid in theoretical products 1, 2 or antiseptic foam.

Aquatic compartments (including sediment)
All the individual PEC/PNEC for the aquatic compartment are below 1 except PT2a (disinfection of the waste water) indicating that there are uses in PT1 - 6 where no unacceptable risk for aquatic compartment is predicted (see table below).

Atmosphere
The exposure assessment showed that the emission of peracetic acid and hydrogen peroxide to air is negligible. Consequently, air is not an environmental compartment of concern.

Terrestrial compartment
All the estimated PEC/PNEC ratios are well below one indicating no unacceptable risk for soil organisms from proposed uses of peracetic acid in theoretical products 1, 2 and antiseptic foam in PT1 - 6. Other terrestrial organisms are not regarded to be exposed with the proposed use pattern.

Groundwater
Predicted concentrations of peracetic acid and hydrogen peroxide in the porewater of agricultural soil were l 9 x 10^{-6} µg/l - 3.7 x 10^{-3} µg/l and 6.4 x 10^{-4}µg/l - 0.10 µg/l,

respectively. Thus, the risk for groundwater contamination by peracetic acid or hydrogen peroxide above the trigger value of 0.1 µg/L as defined in directives 2006/118/EC and 98/83/EC is low.

Overview table of PEC/PNEC for PAA and hydrogen peroxide (aqueous solution). For the groundwater a PEC (µg/l) is presented, since the use of PEC/trigger value -ratio is unconvential for groundwater.

Exposure scenario		Peracetic acid PEC/PNEC	Hydrogen peroxide PEC/PNEC	∑PEC/ PNEC
PT1 – Hand disinfection	Surface water	0.0059	0.014	0.020
	STP	8.0×10^{-5}	3.88×10^{-4}	0.00047
	Soil	2.31×10^{-7}	0.00186	0.00186
	Groundwater	1.1×10^{-4}	0.0038	
PT 2a – Sewage/ waste water treatment in a labyrinth after STP - Standard Dilution factor of 10	Surface water	**56.5**	**16.1**	**72.6**
	STP	n.a.	n.a.	n.a.
	Soil	n.a.	n.a.	n.a.
	Groundwater	n.a.	n.a.	n.a.
PT 2b – Disinfection of surfaces in industrial, public and health care areas	Surface water	0.0143	0.017	0.031
	STP	1.9×10^{-4}	4.5×10^{-4}	6.4×10^{-4}
	Soil	5.56×10^{-7}	0.004	0.004
	Groundwater	2.6×10^{-4}	0.008	
PT 2c – CIP in the pharmaceutical and cosmetic industry	All compartments	See PT 4a/b/c	See PT 4a/b/c	See PT 4a/b/c
PT 2e – Laundry disinfection in closed washing machines by professionals	Surface water	0.075	0.084	0.159
	STP	1.0×10^{-3}	2.3×10^{-3}	3.3×10^{-3}
	Soil	2.9×10^{-6}	0.0109	0.011
	Groundwater	1.34×10^{-3}	0.022	
PT 3a/b/c – Disinfection of animal houses by spraying/ foaming/fogging	Surface water	n.a.	n.a.	n.a.
	STP	n.a.	n.a.	n.a.
	Soil	5.0×10^{-9}	0.000045	<0.0001
	Groundwater	1.0×10^{-5}	6.0×10^{-4}	
PT 3d – Disinfection of boots	Surface water	0.00046	0.00053	0.0010
	STP	6.3×10^{-6}	1.4×10^{-5}	2.0×10^{-5}
	Soil	4.15×10^{-9}	0.000052	<0.0001
	Groundwater	9×10^{-6}	6.4×10^{-4}	
PT 3e – Disinfection of animal's feet	Surface water	0.120	0.13	0.25
	STP	1.6×10^{-3}	3.5×10^{-3}	5.1×10^{-3}
	Soil	5.6×10^{-8}	0.00072	0.00072
	Groundwater	1.2×10^{-4}	8.9×10^{-3}	
PT 3f – Disinfection of equipment	All compartments	See PT3d	See PT3d	See PT3d
PT 4a - Automated spraying in closed	Surface water	0.083	0.062	0.15

Exposure scenario		Peracetic acid PEC/PNEC	Hydrogen peroxide PEC/PNEC	ΣPEC/ PNEC
systems PT 4b - Disinfection of equipment by dipping and immersion PT 4c - CIP and disinfection of ion exchangers	STP	1.1×10^{-3}	1.7×10^{-3}	2.8×10^{-3}
	Soil	3.2×10^{-6}	0.015	0.015
	Groundwater	1.63×10^{-3}	0.035	
PT 4d – Low pressure manual spraying PT 4e - Manual application of foam	Surface water	0.19	0.21	0.40
	STP	2.5×10^{-3}	5.7×10^{-3}	8.2×10^{-3}
	Soil	7.23×10^{-6}	0.052	0.052
	Groundwater	3.7×10^{-3}	0.10	
PT 4f – Disinfection of milking equipment	Surface water	0.0037	0.0046	0.0083
	STP	5.1×10^{-5}	1.2×10^{-4}	1.8×10^{-4}
	Soil	1.5×10^{-7}	0.0012	0.0012
	Groundwater	7.42×10^{-5}	0.0024	
PT5 – Disinfection of animal drinking water	All compartments	n.a.	n.a.	n.a.
PT6 – In can preservatives	All compartments	n.a.	n.a.	n.a.

Potential for secondary poisoning of peracetic acid

The log Kow of -0.60 (at pH 7) for peracetic acid and the log Kow of -1.57 for hydrogen peroxide indicate that both substances have a low potential for bioconcentration and bioaccumulation. Moreover, peracetic acid and hydrogen peroxide dissipate rapidly in the environment which is a further indication of their low accumulation potential.

Aggregated (environmental) exposure assessment for peracetic acid

According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant.

At the moment there is no regulatory interpretation how an identified unacceptable cumulative risk should be taken into account when approving active substances, since for approval one safe use is sufficient. Thus, approval of an active substance could not base on the outcome of the aggregated risk assessment. However, it is important to bring out if a potential cumulative risk is identified.

Aggregated environmental exposure assessment was performed for peracetic acid. For hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance.

For cumulative assessment between PTs emissions from disinfectant uses in PT1 and PT 2 to STP are added up, since they are representing wide dispersive use pattern. These scenarios are marked with "a" in the following table. In addition, there are possible overlapping combinations of emissions to a same STP from wide dispersive uses and industrial, non-dispersive uses. These non-dispersive scenarios are marked with "(a)". For the aggregated assessment, a combination of wide dispersive uses and one industrial use at a time could be selected, since it is unlikely that all possible industries are located in the same catchment area. However, only a worst case Elocal of PT4 (0.025 kg/d) was used in this assessment. In addition, no possible overlapping emissions into the same STP were identified between

PTs 1-5 and PT6, because the capacity of STP in PT 1-5 scenarios is 2000 m^3/d and in PT6 scenarios 5000 m^3/d. Between PT 6 and PT 12 a potential overlapping emission is possible, since the dry-end and wet-end operations in paper production might be discharging into the same STP (5000 m^3/d). However, the measurements performed in the coating colour and ultra-filtrated pigment slurries demonstrated degradation of peracetic acid and hydrogen peroxide in PT6. Therefore, there is no concern for cumulative environmental risks for peracetic acid or hydrogen peroxide when concerning PT 6 and PT12.

Summary of local emissions of peracetic acid and their relevance for cumulative risk assessment within PT and between PTs.

Product Type/Scenario	**Elocal (kg/d) considering degradation in the sewer system**	**Relevance within PT**	**Relevance between PTs**
PT1			
Hand disinfection	0.0008 kg/d		a
PT 2			
Laundry disinfection in closed washing machines (professional use)	0.010 kg/d	x	a
Laundry disinfection in closed washing machine (private use)	0.00087 kg/d	x	a
Disinfection of surfaces in industrial, public and health care areas	0.00192 kg/d	x	a
CIP in the pharmaceutical and cosmetic industry	0.011 kg/d	x	
Disinfection of medical equipment by dipping	0.016 kg/d	x	
PT 3			
Disinfection of boots	6.2×10^{-5} kg	x	
Disinfection of animal's feet	0.016 kg/d	x	
Disinfection of equipment	6.2×10^{-5} kg/d	x	
PT 4			
Automated spraying in closed systems Disinfection of equipment by dipping and immersion CIP and disinfection of ion exchangers	0.011 kg/d	x	(a)
Low pressure manual spraying Manual application of foam	0.025 kg/d	x	(a)
Disinfection of milking equipment	0.0005 kg/d	x	(a)

Summary of PECs for aggregated assessment within PTs (PT2, PT3 and PT4) and between PTs (wide dispersive uses from PT1 and PT2 and the worst case from PT4)

	Elocal kg/d	PEC_{STP} mg/l	$PEC_{aquat\ c}$ µg/l	PEC_{soil} mg/kg	PEC_{gw} µg/l
Within PTs					
PT 2	0.040	0.207	0.0207	3.3×10^{-6}	0.005
PT 3	0.016	0.083	0.008	1.31×10^{-6}	0.002
PT 4	0.037	0.191	0.019	3.0×10^{-6}	0.005
Between PTs					
PT1, PT2, PT4	0.039	0.202	0.020	3.2×10^{-6}	0.005

Summary of PEC/PNECs for aggregated assessment within PTs (PT2, PT3 and PT4) and between PTs (wide dispersive uses from PT1 and PT2 and the worst case from PT4)

	Elocal (kg/d)	$PEC/PNEC_{STP}$	$PEC/PNEC_{aquatic}$	$PEC/PNEC_{soil}$
PT 2	0.040	0.004	0.30	1.2×10^{-5}
PT 3	0.016	0.002	0.12	4.7×10^{-6}
PT 4	0.037	0.004	0.28	1.1×10^{-5}
PT1, PT2, PT4	0.039	0.004	0.29	1.1×10^{-5}

Highest PEC/PNEC values are found in aquatic compartment (see table above), and many of the risks ratio values are very low, thus there is no high concerns for cumulative environmental risks for peracetic acid.

2.2.3. Assessment of endocrine disruptor properties

Peracetic acid is not included in the Commission Staff Working Document on implementation of the 'Community Strategy for Endocrine Disrupters' - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.

2.3. Overall conclusions

The outcome of the assessment for Peracetic acid in product-types 1-6 is specified in the BPC opinions following discussions at the 10th and adoption at the 12th meeting of the Biocidal Products Committee (BPC). The BPC opinions are available from the ECHA website.

2.4. List of endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

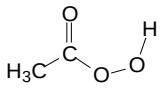
Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Peracetic acid
Product-type	Bactericide, fungicide and virucide

Identity

Chemical name (IUPAC)	Peroxyethanoic acid
Chemical name (CA)	Peracetic acid
CAS No	79-21-0
EC No	201-186-8
Other substance No.	None available
Minimum purity of the active substance as manufactured (g/kg or g/l)	**Pure peracetic acid** does neither exist commercially nor is it an intermediate in the production of peracetic acid products. Furthermore, any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide (H_2O_2) with acetic acid in aqueous solution. In this process, peracetic acid is **not** obtained as a pure substance but in the form of aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide and water. The peracetic acid content in existing aqueous equilibrium solutions (products) can be as low as < 0.1% or as high as > 15% (w/w). The equilibrium solution is typically the biocidal product which is placed on the market. The specifications are based on the starting materials acetic acid and hydrogen peroxide. The specification of (starting material) acetic acid is as in accordance to Regulation 231/2012. The minimum purity of acetic acid is $\geq$99.8% For (starting material) hydrogen peroxide the specification is as in the Hydrogen peroxide CAR in PTs 1-6, and the purity/contents in aqueous solution is 35% – 69.9%, as in Regulation (EU) 2015/1730. **Concentrated (non-equilibrium) PAA** From equilibrium solutions of PAA, non-equilibrium PAA (with only minor amounts of acetic acid and hydrogen peroxide) can be produced by vacuum distillation. The current risk assessment does not cover formulations

	containing higher than 15 % PAA concentrations.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Because the pure active substance is not available, the impurities and additives are not applicable for the active substance peracetic acid. The maximum impurities of acetic acid are in accordance to Regulation 231/2012. The maximum impurities of hydrogen peroxide are as defined in the CAR for HP PTs1-6, including total impurities of 0.2% (w/w), and max limits for heavy metals Hg, Cd, As, Pb. The confidential identity document in HP CAR contains other confidential information. The technical active substance peracetic acid contains also sulphuric acid (max 10 g/kg) as a catalyzer and 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (max 14 g/kg) and dipicolinic acid (max 1.6 g/kg) in aqueous solution, as stabilizers.
Molecular formula	$C_2H_4O_3$
Molecular mass	76.05 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	The melting points of 5% equilibrium solutions are in the range of -26°C to -30°C. The melting points of 15% equilibrium solutions are in the range of -30°C to -50°C. The melting point of the representative "Peracetic acid 15%" is -73°C. The melting point of the pure PAA is 0ºC.
Boiling point (state purity)	The boiling points of 5% equilibrium solutions are in the range of 99°C to 105°C. The boiling points of 15% equilibrium solutions are above 100°C. For neat PAA, a boiling point of 110°C at 760 mmHg was calculated. The boiling point of the representative "Peracetic acid 15%" is 105°C.
Temperature of decomposition	Decomposition of PAA can be initiated by high temperatures, high pH and contamination with metal catalysts such as copper, iron, and chromium, and incompatible organic materials. The decomposition of PAA is strongly exothermic,

	liberating large volume of oxygen gas.
Appearance (state purity)	Clear, colorless liquid (all PAA solutions)
Relative density (state purity)	D^{20}_4 = 1.1535 (15% equilibrium product "PEROXYACETIC ACID 15%") D^{20}_4 = 1.1284 (5% equilibrium product "PEROXYACETIC ACID 5%")
Surface tension	54.0 mN/m at 20°C (ring method, 5% equilibrium product "PEROXYACETIC ACID 5%") 47.7 mN/m at 20°C (ring method, 15% equilibrium product "PEROXYACETIC ACID 15%") This indicates that PAA does not need to be regarded as surface active, because only substances exhibiting a surface tension < 60 mN/m when tested at a concentration of 0.1% are regarded as surface active.
Vapour pressure (in Pa, state temperature)	$p_{(20°C)}$ = 14.1 hPa The overall vapour pressure of the representative product "Peracetic acid 15%" is 17 hPa.
Henry's law constant (Pa m^3 mol^{-1})	0.217 Pa $m^3 mol^{-1}$.
Solubility in water (g/l or mg/l, state temperature)	Completely miscible with water at any ratio
Solubility in organic solvents (in g/l or mg/l, state temperature)	**Solubility at 25°C (**15% equilibrium product "PEROXYACETIC ACID 15%"**):** n-Heptane: < 10 g/l p-Xylene: < 10 g/l 1,2-Dichloroethane: < 10 g/l Propan-2-ol: > 500 g/l Acetone: > 500 g/l Ethyl acetate: 20-25 g/l
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable: Peracetic acid is not formulated with organic solvents.
Partition coefficient (log P_{OW}) (state temperature)	pH___5___: -0.46 (temperature not indicated) pH___7___: -0.60 (temperature not indicated) pH___9___: -0.66 (temperature not indicated) QSAR calculation: logP_{ow} = -0.23 at pH 5, -0.26 at pH 7 and -1.2 at pH 9

Hydrolytic stability (DT_{50}) (state pH and temperature)	Determined for an initial TS concentration (C_0) of 0.001 mol PAA/L (95 ppm): pH___4___: 46.7 hours (at 25°C)
	pH___7___: 31.7 hours (at 25°C)
	pH___9___: 3.6 hours (at 25°C)
Dissociation constant	pK_a = 8.2 (literature data) pK_a = 8.24 (determined using 15% equilibrium product "PEROXYACETIC ACID 15%")
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	The UV-VIS spectra at pH <2, 7 and >12 showed no absorption maxima.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb light in the visible wavelength range.
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable because of lack of absorption of light in the visible wavelength range
Flammability	15% equilibrium product "PEROXYACETIC ACID 15%": Auto-ignition temperature: 280 °C 5% equilibrium product "PEROXYACETIC ACID 5%": Auto-ignition temperature: 435 °C According to information, which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60 °C.
Explosive properties	5% and 15% equilibrium products ("PEROXYACETIC ACID 5% and 15%"): not explosive (no mechanical and thermal sensitivity). Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. Detailed explosive limits are unknown in the literature. Under CLP, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides.

Classification and proposed labelling

with regard to physical/chemical data	**Current classification of peracetic acid according to Regulation 1272/2008:** Flam. Liq. 3; H226 Flammable liquid and vapour Org. Perox. D ****; H242 Heating may cause a fire Pictogram: GHS02 **Current classification of peracetic acid according to Directive 67/548/EEC:**

	O; R7 May cause fire R10 Flammable
with regard to toxicological data	**Current classification of peracetic acid according to Regulation 1272/2008:** Acute Tox. 4 *; H332 Harmful if inhaled Acute Tox. 4 *; H312 Harmful in contact with skin Acute Tox. 4 *; H302 Harmful if swallowed Skin Corr. 1A; H314 Causes severe skin burns and eye damage STOT SE 3; H335 May cause respiratory irritation Specific Concentration Limits: STOT SE 3; H335: C ≥ 1% Pictograms: GHS05, GHS07 Signal Word Code: Danger **Current classification of peracetic acid according to Directive 67/548/EEC:** C; R35 Causes severe burns Xn; R20/21/22 Harmful by inhalation, in contact with skin and if swallowed Concentration Limits: Xn; R20/21/22: C ≥ 10 % C; R35: C ≥ 10 % C; R34: 5 % ≤ C < 10 % Xi; R36/37/38: 1 % ≤ C < 5 %
with regard to fate and behaviour data	No classification
with regard to ecotoxicological data	**Current classification of peracetic acid according to Regulation 1272/2008:** Aquatic Acute 1; H400 Very toxic to aquatic life Pictogram: GHS09 **Current classification of peracetic acid according to Directive 67/548/EEC:** N; R50: very toxic to aquatic organisms

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Peracetic acid and hydrogen peroxide: Titration method. Peracetic acid: The sample is diluted in a solution of potassium iodide and an organic solvent at −10 °C. The liberated iodine is titrated with a sodium thiosulphate solution. Using these conditions, the hydrogen peroxide reacts very slowly with the iodide. If the titration is performed quickly, no significant interference from hydrogen peroxide occurs. Hydrogen peroxide: The sample is dissolved

	in diluted sulphuric acid and cooled with ice. The hydrogen peroxide is titrated with ceric sulphate solution using ferroin as indicator.
Impurities in technical active substance (principle of method)	Acetic acid: Titration method. The sample to be analyzed is dissolved in deionized water and potentiometrically titrated with sodium hydroxide. The potential change is detected with the help of a single-rod pH electrode. Full validation will be required. Sulphuric acid: Ion chromatography: The sample is diluted with Millipore water and fed into the chromatographic system. By means of an anion exchanger, the sulfate is separated from the matrix components and detected *via* its conductivity. Quantification is based on the method of external standard calibration. 1-Hydroxyethane-1,1-diphosphonic acid (HEDP): Ion chromatography. By means of an anion exchange column, HEDP is separated from other components. After the separation, the phosphonates are oxidized in a first reaction step to orthophosphate. In a second step, the reagent vanadate-molybdate is added. As a reaction result, yellow phosphovanadomolybdic acid forms which is detected at 410 nm in the UV-VIS range. Quantification is based on the method of external standard calibration. Full validation of stabilizers will be required.

Analytical methods for residues

Soil (principle of method and LOQ)	Applicant's justification for non-submission of data for analytical method for soil is acceptable, because absorption to sediment is not likely to occur due to the physico-chemical properties of peracetic acid and rapid degradation in contact with organic material
Air (principle of method and LOQ)	Reverse-phase HPLC with UV detection . A special sampling device was developed for the simultaneous sampling of peracetic acid and hydrogen peroxide in air. The device consists of a set of quartz fibre filters impregnated with titanium oxysulfate, to sample hydrogen peroxide (cassette) and a tube filled with basic silica gel impregnated with MTSO. Air samples are first directed through the titanium oxysulfate impregnated filters and then through the MTSO impregnated silica gel. The filters impregnated with titanium oxysulfate sample hydrogen peroxide. The flow rate has to be chosen high enough so

	that the PAA could pass the titanium oxysulfate soaked filter without reaction. PAA is sampled by the MTSO impregnated silica gel under formation of MTSO. Immediately after sampling, the cassettes are desorbed with 5 – 10 mL of molar sulphuric acid. The solution is made up to 10 mL and analysed by reverse-phase column and UV-detection at 224 nm. Hydrogen peroxide is quantified *via* the titanium peroxysulfate by molecular absorption spectrometry. LOQ: 0.00072 mg/L (0.23 ppm) (peracetic acid), 0.32 ppm (hydrogen peroxide)
Water (principle of method and LOQ)	Reverse-phase HPLC with UV detection . The amount of PAA is determined by oxidation of methyl-p-tolyl-sulfide (MTS) to methyl-p-tolyl-sulfoxide (MTSO), which is stable in a solution for several days. The amount of MTS in a solution must be at least twice as much as the expected PAA amount to ensure a quantitative reaction. MTSO is determined by reversed phase HPLC with UV detection. H2O2 is enzymatically reduced with peroxidase in the presence of 4-amino-antipyrine and phenol. Under these conditions 4-(benzoquinone-mono-imino)-phenoxon is formed, a red complex molecule which is quantified photometrically at 505 nm. LOQ: 0.02 ppm (peracetic acid)
Body fluids and tissues (principle of method and LOQ)	Reverse-phase HPLC with UV detection . The amount of PAA is determined after oxidation of methyl-p-tolyl-sulfide (MTS) to methyl-p-tolyl-sulfoxide (MTSO), which is stable in a solution for several days. The amount of MTS in a solution must be at least twice as much as the expected PAA amount to ensure a quantitative reaction. MTSO is determined by reversed phase HPLC with UV detection. LOQ: 0.02 ppm (peracetic acid)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where

	relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the active substance:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the representative product(s):	Not determined, 100% as a default.
Distribution:	20 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin
Potential for accumulation:	No evidence for bioaccumulation
Rate and extent of excretion:	- approx. 30 – 60 % of the applied dose recovered as CO_2 after 72 hours with the majority formed after 24 hours; an initial lag phase of approx. 1 hour evident - about 17 % of given radioactivity excreted via the urine after 72 hours; majority of urinary excretion occurred after 24 hours - about 4 - 5 % of given radioactivity excreted via the faeces and 17 % via urine after 72 hours; majority of faecal excretion occurred after 24 hours
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	1020 mg/kg; (Acute Tox. 4 *, H302; Xn, R22) 85 mg/kg (100% PAA) (Acute Tox. 3; H301)
Rabbit LD_{50} dermal	1147 mg/kg; (Acute Tox. 4 *, H312; Xn, R21) 56.1 mg/kg (100% PAA) (Acute Tox. 2; H310)
Rat LC_{50} inhalation	1 mg/L ≤ LC50 ≤ 5 mg/L; (Acute Tox.4 *, H332; Xn, R20) LC50 0.204 mg/l (100% PAA) (Acute Tox. 2; H330)
Skin irritation	Corrosive; (Skin Corr. 1A, H314; C, R35)
Eye irritation	Corrosive (severe damage to the eyes) ; (Skin Corr. 1A H314; Xi, R41)

Skin sensitization (test method used and result)	Non-sensitising (GPMT)

Repeated dose toxicity

Species/ target / critical effect	Rat (oral): local irritation in stomach/gastro-intestinal-tract, no systemic effects
Lowest relevant oral NOAEL / LOAEL	90-days gavage study in rats NOAEL 15 mg/kg bw/day corresponding to 0.055% PAA
Lowest relevant dermal NOAEL / LOAEL	Not established
Lowest relevant inhalation NOAEL / LOAEL	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)

Genotoxicity

	In vitro: Positive results in *in vitro* cytogenetic assay (chromosome aberrations) in human lymphocytes. Negative results in Ames test, gene mutation assay in mammalian cells, negative/equivocal *in vitro* chromosome aberration assay with Chinese hamster lung fibroblasts *In vivo*: Equivocal in three micronucleus tests and *in vivo* UDS. The biological meaning of any result from the *in vivo* studies is questionable in view of uncertainty of the availability of the test substance in the target organ. Weight of evidence indicates no concern of mutagenic / genotoxic potential

Carcinogenicity

Species/type of tumour	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability) No concern of mutagenic / genotoxic potential. Site of contact carcinogenicity not tested.
lowest dose with tumours	n.a.

Reproductive toxicity

Species/ Reproduction target / critical effect	No indication of reproductive toxicity in 90-days oral and continuous breeding studies In the absence of both teratogenic effect and

	findings on reproductive organs in repeated dose toxicity studies, no study is required for this particular endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)
Lowest relevant reproductive NOAEL / LOAEL	n.a.
Species/Developmental target / critical effect	Rat: maternal effects: reductions in body weight, body weight gain developmental effects: impairment of ossification (bones missing or poor/hypertrophic ossification)
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Maternal: 12.5 mg PAA/kg bw/d Developmental: 12.5 mg PAA/kg bw/d

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No indicative signs from acute and repeated dose studies; no structural alerts
Lowest relevant developmental NOAEL / LOAEL.	n.a.

Other toxicological studies

Toxic effects on livestock and pets	Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid The toxicity of Peracetic acid has been investigated and it has been shown not to be mutagenic or teratogenic. In the summary report of the Committee for Veterinary Medicinal Products (CVMP) on Peracetic acid (EMEA/MRL/060/96-FINAL, Doc. No. 983-001), PAA is admitted for use in livestock animals and that there is no need to establish an MRL for PAA.

Studies related to the exposure of the a.s. to humans	Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. These degradation products will form in any species and no other pathways of degradation occur. No degradation pathways other than those known from animal studies are expected to occur. Thus, PAA will not be transformed to further substances which were not observed and assessed in the available mammalian toxicity studies.
Food and feeding stuffs	Peracetic acid (PAA) is not intended to be used in or on food or feeding stuff. In uses, however, where residues on food stuff packaging material cannot be excluded, no safety concern for does exist since PAA is rapidly degraded to the physiological metabolites hydrogen peroxide, oxygen and acetic acid. Based on the evaluation of and the conclusions made by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food, possible residues of PAA on food and feeding stuff are not considered to be associated with a safety concern.
Other tests related to exposure of the a.s. to human considered to be necessary	No other tests related to the exposure of the active substance to humans for the purpose of performing reliable human health risk assessments studies necessary. The proposed biocidal products are sufficiently covered by the aforementioned tests. There are no endpoints of concern which would require further testing.
Tests to assess toxic effects from metabolites of treated plants	Peracetic acid is not used in products for action against plants. Therefore, no tests to assess toxic effects of metabolites from treated plants are required.

Mechanistic studies	Based upon the known mode of action of peracetic acid, no mechanistic studies are required. The toxicity of PAA is due to its locally irritating properties, i.e. decomposition to hydrogen peroxide, oxygen and acetic acid. After contact with organs and tissues, hydrogen peroxide will undergo decomposition into water and oxygen. The primary toxicological effect (local irritation) is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact. PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. Acetic acid is introduced in the C2-pool or further metabolised via physiological pathways to carbon dioxide and water. All occurring metabolites are rapidly eliminated and do not bioaccumulate.
Further human health related studies	In view of the known mode of action and considering results of available mammalian toxicity studies, no further human health-related studies are required.

Medical data

Medical surveillance data on manufacturing plant personnel	No data available

Direct observations, e.g. clinical cases, poisoning incidents	1: The cytotoxic and irritating potential of peracetic acid in humans used as a disinfectant for hand washing procedures applied by surgeons was investigated. Three of 15 surgeons developed immediately erythema and 6 of 15 surgeons developed dermatosis of the hands after 7 days following daily soaping, brushing and disinfection of skin with PAA at a concentration of 0.5 %. PAA applied as Wofasteril caused dermal irritation reactions in a third of health care workers. 2: Several recommendations were made to allow a safe handling with concentrated PAA solutions: - wearing protective gloves and protective glasses for diluting concentrated PAA - dilutions should be made in a ventilated room - for spray application of dilutions for disinfection purposes a respirator should be used. 3: Effects of diluted PAA solutions used as an aerosol (0.8 % PAA) as a disinfectant for human skin (0.08 or 0.2 % PAA) and for the treatment of a recurrent, pruritic epidermitis (0.1 % PAA): - irritation of the respiratory tract, lachrimation, salivation, increased nasal discharge and partly temporal loss of olfactory senses (0.8 % PAA) - slight skin desquamation after 1 or 2 days without hypersensitivity (0.2 % PAA) - daily skin disinfection for 3 years using solutions of 0.2 % PAA mixed with alcohol did not cause any adverse effects - temporarily reduced skin roughness after 1 day. The hands appeared slippery when wet, smooth and well-manicured (0.2 % PAA) - treatment of a recurrent, pruritic epidermitis using a 0.1 % PAA successful - Concentrations of 0.2 % peracetic acid can be considered as non to only slightly irritating to skin. 4: After a Patch test with dilutions of 1:33 (1500 mg/L PAA), 1:20 (2500 mg/L PAA) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) it was concluded that up to 2500 mg/L PAA (corresponding to an about 0.25 % solution) is non-irritant. At 3300 mg/L PAA (corresponding to an about 0.33 % solution) is a mild irritant.

Health records, both form industry and any other sources	The Persteril dilution containing 0.2 % PAA was well tolerated by the 20 volunteers. The concentration of 0.2 % PAA is sufficient for eradication of pyogenic staphylococci and 97 % reduction of residual flora on the hand within 3 minutes. PAA does not have a residual effect. Solutions of PAA with concentrations of 0.2 % do not damage the skin.
Epidemiological studies on the general population	No data available
Diagnosis of poisoning including specific signs of poisoning and clinical tests	No data available
Sensitization/allergenicity observations	The cases of two subjects who developed cough wheezing and shortness of breath after being exposed to PAA-hydrogen peroxide (PAA-HP) vapours are investigated. The main symptoms observed were rhinorrhoea, conjunctivitis, continuous cough, breathlessness and chest tightness appeared after several hours of exposure to PAA-HP vapours and improved after removal from exposure. It was concluded that symptoms in these subjects were generated by an irritant mechanism and occupational prolonged exposure to vapours of PAA-HP mixtures caused symptoms which were the consequence of a sustained irritation process rather than a real asthmatic reaction.
Specific treatment in case of an accident or poisoning: first aid measures and medical treatment	Basic aid: decontamination and symptomatic treatment is warranted. No specific antidote is known. Eyes: In case of contact with eyes rinse thoroughly with water. Contact a physician immediately. Skin: Remove contaminated clothes. Wash affected body areas carefully with plenty of water and soap. Ingestion: Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Inhalation: Ensure supply of fresh air. Contact a physician as necessary.
Prognosis following poisoning	Depending on severity of effects

Summary	Value	Study	Safety factor
Peracetic acid:			
ADI (acceptable daily intake, external long-term reference dose)	n.a.; PAA does not cause systemic effects	-	-
AEL short-term/medium-term/long-term	n.a.; PAA does	-	-

	not cause systemic effects		
NOAEC dermal	0.2% for short/medium term	Human volunteer study	-
	0.1% for long-term	rabbit one year study	2
AEC inhalation	0.5 mg/m^3 (0.16 ppm)	Human data (NOAEC 0.5 ppm)	3.16
ARfD (acute reference dose)	n.a.; PAA does not cause systemic effects	-	-
Reference value for inhalation (proposed OEL)	-	-	-
Reference value for dermal absorption concerning the active substance:	100% as a default	-	-
Reference value for dermal absorption concerning the representative product(s)[4]:	100% as a default	-	-

Hydrogen peroxide:

Skin irritating threshold	35%	classification limit for irritation	-
AEC inhalation	1.25 mg/m^3	NOAEC in 90-day inhalation rat study	8

Acceptable exposure scenarios (for method of calculation, please refer to Appendix IV)	
Professional users	
Production of active substance:	No risk characterisation is made.
Formulation of biocidal product	No risk characterisation is made.

Intended uses	PT1 Hand disinfection: PPE in mixing & loading (goggles + skin protection), application acceptable at concentration of ≤ 0.2% in the short and medium term use, and ≤ 0.1% in long-term use (dermal NOAEC). PT2a) Disinfection of sewage/ waste water (including municipal waste water): PPE in mixing & loading (goggles + skin protection +RPE if insufficient ventilation) PT2b) Disinfection of surfaces in industrial, public and health care areas: PPE (goggles + skin protection +RPE if insufficient ventilation) PT2c) CIP in the pharmaceutical and cosmetic industry: PPE in mixing & loading (goggles + skin protection +RPE if insufficient ventilation) PT2d) Laundry disinfection in closed washing machines: PPE (goggles + skin protection +RPE if insufficient ventilation) PT3a) Disinfection of animal houses by low-pressure manual spraying: PPE (goggles + skin protection +RPE) PT3b) Disinfection of animal houses by foaming: PPE (goggles + skin protection + RPE) PT3c) Disinfection of animal houses by fogging: PPE (goggles + skin protection + +RPE if insufficient ventilation) PT3d) Disinfection of boots in footbaths in animal production: PPE (goggles + skin protection) PT3e) Disinfection of animal feet (hoof disinfection): PPE (goggles + skin protection) PT3f) Disinfection of equipment by dipping: PPE (goggles + skin protection +RPE if insufficient ventilation) PT4a) Automated spraying in closed system (aseptic filling of PET bottles, sterilisation of crown corks, cheese moulds and food crates in the beverage/ food industry): PPE (goggles + skin protection + +RPE if insufficient ventilation) PT4b) Disinfection of equipment in the food and beverage industry by dipping and immersion: PPE (goggles + skin protection +RPE if insufficient ventilation) PT4c) CIP and disinfection of ion-exchangers in the food and beverage industry: PPE (goggles + skin protection +RPE if insufficient ventilation) PT4d) Disinfection of surfaces and equipment by low pressure manual spraying: PPE (goggles + skin protection + RPE) PT4e) Disinfection of surfaces by foaming: PPE (goggles + skin protection + RPE) PT4f) Disinfection of milking parlours: PPE (goggles + skin protection +RPE if insufficient ventilation) PT5 Disinfection of animal drinking water: PPE (goggles + skin protection +RPE if insufficient ventilation) PT6 In-can preservation in the paper industry: PPE (goggles + skin protection +RPE if insufficient ventilation)

Secondary exposure	Bystander/non-user secondary inhalation exposure during cleaning/disinfection of surfaces (PT2) Bystander/non-user secondary inhalation exposure after spraying, foaming and fogging of animal houses (PT3) Consumer secondary dermal exposure via coated paper Secondary oral exposure of farm animals via disinfected animal drinking water
Non-professional users:	
Intended uses	PT1 Hand disinfection with a ready-to-use product
Indirect exposure as a result of use	-

Chapter 4:Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Determined for an initial TS concentration (C_0) of 0.001 mol PAA/L (95 ppm): pH__5___: 46.7 hours (at 25°C)
	pH__7___: 31.7 hours (at 25°C)
	pH__9___: 3.6 hours (at 25°C)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb light in the visible wavelength range. According to an Atkinson calculation, PAA degrades in the atmosphere with a DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.
Readily biodegradable (yes/no)	yes
Biodegradation in seawater	50% degradation within 2 minutes
Non-extractable residues	Not formed
Distribution in water / sediment systems (active substance)	Peracetic acid is expected to partition mainly into the aquatic compartment (96.9% mass amount), while only 0.132% is expected to partition to soil, 2.99 % to the air and only 0.00001 % into sediment (fugacity level III calculation according to Mackay using EPIWIN v.3.20).
Distribution in water / sediment systems (metabolites)	Peracetic acid remains mainly in the water phase due to its high solubility in water and low K_{oc}. Any amount coming in contact with the sediment is rapidly decomposed. According to a fugacity level III calculation, peracetic acid only partitions into the sediment at very low rates (see above).

Route and rate of degradation in soil

Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Peracetic acid degrades rapidly when in contact with organic matter. This has been shown in the activated sludge test. Thus, peracetic acid is not expected to be persistent in soil. DT_{50lab} (20°C, aerobic): No reliable data available
	DT_{90lab} (20°C, aerobic): No reliable data available
	DT_{50lab} (10°C, aerobic): No reliable data available
	DT_{50lab} (20°C, anaerobic): not data
	Degradation in the saturated zone: no data.
Field studies (state location, range or median with number of measurements)	DT_{50f}: no data from field studies available
	DT_{90f}: no data from field studies available
Anaerobic degradation	Peracetic acid degrades rapidly when in contact with organic matter. This has been shown in the activated sludge test. Though the degradation of peracetic acid is mediated by micro-organisms, the main pathway is through decomposition in contact with organic matter. The latter process is independent of the oxidative status (aerobic/ anaerobic conditions) of the environment. Further, peracetic acid itself liberates oxygen upon decomposition.
Soil photolysis	Not expected to contribute to the degradation of peracetic acid because peracetic acid does not absorb light in the visible wavelength range.
Non-extractable residues	None formed
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	Peracetic acid is degraded to acetic acid, hydrogen peroxide and finally to CO_2, water and oxygen.
Soil accumulation and plateau concentration	No accumulation due to rapid and complete degradation to CO_2, water and oygen.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	The adsorption coefficient was calculated applying QSAR (according to page 26 of TGD) for soil and sediment. The calculated Koc is 1.46 l/kg.

	Consequently, peracetic acid is to be considered as mobile in soil and sediment.

Fate and behaviour in air

Direct photolysis in air	Not applicable: no absorption of light in the visible wavelength range
Quantum yield of direct photolysis	Not applicable: no absorption of light
Photo-oxidative degradation in air	According to an Atkinson calculation of the atmospheric residence time, peracetic acid degrades in the atmosphere with a DT_{50} of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.
Volatilization	The measured Henry's Law constant of 0.217 Pa m^3 mol^{-1} indicates that volatilisation from surface water is not expected to be an important process.

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5:Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Lepomis macrochirus (bluegill sunfish)	96 hours	Mortality	LC_{50} = 1.1 mg/L
Danio rerio (zebra fish)	33 days	Post hatch success / Overall survival	NOEC = 0.00069 mg/L
Invertebrates			
Daphnia magna	48 hours	Immobility	EC_{50} = 0.73 mg/L
Daphnia magna	21 days	Reproduction	NOEC = 0.0121 mg/L

Algae			
Selenastrum capricornutum	72 hours	Growth inhibition	EC_{50} = 0.16 mg/L NOEC = 0.061 mg/L
Microorganisms			
Activated sludge	3 hours	Respiration rate	EC_{50} = 5.1 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	14-day LC_{50}: > 1000 mg/kg dry soil equals > 885 mg/kg wet soil.
Reproductive toxicity to	No data available

Effects on soil micro-organisms

Nitrogen mineralization	28-day EC_{50}: > 933.6 mg/kg dry soil equals 826.2 mg/kg wet soil
Carbon mineralization	28-day EC_{50}: > 933.6 mg/kg dry soil equals 826.2 mg/kg wet soil

Effects on terrestrial plants

	21-day EC_{50}: 320 mg/kg dry soil equals 282 mg/kg wet soil (*Brassica napus)*, based on seedling emergence reduction)

Effects on terrestrial vertebrates

Acute toxicity to mammals	No data available and no data required
Acute toxicity to birds	No data available and no data required
Dietary toxicity to birds	No data available and no data required
Reproductive toxicity to birds	No data available and no data required

Effects on honeybees

Acute oral toxicity	No data available and no data required
Acute contact toxicity	No data available and no data required

Effects on other beneficial arthropods

Acute oral toxicity	No data available and no data required
Acute contact toxicity	No data available and no data required
Acute toxicity	

Bioconcentration

Bioconcentration factor (BCF)	The low $logP_{ow}$ (<< 3, see above) indicates that peracetic acid has a low potential for bio-concentration and bioaccumulation (according to guideline OECD 117, log P_{OW} values below 3 are regarded to be indicators of low accumulation potential). Moreover, peracetic acid dissipates rapidly in the environment. This is a further indication of low accumulation potential. Not experimentally determined
Depuration time (DT_{50}) (DT_{90})	Not applicable: no test performed Uptake of peracetic acid into the organism of fish can be excluded due the instantaneous degradation of peracetic acid in contact with organic material.
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not applicable: no test performed

Chapter 6:Other End Points

Appendix II: List of Intended Uses

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks
(a)		(c)	Type(d-f) and concentration of as (i)	method, kind (f-h), number (k), and interval between applications (min), if relevant		(m)
Equilibrium peracetic acid						
MG/PT1 Hand disinfection in hospitals, health and animal care areas and food industry	PAA 5%, Anti-septic foam	Bacteria, fungi and viruses	Aqueous solution	The product is applied by pumping a pump applicator two to three times onto one hand and then rubbing the product on both sides of both hands for one minute. Product PAA 5% has to be diluted first, antiseptic foam is ready-to-use product. Daily use, 30 times per day	The maximum range of use concentrations is 150 – 2000 ppm PAA (resulting from dilution of PAA5%). Likely range of use concentrations is 150 – 350 ppm (ready-to-use products). Concentration in the ready-to-use product, antiseptic foam, is 170 ppm.	
MG1/PT2 Laundry disinfection in closed washing machines	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	The product is automatically dosed into the washing machine during the washing process. Daily use	The maximum concentration of PAA in the washing solution is 1200 ppm PAA. The application rate used as the basis for the environmental exposure assessment is 30 mL of a 15% - PAA product / kg laundry.	
MG1/PT2 Disinfection of sewage/ waste water	PAA 15%	Reduction of coliform bacteria in effluent	Aqueous solution	The product is automatically and continuously dosed into the effluent of an STP Daily use	The use concentration is 1.5 ppm PAA in the effluent (calculated value).	

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks
		water				
MG1/PT2 Disinfection of surfaces in industrial, public and health care areas	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	The product is applied by wiping of hard surfaces with flat mops or cleaning cloths. 220 days per year	Per m^2 surface, about 20 ml of treatment solution are used. Likely concentration is 1500 ppm.	
MG1/PT2 CIP in the pharmaceutical and cosmetic industry	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	The treatment solution is circulated through the pipework and tanks of the installations. Daily use	The use concentrations range between 50 and 600 ppm	
MG1/PT3 Disinfection of animal houses by low-pressure manual spraying	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Floors and walls of animal houses are disinfected by low pressure spraying with a hand held spray wand. The spraying is performed at low pressure avoiding the formation of aerosols. Frequency: two times a year - weekly applications	The maximum concentration of PAA in the spray solution is 500 ppm. The application rate used as the basis for the environmental exposure assessment is 300 ml spray solution per m^2 surface (150 mg PAA per m^2 surface).	
MG1/PT3 Disinfection of animal houses by foaming	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	The product is applied by foaming onto surfaces to be disinfected. Frequency: two times a year - weekly applications	Application concentrations are 100-1000 ppm PAA. Only 50 ml application solution per m^2 is applied, corresponding to 50 mg peracetic acid/m^2 treated surface.	
MG1/PT3 Disinfection of animal houses by fogging	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Tightly sealed animal houses are fogged in the absence of personnel: The product is applied by means of a thermal fogger, which is installed as a fixed-position machine within the animal house or	Application concentrations are 2000-5000 ppm.	

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks
				installed outside the building. In the latter case, the nozzle of the fogger is directed from the outside of the animal house into its interior through an aperture. Frequency of application: 2-9 times a year		
MG1/PT3 Disinfection of boots in footbaths in animal production	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Footbaths filled with PAA solution are placed at strategic points around the farm (at the entrance of the animal houses, in the interior of the buildings) so that personnel must step through vats when entering or leaving the building. Daily use	500 ppm PAA	
MG1/PT3 Disinfection of animal feet (hoof disinfection)	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Cows walk through vats (hoof baths) filled with PAA solution (100-1000 ppm PAA).	100-1000 ppm	
MG1/PT3 Disinfection of equipment by dipping	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Equipment is dipped into the bath which contains the treatment solutions and is removed after 15-30 minutes. Daily use	250 ppm PPA	
MG1/PT4 Automated spraying in closed systems (aseptic filling and sterilization of crown corks, cheese moulds and food crates in the food and beverage	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	The product is diluted in an automated process. The application, i.e. spraying or rinsing of bottles (inside and outside of bottles) or e.g. food crates, (cheese) moulds, crown corks, etc. takes place in a closed system (e.g. in closed aseptic filling machines). Daily use	The use concentration is between 20 and 3000 ppm peracetic acid in the spraying or rinsing solution.	

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks
industry)						
MG1/PT4 Disinfection of equipment in the food and beverage industry by dipping and immersion	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	The equipment to be disinfected is manually or automatically placed into the dipping baths (open or closed baths) and taken out after a residence time of max. 3 hours. Daily use	The application solution concentration is between 50 and 1000 ppm PAA.	
MG1/PT4 CIP and disinfection of ion exchangers in the food and beverage industry	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	CIP, "Cleaning-In-Place", is a method for cleaning/ disinfecting installations, equipment or machines by circulating the cleaning/ disinfecting solution through the pipework and tanks. This means, that it is not necessary to dismantle the installations before the cleaning process. The following CIP systems exist: - Single-use (single pass) CIP systems: The cleaning solution is not recycled. - Multi-use CIP-Systems: The cleaning solution is re-circulated into a CIP holding tank, and the concentration of the solution is re-adjusted (automatically monitored process). After several uses, the solution is drained to the STP. Daily use	The use concentrations range between 20 and 1500 ppm.	
MG1/PT4 Disinfection of surfaces and equipment by	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	The product is sprayed over the surfaces/ objects to be disinfected. Frequency: 10-100 applications per year	The application concentration is 100-1000 ppm PAA in the treatment solution. Per m^2 surface, 200 ml spray solution are applied.	

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks
low pressure spraying						
MG1/PT4 Disinfection of surfaces by foaming	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	Surfaces in animal houses are disinfected by foaming with a hand-held application wand. Frequency: 10-100 applications per year	Per m^2 surface, 50 ml of application solution are applied. The application concentration is 100-1000 ppm PAA in the treatment solution.	
MG1/PT4 Disinfection of milking parlors	PAA 5%	Bacteria, fungi and viruses	Aqueous solution	The pipe work and tanks of the milking installation are disinfected by circulating the treatment solution through the system. Daily use	The application solution concentration is between 50 and 250 ppm PAA, depending on the disinfection program chosen.	
MG1/PT5 Disinfection of animal drinking water	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	Animal drinking water is disinfected by automated dosing of the product into the water stream. Daily use	The standard concentration of peracetic acid in the application solution is 25 ppm.	
MG1/PT6 In can preservation in the paper industry	PAA 15%	Bacteria, fungi and viruses	Aqueous solution	The product is pumped as such in an automated process into the product to be protected and is then mixed automatically. Daily use	700 -3000 ppm peracetic acid in the product to be protected	

*Theoretical product 1 (PAA 5%) and theoretical product 2 (PAA 15%) are referred to in the table as PAA 5% and PAA 15%; respectively.
(a) e.g. biting and suckling insects, fungi, molds; (b) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, e.g. overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Reference list Doc IIIA by Section Points:

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 2.10/01	Rowbottom, K.	1996	SOLVAY MEMO - ATMOSPHERIC MONITORING DURING FILLING OF IBC´S WITH PERACETIC ACID AT ELLIS AND EVERARD ON THE 27TH MARCH 1996 Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/04	Lebert Weitzel	1990	ARBEITSPLATZMESSUNGEN AUF PERESSIGSÄURE IN DER RAUMLUFT Source: Degussa AG, Hanau, Germany Report No.: U 288/901 Not GLP; (unpublished) Doc. No.: 574-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/07	Rowbottom, K.	1996	SOLVAY MEMO - ATMOSPHERIC MONITORING AT NORTH DEVON DISTRICT HOSPITAL IN BARNSTAPLE - 2ND DECEMBER 1996 Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/08	McDonagh, J.	1997	ATMOSPHERIC MONITORING OF PERACETIC ACID ON THE EXISTING CAPROLACTONE PLANT DISTILLATION HOUSES A & B - ASSESSMENT OF RESULTS Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/09	Fraser, J.A.L. Thorbinson, A.	1986	FOGGING TRIALS WITH TENNECO ORGANICS LIMITED (30TH JUNE, 1986) AT COLLARDS FARM Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 575-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/10	Guiver, R.	1999	A REPORT OF 16 VISITS ADDRESSING OCCUPATIONAL EXPOSURE ARISING FROM DIPPING ACTIVITIES WITH BIOCIDES AND NON AGRICULTURAL PESTICIDES Source: Health and Safety Executive, UK Report No.: 3830/R51.169 Not GLP; (unpublished) Doc. No.: 575-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 3.1.1/01	Anonymous	2001	ECETOC - PERACETIC ACID (CAS NO. 79-21-0) AND ITS EQUILIBRIUM SOLUTIONS Source: European Centre for Ecotoxicology and Toxicology of Chemicals,(2001) , pp. 152, ISSN: 0733-6339-40 Report No.: 40 Not GLP; (published) Doc. No.: 092-003	No	N.R.
A3.1.1/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE MELTING POINT AND BOILING POINT OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.1 GLP; (unpublished) Doc. No.: 112-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.1.2/01	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R XVIII, 1969, Vol. 6, pp. 1167-1170 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-002	No	N.R.
A 3.1.2/02	Swern, D.	1970	ORGANIC PEROXIDES VOLUME 1 Source: Fels Research Institute and Department of Chemistry Temple University, Philadelphia, Pennsylvania Report No.: Not applicable Not GLP; (published) Doc. No.: 192-003	No	N.R.
A3.2/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE VAPOUR PRESSURE OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.3 0649 82474 GLP; (unpublished) Doc. No.: 115-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.2.1/01	Lind, J.A. Kok, G.L.	1986	HENRY´S LAW DETERMINATIONS FOR AQUEOUS SOLUTIONS OF HYDROGEN PEROXIDE, METHYLHYDROPEROXIDE, AND PEROXYACETIC ACID Source: Journal of Geophysical Research, Vol. 91, No. D7, pp. 7889-7895 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-005	No	N.R.
A3.4/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE UV/VIS SPECTRUM OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.4 GLP; (unpublished) Doc. No.: 217-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.4/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE IR SPECTRUM OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.6 GLP; (unpublished) Doc. No.: 217-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.4/03	Mekelburger, H.-B.	2007	DETERMINATION OF THE 1H-NMR SPECTRUM OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.5 GLP; (unpublished) Doc. No.: 217-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A3.6/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE DISSOCIATION CONSTANTS IN WATER OF PEROXYACETIC ACID 15 % (INCLUDING AMENDMENT) Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.7 GLP; (unpublished) Doc. No.: 115-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.7/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE SOLUBILITY IN ORGANIC SOLVENTS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.8 GLP; (unpublished) Doc. No.: 215-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.9/01	Byers, L.	1998	CORRESPONDENCE BETWEEN CAROPRESO AND BYERS (FMC) - OCTANOL-WATER PARTITION COEFFICIENT FOR PERACETIC ACID AND HYDROGEN PEROXIDE Source: Not applicable Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 114-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.9/02	Thus, J.	1994	FAX COMMUNICATION ON CALCULATION OF THE OCTANOL/WATER PARTITION COEFFICIENT OF PERACETIC ACID Source: SOLVAY PHARMACEUTICALS, NL Report No.: JLGT/ybz/56835/cor/94-179 Not GLP; (unpublished) Doc. No.: 114-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.9/03	Brachhold, H.	2007	ESTIMATION OF THE PARTITION COEFFICIENT (N-OCTANOL/WATER) OF PERACETIC ACID Source: Degussa AG, Hanau, Germany Report No.: 2007-0094-DKB Not GLP; (unpublished) Doc. No.: 154-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A3.10/01 Post-submission	Schrieber, M.	2000	BESTIMMUNG SICHERHEITSTECHNISCHER KENNGRÖSSEN FÜR P3-TSUNAMI 100 UND P3-oxonia active Henkel Analytik, Düsseldorf Report No.: 00-10286 Not GLP, unpublished Doc. No.: 241-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.15/01 Post-submission	Kratz, W.	1977	DIE BILDUNG EXPLOSIVER DÄMPFE ÜBER GLEICHGEWICHTSPERESSIGSÄUREN Degussa AG, Hanau, Germany Report No.: 261 Not GLP, unpublished Doc. No.: 241-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries
A 4.1/01	Görg, J.	2005	ROUND ROBIN TEST - STATISTICAL EVALUATION OF THE TEST RESULTS FOR PERACETIC ACID AND HYDROGEN PEROXIDE IN A DISINFECTANTS Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-004 Not GLP; (unpublished) Doc. No.: 411-018	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/02	Richarz, J.	2007	BESTIMMUNG VON ESSIGSÄUREN IN P3 OXONIA ACTIVE 150 DURCH POTENTIOMETRISCHE TITRATION MIT NATRONLAUGE Source: Henkel KGaA Report No.: VTA32X07002.01 Not GLP; (unpublished) Doc. No.: 412-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/03	Richarz, J.	2007	IONENCHROMATOGRAPHISCHE BESTIMMUNG VON SULFAT IN OXONIA ACTIVE 150 Source: Henkel KGaA Report No.: VTA23X07001.01 Not GLP; (unpublished) Doc. No.: 412-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/04	Richarz, J.	2007	IONENCHROMATOGRAPHISCHE BESTIMMUNG VON HYDROXYETHAN-1,1-DIPHOSPHONSÄURE IN OXONIA ACTIVE 150 Source: Henkel KGaA Report No.: VTA23X07002.01 Not GLP; (unpublished) Doc. No.: 412-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.2b/01	Hecht, G. Héry, M. Hubert, G. Subra, I.	2004	SIMULTANEOUS SAMPLING OF PEROXYACETIC ACID AND HYDROGEN PEROXIDE IN WORKPLACE ATMOSPHERES Source: Ann. Occup. Hyg., Vol. 48, pp. 715-721, 2004, © 2004 British Occupational Hygiene Society, Published for Oxford University Press Report No.: Not applicable Not GLP; (published) Doc. No.: 436-003	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 4.2c/01	van Egdom, T.R.	2007	EVALUATION OF THE DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN EFFLUENT FROM A WASTE WATER TREATMENT PLANT Source: SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.025 GLP; (unpublished) Doc. No.: 714-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.2d/01	van Egdom, T.R.	2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.013 GLP; (unpublished) Doc. No.: 593-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/01	Alasri, A. Roques, C. Michel, G.	1992	BACTERICIDAL PROPERTIES OF PERACETIC ACID AND HYDROGEN PEROXIDE, ALONE AND IN COMBINATION, AND CHLORINE AND FORMALDEHYDE AGAINST BACTERIAL WATER STRAINS Source: Can. J. Microbiol, 1992, 38, 635-642 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-041	No	N.R.
A 5.3/02	Alasri, A. et al.	1993	SPOROCIDAL PROPERTIES OF PERACETIC ACID AND HYDROGEN PEROXIDE, ALONE AND IN COMBINATION, IN COMPARISON WITH CHLORINE AND FORMALDEHYDE FOR ULTRAFILTRATION MEMBRANE DISINFECTION Source: Can. J. Microbiol, 1993, 39, 52-60 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-042	No	N.R.
A 5.3/03	Mourcel, P.	2007	TEST CERTIFICATE N° 294 - DEPTIL POH - BATCH 10/28/24/2 Source: Laboratoire de Microbiologie et d´Hygiene, Dinard Cedex, France Report No.: FM 064G -2 Not GLP; (unpublished) Doc. No.: 321-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/04	Anonymous	2007	TEST CERTIFICATE N° 1014 - PRIMACID - BATCH C60P02 Source: Laboratoire de Microbiologie et d´Hygiene, Dinard Cedex, France Report No.: FM 064G -2 Not GLP; (unpublished) Doc. No.: 321-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/05	Schröder, W.	1982	PERESSIGSÄURE (PES) ALS DESINFEKTIONSWIRKSTOFF FÜR DIE LEBENSMITTELINDUSTRIE Source: Confrocia, Bd. 26 (9182) Nr. 5, pp. 139-147 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/06	Sagripanti, J.-L. Bonifacino, A.	1996	COMPARATIVE SPORICIDAL EFFECTS OF LIQUID CHEMICAL AGENTS Source: Applied and Environmental Microbiology, Feb. 1996, 62, 2, 545-551 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-056	No	N.R.
A 5.3/07	Baldry, M.G.	1983	THE BACTERICIDAL, FUNGICIDAL AND SPORICIDAL PROPERTIES OF HYDROGEN PEROXIDE AND PERACETIC ACID Source: Journal of Applied Bacteriology 1983, 54, 417-423 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-044	No	N.R.
A 5.3/08	Kliene, L.B. Hull, R.N.	1960	THE VIRUCIDAL PROPERTIES OF PERACETIC ACID Source: American Journal of Clinical Pathology, 1960, 30-33 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-051	No	N.R.
A 5.3/09	Kretzschmar, C. Agerth, R. Bauch, R. Friedrich, D.	1971	PERESSIGSÄURE - NUR EIN DESINFEKTIONSMITTEL? Source: Monatsheft, Veterinär Medizin, 27, pp. 324-332 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-003	No	N.R.
A 5.3/10	Meyer, E.	1976	ABWASSERDESINFEKTION IN TIERKÖRPERBESEITIGUNGSANSTALTEN MIT HILFE DER PERESSIGSÄURE Source: Journal of Hygiene, Epidemiology, Microbiology and Immunology 20, 1976, No. 3, pp. 266-273 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-004	No	N.R.
A 5.3/11	Juhr, N.-C. Klomburg, S. Haas, A.	1978	TRÄNKWASSERSTERILISATION MIT PERESSIGSÄURE Source: Z. Versuchstierk., Bd. 20, pp. 63-72 (1978) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-006	No	N.R.
A 5.3/12	Poffé, R. De Burggrave, A. Houtmeyers, J. Verachtert, H.	1978	DISINFECTION OF EFFLUENTS FROM MUNICIPAL SEWAGE TREATMENT PLANTS WITH PEROXY ACID Source: Zbl. Bakt. Hyg., I.Abt.-Orig. B 167, pp. 337-346, 1978 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-007	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/13	Jäger, P. Püspök, J.	1980	PERESSIGSÄURE ALS DESINFEKTIONSMITTEL IN BRAUEREIEN UND BETRIEBEN DER ALKOHOLFREIEN GETRÄNKEINDUSTRIE Source: Sonderdruck aus der Zeitschrift "Mitteilungen der Versuchsstation für das Gärungsgewerbe in Wien" - Nr. 3/4/1980 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-008	No	N.R.
A 5.3/14	Schröder, W.	1982	PERESSIGSÄURE (PES) ALS DESINFEKTIONSWIRKSTOFF FÜR DIE LEBENSMITTELINDUSTRIE Source: Confrocia, Bd. 26 (9182) Nr. 5, pp. 139-147 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.
A 5.3/15	Fraser, J.A.L.	1986	PEROXYGENS IN ENVIRONMENTAL PROTECTION Source: Effluent and Water Treatment Journal, June 1986, pp. 186-199 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-011	No	N.R.
A 5.3/16	Baldry, M.G.C. Fraser, J.A.L.	N.I.	DISINFECTION WITH PEROXYGENS Source: Industrial Biocides, Wiley, 91-116 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-061	No	N.R.
A 5.3/17	Anonymous	1988	REVIEW OF OPERATIONAL & EXPERIMENTAL TECHNIQUES FOR THE REMOVAL OF BACTERIA, VIRUSES & PATHOGENS FROM SEWAGE EFFLUENTS Source: Department of the EnvironmentConsultants in environmental sciences Ltd Report No.: PECD 7/7/260 Not GLP; (published) Doc. No.: 392-012	No	N.R.
A 5.3/18	Hopkinson, L.M.	1989	COMPARISON OF DISINFECTION TECHNIQUES FOR SEWAGE AND SEWAGE EFFLUENTS Source: J. IWEM. 1989, Vol. 3 December, pp. 612 -618 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-013	No	N.R.
A 5.3/19	Lefevre, F. Audic, J.M. Ferrand, F.	1992	PERACETIC ACID DISINFECTION OF SECONDARY EFFLUENTS DISCHARGED OFF COASTAL SEAWATER Source: Wst. Sci. Tech., Vol. 25, No. 11, pp. 155-164, 1992 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-014	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/20	Cords, B.R. Dychdala, G.R.	1993	SANITIZERS: HALOGENS, SURFACE-ACTIVE AGENTS, AND PEROXIDES Source: Name of Journal not indicated, pp. 469-537 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-016	No	N.R.
A 5.3/21	Liberti, L. Lopez, A. Notarnicola, M.	1998	DISINFECTION WITH PERACETIC ACID FOR MUNICIPAL WASTEWATER REUSE IN AGRICULTURE Source: Proc. Of Innovations 2000 - WEF/EWPCA Specialty Conference, 7-10 July 1998, Cambridge UK Report No.: Not applicable Not GLP; (published) Doc. No.: 392-023	No	N.R.
A 5.3/22	Veschetti, E. Cutilli, D. Bonadonna, L. Della Libera, S. Ottaviani, M.	1998	PRELIMINARY RESULTS ON THE POSSIBILITY OF USING PERACETIC ACID AS DISINFECTANT OF WASTEWATER Source: AWT98 - Advanced Wastewater Treatment, Recycling and Reuse, Milano 14+16 September 1998 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-024	No	N.R.
A 5.3/23	Liberti, L. Notarnicola, M.	1999	ADVANCED TREATMENT AND DISINFECTION FOR MUNICIPAL WASTEWATER REUSE IN AGRICULTURE Source: Wat. Sci. Tech. Vol 40, No. 4-5, pp. 235-245, 1999 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-025	No	N.R.
A 5.3/24	Baldry, M.G. French, M.S. Slater, D.	1991	THE ACTIVITY OF PERACETIC ACID ON SEWAGE INDICATOR BACTERIA AND VIRUSES Source: Wat. Sci. Tech., Vol. 24, No. 22, pp. 353-357, 1991 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-030	No	N.R.
A 5.3/25	Schließer, T._ Wiest, J.M.	1979	ZUR TEMPERATURABHÄNGIGKEIT DER BAKTERIZIDEN WIRKUNG EINIGER CHEMISCHER DESINFEKTIONSMITTEL - ABOUT THE TEMPERATURE DEPENDENCE OF THE BACTERICIDAL EFFECT OF SOME CHEMICALS DISINFECTANTS Source: Zbl. Bakt. Hyg., I. Abt. Orig. B 169, pp. 560-566, 1979 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-031	No	N.R.
A 5.3/26	Baldry, M.G. et al.	N.I.	DÉSINFECTION PAR L´ACIDE PERACÉTIQUE DES EFFLUENTS URBAINS - L´EXPÉRIENCE ANGLAISE Source: L´EAU, L´Industrie, Les Nuisances, N° 137, pp. 42-44, Mai 1990 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-032	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/27	Gönholm, L. et al.	1999	SCREENING OF ANTIMICROBIAL ACTIVITIES OF DISINFECTIONS AND CLEANING AGENTS FOODBORNE SPOILAGE MICROBES Source: Z Lebensm. Unters Forsch A 208 (1999), 289-298 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-035	No	N.R.
A 5.3/28	Antonelli, M. et al.	2006	SECONDARY EFFLUENT DISINFECTION: PAA LONG TERM EFFICIENCY Source: Environ. Sci. Technol., 2206, 40, 4771-4775 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-037	No	N.R.
A 5.3/29	Gilbert, P. et al.	2001	ASSESSMENT OF RESISTANCE TOWARDS BIOCIDES FOLLOWING THE ATTACHMENT OF MICRO-ORGANISMS TO, AND GROWTH ON, SURFACES Source: Journal of Applied Microbiology, 2001, 91, 248-254 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-038	No	N.R.
A 5.3/30	Colgan, S. Gehr, R.	2001	DISINFECTION - PERACETIC ACID GAINS FAVOR AS AN EFFECTIVE, ENVIRONMENTALLY BENIGN DISINFECTION ALTERNATIVE FOR MUNICIPAL WASTEWATER TREATMENT APPLICATIONS Source: WE&T, pp. 29-33, November 2001 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-015	No	N.R.
A 5.3/31	Clapp, P.A. et al.	1994	THE BACTERICIDAL ACTION OF PEROXIDES - AN E.P.R. SPIN-TRAPPING STUDY Source: Free Rad. Res. 1994, 21 (3), 147-167 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-045	No	N.R.
A 5.3/32	Marquis, R.E. et.al.	1995	SPORICIDAL ACTION OF PERACETIC ACID AND PROTECTIVE EFFECTS OF TRANSITION METAL IONS Source: Journal of Industrial Microbiology, 1995, 15, 486-492 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-054	No	N.R.
A 5.3/33	Block, S.	2001	DISINFECTION, STERILLISATION AND PRESERVATION Source: Lippincott Williams and Wilkins, 2001, (5), 191-200 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-040	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/34	Taylor, D.M.	1991	RESISTANCE OF THE ME7 SCRAPIE AGENT TO PERACETIC ACID Source: Verterinary Microbiology, 1991, 27, 19-24 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-058	No	N.R.
A 5.3/35	Antloga, K. et.al.	2000	PRION DISEASE AND MEDICAL DEVICES Source: Asaio Journal 2000, 46 (6), 69-72 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-043	No	N.R.
A 5.3/36	Ercken, D. et al.	2003	EFFECTS OF PERACETIC ACID AND MONOCHLORAMINE ON THE INACTIVATION OF NAEGLERIA LOVANIENSIS Source: Water Science and Technology, 2003, 47, 3, 167-171 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-066	No	N.R.
A 5.3/37	Sagripanti, J.-L. Bonifacino, A.	1996	COMPARATIVE SPORICIDAL EFFECTS OF LIQUID CHEMICAL AGENTS Source: Applied and Environmental Microbiology, Feb. 1996, 62, 2, 545-551 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-056	No	N.R.
A 5.3/38	Hussaini, S.N. Ruby, K.R.	1976	SPORICIDAL ACTIVITY OF PERACETIC ACID AGAINST B ANTHRACIS SPORES Source: Veterinary Record 1976, 98, 257-259 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-049	No	N.R.
A 5.3/39	Lensing, H.H. Oei, H.L.	1984	EEN ONDERZOEK NAAR DE WERKZAAMHEID VAN ONTSMETTINGSMIDDELEN TEN OPZICHTE VAN MILTVUURSPOREN - A STUDY ON THE EFFICACY OF DISINFECTANTS AGAINST ANTHRAX SPORES Source: Tijdschr. Diergeneeskd. 1984, 109, 557-563 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-052	No	N.R.
A 5.3/40	Lensing, H.H. Oei, H.L.	1985	INVESTIGATIONS ON THE SPORICIDAL AND FUNGICIDAL ACTIVITY OF DISINFECTANTS Source: Zbl. Bakt. Hyg., I.Abt. Orig. B. 1985, 181, 487-495 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-053	No	N.R.
A 5.3/41	Coates, D.	1996	SPORICIDAL ACTIVITY OF SODIUM DICHLOROISOCYANURATE, PEROXYGEN AND GLUTARALDEHYDE DISINFECTANTS AGAINST BACILLUS SUBTILIS Source: Journal of Hospital Infection, 1996, 32, 283-294 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-046	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/42	Ossia-Ongagnia, Y. Sabatier, R.	1993	COMPARAISON DE L´ACTIVITÉ IN VITRO DE SIX DÉSINFECTANTS SUR DES BACTÉRIES DE CONTAMINATION DES EAUX D´HÉMODIALYSE Source: J. Pharm. Belg., 1993, 48, 5, 341-351 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-055	No	N.R.
A 5.3/43	Griffiths, P.A. Babb, J.R. Fraise,A.P.	1999	MYCOBACTERICIDAL ACTIVITY OF SELECTED DISINFECTANTS USING A QUANTITATIVE SUSPENSION TEST Source: Journal of Hospital Infection, 1999, 41, 111-121 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-047	No	N.R.
A 5.3/44	Holton, J. Nye, P. McDonald, V.	1944	EFFICACY OF SELECTED DISINFECTANTS AGAINST MYCOBACTERIA AND CRYPTOSPORIDIA Source: Journal of Hospital Infection, 1994, 27, 105-115 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-048	No	N.R.
A 5.3/45	Jursch, C.A.	2002	MOLECULAR APPROACHES TO VALIDATE DISINFECTANTS AGAINST HUMAN HEPATITIS B VIRUS Source: Med Microbiol Immunol 2002, 190, 189-197 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-050	No	N.R.
A 5.3/46	Thamlikitkul, V. et al.	2001	MICROBIAL KILLING ACTIVITY OF PERACETIC ACID Source: J Med Assoc Thai, October 2001, 1375-1382 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-060	No	N.R.
A 5.3/47	Anonymous	2003	CONTROL OF POND ALGAE UTILIZING PERACETIC ACID CITY OF MODESTO, CA Source: Enviro Tech Chemcials, Inc, 2003, 1-6 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-067	No	N.R.
A 5.3/48	Anonymous	2002	DECONTAMINATION OF ENDOSCOPES Source: Device Bulletin DB 2002(05) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-064	No	N.R.
A 5.3/49	Bernet, C. Garcia, V.	2005	ACIDE PERACÉTIQUE - ACTIVITÉS ET USAGES EN ÉTABLISSEMENTS DE SANTÉ Source: Centre de Coordination de la Lutte contre les Infections Nosocomiales de l´inter-région Sud-Est, 2005 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-063	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/50	Mazzola, P.G. Martins, A.M. Penna, T.C.	2006	CHEMICAL RESISTANCE OF THE GRAM-NEGATIVE BACTERIA TO DIFFERENT SANITIZERS IN A WATER PURIFICATION SYSTEM Source: BMC Infectious Diseases 2006, 6, 131 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-078	No	N.R.
A 5.3/51	Landsrud, S. Sundheim, G. Borgmann-Strahsen, R.	2003	INTRINSIC AND ACQUIRED RESISTANCE TO QUATERNARY AMMONIUM COMPOUNDS IN FOOD-RELATED PSEUDOMONAS SPP. Source: Journal of Applied Microbiology, 2003, 95, 874-882 Report No.: Not indicated Not GLP; (published) Doc. No.: 392-077	No	N.R.
A 5.3/52	Ernst, C. et al.	2006	EFFICACY OF AMPHOTERIC SURFACTANT - AND PERACETIC ACID - BASED DISINFECTANTS ON SPORES OF BACILLUS CEREUS IN VITRO AND ON FOOD PREMISES OF THE GERMAN ARMED FORCES Source: Journal of Food Protection, 2006, 69, 7, 1605-1610 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-080	No	N.R.
A 5.3/53	Block, C.	2004	THE EFFECT OF PERASAFE AND SODIUM DICHLOROISOCYNURATE (NADCC) AGAINST SPORES OF CLOSTRIDIUM DIFFICILE AND BACILLUS ATROPHAEUS ON STAINLESS STEEL AND POLYVINYL CHLORIDE SURFACES Source: Journal of Hospital Infection, 2004, 57, 144-148 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-081	No	N.R.
A 5.3/54	Nattermann, H. et al.	2005	EFFIZIENTE ABTÖTUNG VON MILZBRANDSPOREN DURCH WÄSSRIGE UND ALKOHOLISCHE PERESSIGSÄURE-LÖSUNGEN Source: Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz, 2005, 8, 939-950 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-082	No	N.R.
A 5.3/55	Penney, N. et al.	2007	EFFICACY OF A PEROXYACETIC ACID FORMULATION AS AN ANTIMICROBIAL INTERVENTION TO REDUCE LEVELS OF INOCULATED ESCHERICHIA COLI O157;H7 ON EXTERNAL CARCASS SURFACES OF HOT-BONED BEEF AND VEAL Source: Journal of Food Protection, 2007, 70, 1, 200-203 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-086	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/56	Kasková, A. et al.	2007	APPLICATION OF PERACETIC ACID AND QUARTERNARY AMMONIUM DISINFECTANTS AS PART OF SANITARY TREATMENT IN A POULTRY HOUSE AND POULTRY PROCESSING PLANT Source: Zoonoses Public Health, 2007, 54, 125-130 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-087	No	N.R.
A 5.3/57	Lagacé, L. et al.	2006	BIOFILM FORMATION AND BIOCIDES SENSITIVITY OF PSEUDOMONAS MARGINALIS ISOLATED FROM A MAPLE SAP COLLECTION SYSTEM Source: Journal of Food Protection, 2006, 69, 10, 2411-2416 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-089	No	N.R.
A 5.3/58	Stampi, S. De Luca, G. Zanetti, F.	2001	EVALUATION OF THE EFFICIENCY OF PERACETIC ACID IN THE DISINFECTION OF SEWAGE EFFLUENTS Source: Journal of Applied Microbiology, 2001, 91, 833-838 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-072	No	N.R.
A 5.3/59	Brinez, W.J. et al.	2006	BACTERICIDAL EFFICACY OF PERACETIC ACID IN COMBINATION WITH HYDROGEN PEROXIDE AGAINST PATHOGENIC AND NON PATHOGENIC STRAINS OF STAPHYLOCOCCUS SPP., LISTERIA SPP., AND ESCHERICHIA COLI Source: Food Control, 2006, 17, 516-521 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-071	No	N.R.
A 5.3/60	Maillard, J.-Y. et al.	1994	EFFECT OF BIOCIDES ON MS2 AND K COLIPHAGES Source: Applied and Environmental Microbiology, June 1994, 60, 6, 2205-2206 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-073	No	N.R.
A 5.3/61	Ryu, J.-H. Beuchat, L.R.	2005	BIOFILM FORMATION AND SPORULATION BY BACILLUS CEREUS ON A STAINLESS STEEL SURFACE AND SUBSEQUENT RESISTANCE OF VEGETATIVE CELLS AND SPORES TO CHLORINE , CHLORINE DIOXIDE, AND A PEROXYACETIC ACID-BASED SANITIZER Source: Journal of Food Protection, 2005, 68, 12, 2614-2622 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-084	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/62	Bore, E. Langsrud, S.	2005	CHARACTERIZATION OF MICRO-ORGANISMS ISOLATED FROM DAIRY INDUSTRY AFTER CLEANING AND FOGGING DISINFECTION WITH ALKYL AMINE AND PERACETIC ACID Source: Journal of Applied Microbiology, 2005, 98, 96-105 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-092	No	N.R.
A 5.3/63	Hatunen, T.	2004	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI, FINLAND Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0603	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/64	Hatunen, T.	2005	PRESERVATION TEST - STORA ENSO FINE PAPERS OY OULU MILLS, OULU, FINLAND Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0604	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/65	Krapu, S.	2006	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI FINLAND Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0602	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/66	Hatunen, T.	2004	PRESERVATION TESTS - STORA ENSO OY OULU PPK 7, OULU, FINLAND Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0605	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/67	Krapu, S.	2006	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0601	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A A5.3/68	Mathieu, L. et al.	1990	EFFET DE L´ACIDE PERACETIQUE SUR DES BACTERIES EN SUSPENSION ET FIXEES Journal Francais d´Hydrologie, 1990, Fasc. 1, 101-111 Report No.: Not applicable Not GLP, published Doc. No.: 392-122	No	N.R.
A5.3/69	Marques, S.C. et al.	2007	FORMATION OF BIOFILMS BY STAPHYLOCOCCUS AUREUS ON STAINLESS STEEL AND GLASS SURFACE AND ITS RESISTANCE TO SOME SELECTED CHEMICAL SANITIZERS Brazilian Journal of Microbiology, 2007, 38, 538-543, ISSN 1517-8382 Report No.: Not applicable Not GLP, published Doc. No.: 392-109	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A5.3/70	Alasri, A.	1992	EFFETS DE DIFFÉRENTS BIOCIDES SUR UN BIOFILM MIXTE RÉALISÉ SUR TUBES TYGON ET SUR MEMBRANES D´ULTRAFILTRATION Spectra 2000, Octobre 1992, 168, 21-24 Report No.: Not applicable Not GLP, published Doc. No.: 392-128	No	N.R.
A5.3/71	Gebel, J.	N.I.	WIRKSAMKEITSPRÜFUNG BIOZIDER WIRKSTOFFE IN BIOFILMKONTAMINIERTEN SYSTEMEN UNTER PRAXISNAHEN BEDINGUNGEN Institut für Hygiene und Öffentliche Gesundheit der Universität Bonn Report No.: Not applicable Not GLP, published Doc. No.: 392-131	No	N.R.
A5.3/72	Flemming, H.-C.	2003	WIRKSAMKEIT VON WASSERSTOFFPEROXID GEGENÜBER BIOFILMEN Fakultät für Naturwissenschaften der Universität Duisburg-Essen Report No.: Not applicable Not GLP, published Doc. No.: 392-130	No	N.R.
A 6.1.1/01	[redacted]	1998	PERACETIC ACID 5 % - ACUTE ORAL TOXICITY STUDY IN RATS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 521-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/02	[redacted]	1985	ACUTE ORAL TOXICITY TO RATS OF 5% PEROXYACETIC ACID Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 521-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/03	[redacted]	1982	BERICHT - ÜBER DIE TOXIKOLOGISCHE PRÜFUNG VON PERESSIGSÄURE 15% NACH EINMALIGER ORALER GABE AN DER RATTE Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 521-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/04	[redacted]	1995	ACUTE ORAL TOXICITY IN RATS - MEDIAN LETHAL DOSAGE DETERMINATION OF: [redacted] Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 526-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.1.2/01	[redacted]	1996	[redacted] - ACUTE DERMAL TOXICITY STUDY IN RABBITS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 527-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.2/02	[redacted]	1996	[redacted] - ACUTE DERMAL TOXICITY STUDY IN RABBITS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 527-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.3/01	[redacted]	1994	ACUTE INHALATION TOXICITY STUDY WITH [redacted] IN MALE AND FEMALE RATS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 528-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.3/02	[redacted]	1985	INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF PEROXYACETIC ACID Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 523-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.3/03	Gagnaire, F. Marignac, B. Hecht, G. Hery, M.	2002	SENSORY IRRITATION OF ACETIC ACID, HYDROGEN PEROXIDE, PEROXYACETIC ACID AND THEIR MIXTURE IN MICE Source: © British Occupational Hygiene Society, Ann. Eurcup. Hyg., Vol. 46, No. 1, pp. 97-102, 2002 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-048	No	N.R.
A 6.1.4/01	[redacted]	1987	PRIMARY IRRITATION STUDY OF [redacted] TO THE SKIN OF THE MALE RABBIT Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 565-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/02	[redacted]	1988	PEROXYACETIC ACID 5% - ACUTE TOXICITY - TESTING THE PRIMARY IRRITANCY AFTER SINGLE APPLICATION TO THE SKIN OF THE RABBIT (PATCH TEST) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 565-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.1.4/03	[redacted]	1982	BERICHT ÜBER DIE PRÜFUNG DER LOKALEN REIZWIRKUNG VON PERESSIGSÄURE 15% NACH EINMALIGER APPLIKATION AN DER HAUT DES KANINCHENS (PATCH-TEST) Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 565-011	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/04	[redacted]	1991	PERACETIC ACID 0.15% USE DILUTION - PRIMARY EYE IRRITATION STUDY IN RABBITS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 566-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/05	[redacted]	1983	PRIMARY EYE IRRITATION STUDY OF DILUTE PERACETIC ACID IN RABBITS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 566-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.5/01	[redacted]	2000	UNTERSUCHUNGEN ZUR SENSIBILISIERUNG DER HAUT DURCH [redacted] IM MEERSCHWEINCHEN-MAXIMIERUNGSTEST Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 567-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/01	[redacted]	1994	PHARMACOKINETIC STUDIES ON PEROXYACETIC ACID AS A COMPONENT OF [redacted] IN THE RAT Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/02	[redacted]	2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 593-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/03	[redacted]	2003	DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN RAT BLOOD Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 514-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.2/04	Krüger, S. Jancke, S.	1976	ZUR PROBLEMATIK DER TIERVERTRÄGLICHKEIT VON PERESSIGSÄURE - 2. MITT.: QUALITÄTS- UND RÜCKSTANDSUNTERSUCHUNGEN AN FLEISCH NACH APPLIKATIONEN VON PERESSIGSÄUREHALTIGEN LÖSUNGEN AUF DIE HAUT VON SCHWEINEN Source: Monatsheft, Veter., Med., 31(2), pp. 65-68 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-006	No	N.R.
A 6.2/05	Anonymous	2001	ECETOC - PERACETIC ACID (CAS NO. 79-21-0) AND ITS EQUILIBRIUM SOLUTIONS Source: European Centre for Ecotoxicology and Toxicology of Chemicals,(2001) , pp. 152, ISSN: 0733-6339-40 Report No.: 40 Not GLP; (published) Doc. No.: 092-003	No	N.R.
A 6.3.1/01	Juhr, N.-C. Klomburg, S. Haas, A.	1978	TRÄNKWASSERSTERILISATION MIT PERESSIGSÄURE Source: Z. Versuchstierk., Bd. 20, pp. 63-72 (1978) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-006	No	N.R.
A 6.3.1/02	[redacted]	2004	PALATABILITY STUDY OF PERACETIC ACID BY REPEATED ORAL ADMINISTRATION VIA THE DRINKING WATER TO CD RATS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 568-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.3.1/03	Veger, J. Svihovcová, P. Benesová, O. Nejedlý, K.	1977	TOXICITE SUB-CHRONIQUE DU PERSTERIL PAR VOIE BUCCALE DU PERSTERIL Source: Journal "Ceskoslovenská Hygenia", N°22, 1977, C 2 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-011	No	N.R.
A 6.3.2/01	Kramer, A. et al.	1982	SUBAKUTE UND SUBCHRONISCHE PERCUTANE VERTRÄGLICHKEITSPRÜFUNG IM 28- UND 90-TAGE-TEST VON DESINFEKTIONSMITTELN BEI EPICUTANER APPLIKATION, DARGESTELLT AM BEISPIEL VON PEROXYETHANSÄURE Source: Pharmazie 37, H. 1,1982 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-019	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.3.3/01	Heinze, W. Werner, E. Fischer, A.R.	1981	WIRKUNG UND WIRKUNGSWEISE VON PERESSIGSÄURE-AEROSOLEN AUF DEN TIERISCHEN ORGANISMUS Source: Mh. Vet.-Med. 36, 1981, pp. 343-349 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-016	No	N.R.
A 6.3.3/02	Heinze, W. Hahn, T. Wrensch, G. Fischer, A.R.	1982	WIRKUNGSWEISE UND GRENZEN DER SCHADWIRKUNG VON PERESSIGSÄURE-(PES-), MILCHSÄURE- UND ESSIGSÄURE-AEROSOLEN SOWIE DEN PERESSIGSÄURE- UND SCHWEFELDIOXID-GASEN BEI SÄUGETIEREN Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. 1982, pp. 549-555 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-020	No	N.R.
A 6.3.3/03	Heinze, W. Werner, E. Krüger, S. Wilsdorf, G.	1979	ZUR TIERVERTRÄGLICHKEIT VON PERESSIGSÄURE-AEROSOLEN UNTER BESONDERER BERÜCKSICHTIGUNG DER BEEINTRÄCHTIGUNG DER ABWEHRLEISTUNG Source: Mh. Vet.-Med., Volume 34, 1979, pp. 212-217 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-012	No	N.R.
A 6.4.1/01	[redacted]	2003	13-WEEK TOXICITY STUDY BY ORAL ROUTE (GAVAGE) IN RATS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 533-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.4.2/01	Kramer, A. et al.	1982	SUBAKUTE UND SUBCHRONISCHE PERCUTANE VERTRÄGLICHKEITSPRÜFUNG IM 28- UND 90-TAGE-TEST VON DESINFEKTIONSMITTELN BEI EPICUTANER APPLIKATION, DARGESTELLT AM BEISPIEL VON PEROXYETHANSÄURE Source: Pharmazie 37, H. 1,1982 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-019	No	N.R.
A 6.4.3/01	Heinze, W. Nattermann, H.	1984	PERESSIGSÄURE-AEROSOL-WIRKUNG BEI LANGZEITANWENDUNG NIEDRIGER KEIMWIRKSAMER KONZENTRATION AUF VERSUCHSTIERE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R. XXXIII, 1984 Report No.: 6075 Not GLP; (published) Doc. No.: 592-057	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.5/01	Müller, P. Raabe, G. Hörold, J. Juretzek, U.	1988	ACTION OF CHRONIC PERACETIC ACID (WOFASTERIL) ADMINISTRATION ON THE RABBIT ORAL MUCOSA, VAGINAL MUCOSA, AND SKIN Source: Epx. Pathol. 1988, Volume 34, pp. 223-228 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-028	No	N.R.
A 6.6.1/01	Wallat	1984	P3 OXONIA AKTIV - PRÜFUNG AUF MUTAGENITÄT IM AMES-TEST Source: Henkel KGaA Report No.: 840154 Not GLP; (unpublished) Doc. No.: 557-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.1/02	Zeiger, E. Anderson, B. Hawort, S. Lawlor, T. Mortelmans, K.	1988	SALMONELLA MUTAGENICITY TESTS: IV. RESULTS FROM THE TESTING OF 300 CHEMICALS Source: Environmental and Molecular Mutagenesis Volume 11, Supplement 12, pp. 1-158, 1988 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-029	No	N.R.
A 6.6.2/01	Phillips, B.J.	1994	THE EFFECTS OF PROXITANE-0510 ON THE CHROMOSOMES OF CULTURED HUMAN LYMPHOCYTES Source: BIBRA Toxicology International Report No.: 1295/1/3/94 1295/1 GLP; (unpublished) Doc. No.: 557-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.2/02	[redacted]	2002	CHROMOSOME ABERRATION TEST IN CHINESE HAMSTER V79 CELLS IN VITRO WITH [redacted] Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.3/01	[redacted]	2002	GENE MUTATION TEST IN CHINESE HAMSTER V79 CELLS IN VITRO WITH [redacted] (HPRT-TEST) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.3/02	Coppinger, W.J. Wong, T.K. Thompson, E.D.	1983	UNSCHEDULED DNA SYNTHESIS AND DNA REPAIR STUDIES OF PEROXYACETIC AND MONOPEROXYDECANOIC ACIDS Source: Environmental Mutagenesis 5: pp. 177-192,1983 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-023	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.3/03	Buschini, A. Carboni, P. Furlini, M. Poli, P. Rossi, C.	2004	SODIUM HYPOCHLORITE-, CHLORINE DIOXIDE- AND PERACETIC ACID-INDUCED GENOTOXICITY DETECTED BY THE COMET ASSAY AND SACCHAROMYCES CEREVISIAE D7 TESTS Source: Mutagenesis, Vol. 19, No. 2, pp. 157-162 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-053	No	N.R.
A 6.6.4/01	[redacted]	1984	[redacted] - PRÜFUNG AUF MUTAGENITÄT IM MIKROKERN-TEST IN VIVO Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 557-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.4/02	[redacted]	1994	A MICRONUCLEUS TEST WITH [redacted] Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.4/03	[redacted]	2001	Maus-Mikrokerntest mit [redacted] nach oraler Applikation Source: [redacted] Report No.: [redacted] Doc. No.: 557-013 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.4/04	[redacted]	2003	Bone Marrow Micronucleus Test by Oral Route in Mice Source: [redacted] Report No.: [redacted] Doc. No.: 557-009 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.5/01	[redacted]	2002	MEASUREMENT OF UNSCHEDULED DNA SYNTHESIS (UDS) IN RAT HEPATOCYTES USING AN IN VIVO PROCEDURE WITH ACIDE PERACETIQUE 5 % Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.5/02	[redacted]	1994	AN IN VIVO UNSCHEDULED DNA SYNTHESIS ASSAY WITH [redacted] Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01a	Monarca, S. et al.	2001	MUTAGENICITY AND DISINFECTION BY-PRODUCTS IN SURFACE DRINKING WATER DISINFECTED WITH PERACETIC ACID Source: Environmental Toxicology and Chemistry, Vol. 21, No. 2, pp. 309-318, 2002 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-018	No	N.R.
A 6.6.7/01b	Crebelli, R. et al.	2003	EFFETTI GENOTOSSICI ED ECOTOSSICOLOGICI DI ACQUE REFLUE URBANE SOTTOPOSTE A DISINFEZIONE CON IPOCLORITO DI SODIO O ACIDO PERACETICO Source: Ann IG 2003, 15, 277-302 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-097	No	N.R.
A 6.6.7/01c	Monarca, S. Zani, C. Richardson, S.D. Thruston, A.D. Moretti, M. Feretti, D.	2004	A NEW APPROACH TO EVALUATION THE TOXICTY AND GENOTOXICITY OF DISINFECTED DRINKING WATER Source: Water Research 38, 2004, pp. 3809 - 3819 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-052	No	N.R.
A 6.6.7/01d	Guzzella, L. et al.	2004	IN VITRO POTENTIAL GENOTOXIC EFFECTS OF SURFACE DRINKING WATER TREATED WITH CHLORINE AND ALTERNATIVE DISINFECTANTS Source: Mutation Research 564, 2004, 179-193 Report No.: not applicable Not GLP; (published) Doc. No.: 592-099	No	N.R.
A 6.6.7/01e	Marabini, L. et al.	2006	TOXICITY EVALUATION OF SURFACE WATER TREATED WITH DIFFERENT DISINFECTANTS IN HEPG2 CELLS Source: Water Research, 40, 2006, pp.267-272 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-111	No	N.R.
A 6.6.7/01f	Crebelli, R. et al.	2005	GENOTOXICITY OF THE DISINFECTION BY-PRODUCTS RESULTING FROM PERACETIC ACID- OR HYPOCHLORITE-DISINFECTED SEWAGE WASTEWATER Source: Water Research 39, 2005, pp. 1105-1113 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-055	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01g	Maffei, F. et al.	2005	USE OF THE COMET TEST AND MICRONUCLEUS ASSAY ON HUMAN WHITE BLOOD CELLS FOR IN VITRO ASSESSMENT OF GENOTOXICITY INDUCED BY DIFFERENT DRINKING WATER DISINFECTION PROTOCOLS Source: Environmental and Molecular Mutagenesis 2005, 46, 116-125 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-100	No	N.R.
A 6.6.7/01h	Feretti, D. et al.	2003	VALUTAZIONE DELLA GENOTOSSICITÁ DI IPOCLORITO DI SODIO, BIOSSIDO DI CLORO E ACIDO PERACETICO MEDIANTE VEGETALI Source: Ann Ig 2003, 15, 959-963 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-098	No	N.R.
A 6.6.7/01i	Anonymous	2003	VALUTAZIONE DELLA GENOTOSSICITÁ DI ACQUE SUPERFICIALI TRATTATE CON DIVERSI DISINFETTANTI MEDIANTE TEST SU VEGETALI Source: Ann IG 2003, 15, 953-957 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-096	No	N.R.
A 6.6.7/01j	Monarca, S. et al.	2003	GENOTOXICITY OF SURFACE WATER TREATED WITH DIFFERENT DISINFECTANTS USING IN SITU PLANT TESTS Source: Environmental and Molecular Mutagenesis, 2003, 41, 353-359 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-093	No	N.R.
A 6.6.7/01k	Monarca, S. et al.	2005	GENOTOXICITY OF DRINKING WATER DISINFECTANTS IN PLANT BIOASSAYS Source: Environmental and Molecular Mutagenesis, 2005, 46, 96-103 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-092	No	N.R.
A 6.6.7/01l	Bolognesi, C. et al.	2004	COMET AND MICRONUCLEUS ASSAYS IN ZEBRA MUSSEL CELLS FOR GENOTOXICITY ASSESSMENT OF SURFACE DRINKING WATER TREATED WITH THREE DIFFERENT DISINFECTANTS Source: Science of the Total Environment 333, 2004, pp. 127-136 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-054	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01m	Buschini, A. et al.	2004	COMET ASSAY AND MICROUNUCLEUS TEST IN CIRCULATING ERYTHROCYTES OF CYPRINUS CARPIO SPECIMENS EXPOSED IN SITU TO LAKE WATERS TREATED WITH DISINFECTANTS FOR POTABILIZATION Source: Mutation Research 2004, 119-129 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-095	No	N.R.
A 6.6.7/01n	Gustavino, B. et al.	2005	MODULATING EFFECTS OF HUMIC ACIDS ON GENOTOXICITY INDUCED BY WATER DISINFECTANTS IN CYPRINUS CARPIO Source: Mutation Research 2007, 587, 103-113 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-101	No	N.R.
A 6.6.7/01o	Ferraris, M. et al.	2005	STUDY OF POTENTIAL TOXIC EFFECTS ON RAINBOW TROUT HEPATOCYTES OF SURFACE WATER TREATED WITH CHLORINE OR ALTERNATIVE DISINFECTANTS Source: Chemosphere, 2005, 60, 65-73 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-105	No	N.R.
A 6.6.7/01p	Monarca, S.	2002	STUDIES ON MUTAGENICITY AND DISINFECTION BY-PRODUCTS IN RIVER DRINKING WATER DISINFECTED WITH PERACETIC ACID OR SODIUM HYPOCHLORITE Source: Water Science and Technology: Water Supply. Vol. 2, No. 3, pp. 199-204 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-050	No	N.R.
A 6.6.7/01q	Sapone, A. et.al.	2007	PERTURBATION OF CYTOCHROME P450, GENERATION OF OXIDATIVE STRESS AND INDUCTION OF DNA DAMAGE IN CYPRINUS CARPIO EXPOSED IN SITU TO POTABLE SURFACE WATER Source: Mutation Research, 2007, 626, 143-154 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-112	No	N.R.
A 6.6.7/01r	Kitis, M.	2004	DISINFECTION OF WASTEWATER WITH PERACETIC ACID: A REVIEW Source: Environment Internation, 2004, 30, 47-55 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-093	No	N.R.
A 6.7/01	Bock, F.G. Myers, H.K. Fox, H.W.	1975	COCARCINOGENIC ACTIVITY OF PEROXY COMPOUNDS Source: Journal of the National Cancer Institute, Vol. 55, No. 6, December 1975, pp. 1359-1361 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-007	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.8.1/01	[redacted]	2005	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [redacted] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 551-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
6.8.1/01	[redacted]	2007	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [redacted] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION ([redacted]) – Peer Review and Re-Evaluation of Discoloration in Fetal Liver Preparations; Source: [redacted] Report No. [redacted] Not GLP (unpublished) Doc. No. 581-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
6.8.1/03	[redacted]	2010	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [redacted] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION ([redacted]) – 2nd Peer Review and Re-Evaluation of Discoloration in Fetal Liver Preprations; Source: [redacted] Report No. [redacted] GLP (unpublished) Doc. No. 581-014	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.11/01	[redacted]	1983	PRÜFUNG DER AKUTEN INTRAVENÖSEN TOXIZIZÄT VON [redacted] IM VERGLEICH ZU FORMALIN Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 524-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.12.2/01	Kramer, A. Weuffen, W. Adrian, V.	1987	TOXISCHE RISIKEN BEI DER ANWENDUNG VON DESINFEKTIONSMITTELN AUF DER HAUT Source: Hyg. + Med. 12,1987,pp. 134-142 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-027	No	N.R.
A 6.12.2/02	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R XVIII, 1969, Vol. 6, pp. 1167-1170 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-002	No	N.R.
A 6.12.2/03	Kretzschmar, C. Agerth, R. Bauch, R. Friedrich, D.	1971	PERESSIGSÄURE - NUR EIN DESINFEKTIONSMITTEL? Source: Monatsheft, Veterinär Medizin, 27, pp. 324-332 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-003	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.12.2/04	Schröder, W.	1982	PERESSIGSÄURE (PES) ALS DESINFEKTIONSWIRKSTOFF FÜR DIE LEBENSMITTELINDUSTRIE Source: Confrocia, Bd. 26 (9182) Nr. 5, pp. 139-147 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.
A 6.12.2/05	French, M.S.	1993	SOLVAY INTERNAL MEMO - IRRITANCY TESTING OF PERACETIC ACID TO SKIN Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 572-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.12.3/01	Pazdiora, A. Kubicek, V.	1967	RAPID PRE-OPERATIVE PREPARATION OF THE HAND WITH PERSTERIL Source: Vojenské Zdravotnické Listy, 1967, 36, (3), pp. 116-117 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-002	No	N.R.
A 6.12.6/01	Cristofari-Marquand, E. et al.	2007	ASTHMA CAUSED BY PERACETIC ACID-HYDROGEN PEROXIDE MIXTURE Source: J. Occup. Health 2007, 49, 155-158 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-094	No	N.R.
A 7.1.1.1.1/01a	Gamet, J.-C. et al.	2000	REPORT ABOUT ABIOTIC DEGRADATION OF PERACETIC ACID: HYDROLYSIS VERSUS ph Source: Bioxal Report No.: 04/00 MPP/DB Not GLP; (unpublished) Doc. No.: 711-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.1.1/01b	Klein, C. Goossens, S.	2007	RECALCULATION OF DT50 AND DT70 FOR THE ABIOTIC DEGRADATION OF PERACETIC ACID ON THE BASIS OF RESULTS GAMET, J. C. ET AL. (2000), DOC.-NO. 711-005 Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-008 Not GLP; (unpublished) Doc. No.: 781-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.1.1/02a	Yuan, Z. Ni, Y. van Heiningen, A.R.P.	1997	KINETICS OF PERACETIC ACID DECOMPOSITION - PART I: SPONTANEOUS DECOMPOSITION AT TYPICAL PULP BLEACHING CONDITIONS Source: The Canadian Journal of Chemical Engineering, Volume 75, February 1997, pp. 37-41 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-012	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.1.1.1.1/0b	Yuan, Z. Ni, Y. van Heiningen, A.R.P.	1997	KINETICS OF THE PERACETIC ACID DECOMPOSITION PART II: ph EFFECT AND ALKALINE HYDROLYSIS Source: The Canadian Journal of Chemical Engineering, Volume 75, February 1997, pp. 42-47 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-013	No	N.R.
A 7.1.1.2.1/01a	Richterich Gode	1986	ABBAUPRÜFUNG TOXISCHER STOFFE: VERMEIDUNG STÖRENDER TOXISCHER SELBSTHEMMUNG DURCH GESTUFTE PRÜFMUSTERZUGABE Source: Not applicable Report No.: 1986/2418 Not GLP; (unpublished) Doc. No.: 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.
A 7.1.1.2.1/01b	Steber, J. Berger, H.	2002	AEROBIC BIODEGRADATION: MODIFIED OECD SCREENING TEST Source: Henkel KGaA Report No.: 5947 458 Not GLP; (unpublished) Doc. No.: 713-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.2.1/02	L´Haridon, J.	2003	DETERMINATION OF READY BIODEGRADABILITY CLOSED BOTTLE TEST Source: Centre International de Toxicologie, France Report No.: 23246 ECS GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.2.3/01	Kuhn, F.	2000	DECOMPOSITION OF PERACETIC ACID IN SYNTHETIC SEAWATER Source: Degussa AG, Hanau, Germany Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 711-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.1.2.1.1/01	van Egdom, T.R.	2007	EVALUATION OF THE DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN EFFLUENT FROM A WASTE WATER TREATMENT PLANT SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.025 GLP, unpublished Doc. No.: 714-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.2.1/01	Howarth, J.	2003	THE ENVIRONMENTAL FATE AND IMPACT OF PERASAN TM AND PERASAN TM "A" (EQUILIBRIUM MIXTURES OF PEROXYACETIC ACID AND HYDROGEN PEROXIDE) IN SOIL Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 721-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.3.1/01	Görg, J. Glöckner, T.	2007	ESTIMATION OF THE ATMOSPHERIC RESIDENCE TIME OF PERACETIC ACID USING THE ATKINSON METHOD Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 743-001 Atkinson 834-008 Not GLP; (unpublished) Doc. No.: 743-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.1/01	[redacted]	2003	ACUTE TOXICITY IN THE RAINBOW TROUT UNDER SEMI-STATIC CONDITIONS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 821-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.1/02	[redacted]	1996	STATIC RENEWAL ACUTE TOXICITY OF 5% PERACETIC ACID (VIGOR OX) TO BLUEGILL (LEPOMIS MACROCHIRUS) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 821-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.1/03	[redacted]	1987	THE ACUTE TOXICITY OF OXYMASTER TO PLAICE PLEURONECTES PLATESSA UNDER SEMI-STATIC CONDITIONS [redacted] Report No.: [redacted] Not GLP, unpublished Doc. No.: 821-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.1/04/05	[redacted]	2005	PACIFIC HERRING TOXICITY TESTING USING PERACLEAN® OCEAN [redacted] Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A7.4.1.1/06 A7.4.1.2/05/06	[redacted]	2005	TOXICOLOGICAL EVALUATIONS OF PERACETIC ACID (15%) [redacted] Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A 7.4.1.2/01	Gardner, C. Bucksath, J.D.	1996	STATIC ACUTE TOXICITY OF 5% PERACETIC ACID (VIGOR OX) TO DAPHNIA MAGNA Source: ABC Laboratories, USA Report No.: I95-2021 42349 GLP; (unpublished) Doc. No.: 822-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.2/02	Fairhurst, F.	1987	DETERMINATION OF THE 48 HOUR MEDIAN EFFECT CONCENTRATION (EC50) OF OXYMASTER TO THE COMMON MUSSEL, MYTILUS EDULIS, IN TERMS OF LARVAL SURVIVAL AND DEVELOPMENT WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1644-M/EV 8687 Not GLP, unpublished Doc. No.: 824-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.2/03	Butler, R.	1987	DETERMINATION OF THE 48 HOUR MEDIAN EFFECT CONCENTRATION (EC50) OF OXYMASTER TO THE PACIFIC OYSTER, CRASSOSTREA GIGAS IN TERMS OF LARVAL SURVIVAL AND DEVELOPMENT WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1643-M/EV 8687 Not GLP, unpublished Doc. No.: 825-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.2/04	Tinsley, D. Sims, I.	1987	THE ACUTE TOXICITY OF OXYMASTER TO BROWN SHRIMP CRANGON UNDER SEMI-STATIC CONDITIONS WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1649-M/EV 8687 Not GLP, unpublished Doc. No.: 825-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.3/01	Hicks, S.L.	1996	ACUTE TOXICITY OF 5% PERACETIC ACID (VIGOR OX) TO SELENASTRUM CAPRICORNUTUM PRINTZ Source: ABC Laboratories, USA Report No.: 42866 I95-2027 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.3/02/03	Anonymous	2005	ALGAL TOXICITY TESTING USING PERACLEAN® OCEAN Nautilus Environmental LLC, Tacoma, WA, USA Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A 7.4.1.4/01	Hanstveit, A.O. Schoonmade, J.A. van Asten, J.G.	1999	SCREENING OF THE EFFECT OF SOPUROXID 15 ON THE RESPIRATION RATE OF ACTIVATED SLUDGE Source: TNO, Department of Environmental Toxicology, Delft, Netherlands Report No.: IMW-98-0044-02 40862.01.01 GLP; (unpublished) Doc. No.: 842-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.4/02	de Groot, W.A.	2001	ACTIVATED SLUDGE, RESPIRATION INHIBITION TEST WITH PERACETIC ACID Source: SOLVAY PHARMACEUTICALS, NL Report No.: A.SOL.S.024 8320/38/01 GLP; (unpublished) Doc. No.: 842-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.3.2/01	[redacted]	2007	PERACETIC ACID 15 % - EARLY-LIFE STAGE TOXICITY TEST WITH ZEBRAFISH (DANIO RERIO) UNDER FLOW-THROUGH CONDITIONS (INCLUDING EXPERT STATEMENT) [redacted] Report No.: [redacted] [redacted] GLP, unpublished Doc. No.: 826-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.3.4/01	Wetton, P. M. Mullee, D.M.	2000	FENNOSAN PAA: DAPHNIA MAGNA REPRODUCTION TEST Source: Safepharm Laboratories Limited, Derby Report No.: 663/007 GLP; (unpublished) Doc. No.: 827-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.1/01	Scheerbaum, D.	2008	PERACETIC ACID 15 % - SOIL MICROORGANISMS - CARBON TRANSFORMATION TEST Dr. Noack Laboratorium für angewandte Biologie, Hildesheim, Germany Report No.: 070425PB TBC117061 TBC11706- GLP, unpublished Doc. No.: 841-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.1/02	Scheerbaum, D.	2008	PERACETIC ACID 15 % - SOIL MICRO-ORGANISMS - NITROGEN TRANSFORMATION TEST Dr. Noack Laboratorium für angewandte Biologie, Hildesheim, Germany Report No.: 070425PB TBN117061 TBN11706- GLP, unpublished Doc. No.: 841-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.2/01	Winkelmann, G.	2007	PERACETIC ACID 15 % - EARTHWORM (EISENIA FETIDA), ACUTE TOXICITY TEST IN ARTIFICAL SOIL - LIMIT-TEST Noack-Laboratorium für angewandte Biologie, Sarstedt Report No.: 070425PB RRA114062 GLP, unpublished Doc. No.: 833-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.3/01	Fiebig, S.	2007	PERACETIC ACID 15 % - TERRESTRIAL PLANT TEST, SEEDLING EMERGENCE AND GROWTH TEST Noack-Laboratorium für angewandte Biologie, Sarstedt Report No.: 070425PB TNC117061 GLP, unpublished Doc. No.: 851-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Reference list Doc IIIB by Section Points:

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B3.2/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE EXPLOSION PROPERTIES OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.6 GLP; (unpublished) Doc. No.: 241-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.2/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE EXPLOSION PROPERTIES OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.14 GLP; (unpublished) Doc. No.: 241-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.3/01	Nims, R.W.	1996	CORROSITEX CONTINUOUS TIME MONITOR ASSAY - VIGOR OX Source: Microbiological Associated, Inc. Report No.: A95BO06.520004 I95-2035 A001267 GLP; (unpublished) Doc. No.: 246-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation
B3.4/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE AUTO-IGNITION TEMPERATURE OF PEROXYACETIC ACID 5% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.3 GLP; (unpublished) Doc. No.: 242-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.4/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE AUTO-IGNITION TEMPERATURE OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.11 GLP; (unpublished) Doc. No.: 242-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.5/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE ACIDITY / ALKALINITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.8 0649 82473 GLP; (unpublished) Doc. No.: 215-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.5/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE PH VALUE (1 % IN WATER) OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.7 GLP; (unpublished) Doc. No.: 215-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.5/03	Mekelburger, H.-B.	2007	DETERMINATION OF THE ACIDITY / ALKALINITY OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.16 GLP; (unpublished) Doc. No.: 215-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 3.5/04	Mekelburger, H.-B.	2007	DETERMINATION OF THE PH VALUE (1 % IN WATER) OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.15 GLP; (unpublished) Doc. No.: 215-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.6/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE RELATIVE DENSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.1 GLP; (unpublished) Doc. No.: 213-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.6/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE RELATIVE DENSITY OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.2 GLP; (unpublished) Doc. No.: 213-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.10/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.4 GLP; (unpublished) Doc. No.: 216-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.10/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.12 GLP; (unpublished) Doc. No.: 216-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.11/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE KINEMATIC VISCOSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.5 GLP; (unpublished) Doc. No.: 214-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.11/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE KINEMATIC VISCOSITY OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.13 GLP; (unpublished) Doc. No.: 214-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 5.10/01	Werner, H.-P. Naujox, K.	2002	PROXITANE 05 - QUANTITATIVE SUSPENSION TEST FOR EVALUATION OF BACTERIAL ACTIVITY (PHASE 2/STEP 1) Source: HygCen GmbH, Schwerin, Germany Report No.: SN-2270.1 Not GLP; (unpublished) Doc. No.: 336-0201	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 5.10/02	Naujox, K. Werner, H.-P.	2002	PROXITANE 05 - QUANTITATIVE SUSPENSION TEST FOR EVALUATION OF FUNGICIDAL ACTIVITY (PHASE 2/STEP 1) Source: HygCen GmbH, Schwerin, Germany Report No.: SN-2270.1 Not GLP; (unpublished) Doc. No.: 336-0202	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay
B 5.10/03	Anonymous	2005	THE EVALUATION OF DISINFECTANT PRODUCTS BY SUSPENSION TESTING AND SURFACE TESTING Source: MGS Laboratories Limited Report No.: 063 Not GLP; (unpublished) Doc. No.: 336-0303	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay
B 5.10/04	Debevere, J.	2005	REPORTS - EVALUATION OF THE BACTERICIDAL ACTIVITY OF CHRIOX 15 Source: State University of Gent, Belgium Report No.: 05-P180-1 Not GLP; (unpublished) Doc. No.: 336-0101	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/05	Debevere, J.	2006	REPORT - EVALUATION OF THE BACTERICIDAL ACTIVITY OF CHIROX 15 Source: State University of Gent, Belgium Report No.: 06-P253-1 Not GLP; (unpublished) Doc. No.: 336-0105	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/06	Debevere, J.	2006	REPORT - EVALUATION OF THE FUNGICIDAL ACTIVITY OF CHIROX 15 Source: State University of Gent, Belgium Report No.: 06-P253-1 Not GLP; (unpublished) Doc. No.: 336-0104	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/07	Debevere, J.	2005	REPORTS - EVALUATION OF THE SPORICIDAL ACTIVITY OF CHRIOX 15 Source: State University of Gent, Belgium Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0401	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/08	Kaleta, E.F.	2003	GUTACHTEN ÜBER DIE VIRUZIDE WIRKSAMKEIT DES CHEMISCHEN DESINFEKTIONSMITTELS - BACTROZON CIP Source: Justus Liebig University Giessen Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0305	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bactria/Stockmeier
B 5.10/09	Martin, J.M.R.	2004	DETERMINATION DE LA ACTIVIDAD BACTERICIDA FRENTE A LEGIONELLA PNEUMOPHILA - OXYPURE BIO 5% Source: Laboratorio de Diagnostico General, Barcelona Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0501	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 5.10/10	Martin, J.M.R.	2004	DETERMINACION DE LA ACITIVIDAD BACTERICIDA FRENTE A LEGIONELLA PNEUMOPHILA - OXYPURE BIO 15% Source: Laboratorio de Diagnostico General, Barcelona Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0502	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation
B 5.10/11	van Hülst, R.	2002	FACHHYGIENISCHES GUTACHTEN ZUR EIGNUNG DER PRÄPARATEKONZENTRATION MAJESTIC UND BLEIX PERAXID FORTE ALS CHEMISCHES WÄSCHEDESINFEKTIONSMITTEL IM EINBADVERFAHREN Source: van Hülst, Onsabrück Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0103	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5	Anonymous	2009	CHRIOX SAFE – ECOLOGICAL FOAM FOR HAND DISINFECTION Source: Christeyns UK Ltd. Report No.: n.a. Not GLP; (unpublished) Doc. No.: 262-002	No	N.R.
B 5.10/12	Carre, A. Strohl, P.	2009	RAPPORT D'ESSAI N° 292/0709 CHRIOX SAFE – ESSAI: NF EN 1500 (SEPTEMBRE 1997) Source: Institut de Recherche Microbiologique, Mitry-Mory, France Report No.: 292/0709 Not GLP; (unpublished) Doc. No.: 336-0106	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 6.4/01	Maas, W.	2007	LETTER REPORT OF THE PILOT STUDY ON SKIN MEMBRANE DAMAGING PROPERTIES OF PAA SOLUTIONS Source: TNO, Nutrition and Food Research, Zeist, The Netherlands Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 511-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B7.1/01	Van de Velde, A.	2005	DEGRADATION STUDY OF PERACETIC ACID AND HYDROGEN PEROXIDE IN LAUNDRY APPLICATION Source: University Twente Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 752-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B7.1/02	Hölzgen, U. Wirth, K.	2005	ECOLAB INTERNAL - PERACETIC ACID DETERMINATION IN WASTE WATER Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 3 AA/02	Harzadours Substance Data Bank (HSDB)	2007	HAZARDOUS SUBSTANCES DATA BANK - ACETIC ACID (HSDB) [(CASRN: 64-19-7)] Source: Hazardous Substances Database Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 581-007	No	N.R.
B 3 AA/03	Anonymous	2007	LITERATURE SEARCH - ACETIC ACID Source: NIST, National Institute of Standards and Technology Report No.: Not applicable Not GLP; (published) Doc. No.: 191-001	No	N.R.
B 3 AA/04	Anonymous	2003	EG-SICHERHEITSDATENBLATT - ESSIGSÄURE>=90% Source: Celanese Report No.: 5 / CH Not GLP; (unpublished) Doc. No.: 955-035	No	N.R.
B 3 AA/05	Glöckner, T. Görg, J.	2007	STATEMENT RELATED TO THE OXIDISING PROPERTIES OF ACETIC ACID Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-008 Not GLP; (unpublished) Doc. No.: 143-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Appendix IV: Tables of Risk characterisation for human health

Table Appendix IV-1 Primary exposure industrial use

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
PT2 Disinfectants and algaecides not intended for direct application to humans or animals: **Disinfection of sewage/ waste water** (including municipal waste water)	Mixing/ Loading (2x/year up to 1x/wk)	PAA: 15	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation,	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
PT2: Disinfection of surfaces in industrial, public and health care areas	Mixing/ Loading+ Application 15 min/d + 330 min/d, 220 days/year	PAA: 5 (in m&l) 0.15 (in applic.)	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.043 0.011 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: manual surface disinfection model no. 1 "Dilution and mixing of disinfectant and cleaning surfaces with a wrung cloth or mop and wringer bucket"
		HP: 25		HP: higher; skin protection needed	HP: 0.217 0.054 (RPE)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
	Post-application	PAA: 0.15	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA 0.0014	PAA: 0.5	PAA: lower (0.3%)	gloves, goggles	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 0.75		HP: higher; skin protection needed	HP: 0.0071	HP: 1.25	HP: lower		
PT2: CIP in the pharmaceutical and cosmetic industry	Mixing/ Loading	PAA: 15	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation,	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
PT4 Food and feed area disinfectants: **Automated spraying in closed systems - aseptic filling** of PET bottles, sterilisation of crown corks, cheese moulds and	Mixing/ Loading - Manual pouring 30 min/10-365 days/year	PAA: 15	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Automated spraying	PAA: 0.3	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.228 0.057 (RPE)	PAA: 0.5	PAA: lower (46%)	gloves, coverall, goggles, boots, RPE if insufficient ventilation	TNsG, part II: spraying model no. 2
		HP: 0.5			HP: 0.38 0.095 (RPE)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
food crates in the beverage and food industry	Post-application - Water rinse	PAA: 0.003	PAA: 0.1 (long-term)	PAA: lower (3%)	PAA: 0.00228	PAA: 0.5	PAA: lower (0.5%)	gloves	TNsG, part II: spraying model no. 2
		HP: 0.005			HP: 0.0038	HP: 1.25	HP: lower		
PT4: Disinfection of equipment in the food and beverage industry by dipping and immersion	Mixing/ Loading - Manual pouring (5 min/1-365 days/year)	PAA: 15	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.141 (no RPE) 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 (no RPE) 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Dipping (placing/removal) of equipment 3h/daily	PAA: 0.1	PAA: 0.1 (long-term)	PAA: equal	PAA: 0.0002	PAA: 0.5	PAA: lower (0.04%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: dipping model no. 4 (dermal and inhalation exposure)
		HP: 0.167			HP: 0.0003	HP: 1.25	HP: lower		
	Post-application - Draining	PAA: 0.1	PAA: 0.1 (long-term)	PAA: equal	PAA: 0.00094	PAA: 0.5	PAA: lower (0.2.%)	gloves	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids
		HP: 0.167			HP: 0.0016	HP: 1.25	HP: lower		
PT4: CIP and disinfection of	Mixing/ Loading (30 min/10-	PAA; 15	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face	TNsG, part II: revised mixing/ loading model no.

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
ion exchangers in the food and beverage industry	365 days/year)	HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower	shield, boots, RPE if insufficient ventilation	7 "pouring liquids"
PT4: Disinfection of surfaces and equipment by low pressure manual spraying	Mixing/ Loading (10 min/day, 10-100 days/ year)	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Spraying	PAA: 0.1	PAA: 0.1 (long-term)	PAA: equal	PAA: 0.076 0.019 (RPE)	PAA: 0.5	PAA: lower (15%)	RPE, gloves, coverall, goggles, boots	TNsG, part II: spraying model no. 2
		HP: 0.5			HP: 0.38 0.095 (RPE)	HP: 1.25	HP: lower		
PT4: Disinfection of surfaces and equipment by foaming	Mixing/ Loading (10 min/day, 10-100 days/ year)	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Foaming	PAA: 0.1	PAA: 0.1 (long-term)	PAA: equal	PAA: 0.076 0.019 (RPE)	PAA: 0.5	PAA: lower (15%)	RPE, gloves, coverall, goggles, boots	TNsG, part II: spraying model no. 2
		HP: 0.5			HP: 0.38 0.095 (RPE)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
PT6: In-can preservatives In-can preservation in the paper industry	Mixing/ Loading	PAA: 15	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		

Table Appendix IV-2 Primary exposure professional use

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
PT1 Human hygiene: **Hand disinfection** in hospitals / health and animal care areas / food industry	Mixing/ Loading	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids" (revised)
		HP: 25		HP: higher; skin protection needed	HP: 0.235	HP: 1.25	HP: lower		
	Application	PAA: 0.2	PAA: 0.1 (long-term)	PAA: higher ; 0.2% not acceptable in the long-term use	PAA: 0.06 (8-h TWA) 0.05 (event)	PAA: 0.5	PAA: lower (12%)		ConsExpo 4.1 "Exposure to vapour: Instantaneous release" (worst case for 8-h TWA), "Constant rate release" (event)
		HP: 1.24			HP: 0.36 (8-h TWA) 0.31 (event)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
PT2: Disinfectants and algaecides not intended for direct application to humans or animals **Laundry disinfection** in closed washing machines	Mixing/ Loading (30 min/d, daily or 2x/wk)	PAA: 15	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield and boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
PT3: Veterinary hygiene **Spraying of animal houses**	Mixing/ Loading (30 min/d, weekly to 2x/year)	PAA: 5	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Spraying (0.5 to 2 h/d, weekly to 2x/year)	PAA: 0.05	PAA: 0.2 (short/ medium-term)	PAA: lower	PAA: 0.038 0.0095 (RPE)	PAA: 0.5	PAA: lower (8%)	RPE, gloves, coverall, goggles, boots	TNsG, part II: spraying model no. 2
		HP: 0.25			HP: 0.19 0.05 (RPE)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
					PAA: 3.43 (vapour) 0.343 (RPE) 0.052 (aerosol)	PAA: 0.5	PAA: lower with RPE	RPE, gloves, coverall, goggles, boots	ConsExpo 4.1 (evaporation - the area of release increases over time) TNsG, part II: spraying model no. 1
PT3: Foaming of animal houses	Mixing/ Loading	PAA: 5	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Foaming	PAA: 0.1	PAA: 0.2 (short/ medium-term)	PAA: lower	PAA: 0.076 0.019 (RPE)	PAA: 0.5	PAA: lower (15%)	RPE, gloves, coverall, goggles/face shield, boots	TNsG, part II: spraying model no. 2
		HP: 0.5			HP: 0.38 0.095 (RPE)	HP: 1.25	HP: lower		
PT3: Thermal fogging of animal houses	Mixing/ Loading	PAA: 5	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
	Post-application	PAA: 0.5	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.38 0.095 (RPE)	PAA: 0.5	PAA: lower (76%)	RPE if re-entry before safe level has been reached	TNsG, part II: spraying model no. 2
		HP: 2.5			HP: 1.9 0.48 (RPE)	HP: 1.25	HP: higher (152%)		
PT3: Disinfection of footwear in footbaths in animal production	Mixing/ Loading 10 min/d, daily	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application	PAA: 0.05	PAA: 0.1 (long-term)	PAA: lower)	PAA: 0.014	PAA: 0.5	PAA: lower (3%)	gloves	Default values of TGD on Risk Assessment, part I and TNsG, part II: manual surface disinfection model no. 1
		HP: 0.25			HP: 0.072	HP: 1.25	HP: lower		
	Post-application	PAA: 0.05	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.00047	PAA: 0.5	PAA: lower (1%)	gloves	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 0.25			HP: 0.00235	HP: 1.25	HP: lower		
PT3: Disinfection of animal feet	Mixing/ Loading 3 x 1 min/d	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face	TNsG, part II: revised mixing/ loading model no.

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
(hoof disinfection)		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower	shield, boots, RPE if insufficient ventilation	7 "pouring liquids"
	Post application	PAA: 0.1	PAA: 0.1 (long-term)	PAA: equal	PAA: 0.00094	PAA: 0.5	PAA: lower (0.2%)	gloves, coverall	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids
		HP: 0.5			HP: 0.0047	HP: 1.25	HP: lower		
PT3: Disinfection of equipment by dipping and immersion	Mixing/ Loading - Manual pouring (5-10 min/daily)	PAA: 5	PAA: 0.1 (long-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
	Application - Dipping (placing/removal) of equipment (15-30 min)	PAA: 0.025	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.00005	PAA: 0.5	PAA: lower (0.01%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: dipping model no. 4 (dermal and inhalation exposure)
		HP: 0.125			HP: 0.00025	HP: 1.25	HP: lower		
	Post-application - Draining	PAA: 0.025	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.000235	PAA: 0.5	PAA: lower (0.05%)	gloves	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 0.125			HP: 0.0012	HP: 1.25	HP: lower		

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used
		Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m^3] (RPE=25%penetration)	Inhalation AEC value [mg/m^3]	Comparing to inhalation AEC		
PT4 Food and feed area: **Disinfection of milking parlours**	Mixing/ Loading 1 min/d, 50x/year	PAA: 5	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.047 0.012 (RPE)	PAA: 0.5	PAA: lower (9%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		
PT5 Drinking water disinfectants: **Disinfection of animal drinking water**	Mixing/ Loading (10 min/day, 10-100 days/ year)	PAA: 15	PAA: 0.2 (short/ medium-term)	PAA: higher ; skin protection needed	PAA: 0.141 0.035 (RPE)	PAA: 0.5	PAA: lower (28%)	gloves, coverall, goggles/face shield, boots, RPE if insufficient ventilation	TNsG, part II: revised mixing/ loading model no. 7 "pouring liquids"
		HP: 25		HP: higher; skin protection needed	HP: 0.235 0.059 (RPE)	HP: 1.25	HP: lower		

Table Appendix IV-3 Secondary exposure – short term (acute)

Exposure scenario	Exposure route	Person	In-use concentration [%]	Inhalation exposure [mg/m^3]	AEC-inhalation value [mg/m^3]	Comparing to AEC-inhalation
PT2: Disinfection of surfaces in industrial, public and health care areas	inhalation	adult/child	PAA: 0.15 HP: 0.75	PAA: 0.0448 HP: 0.224	PAA: 0.5 HP: 1.25	PAA: lower (9%) HP: lower
PT3: Spraying of animal houses	inhalation	adult/child	PAA: 0.05 HP: 0.25	PAA: 0.038 HP: 0.19	PAA: 0.5 HP: 1.25	PAA:lower (8%) HP: lower
PT3: Foaming of animal houses	inhalation	adult/child	PAA: 0.1 HP: 0.5	PAA: 0.076 HP: 0.38	PAA: 0.5 HP: 1.25	PAA: lower (15%) HP: lower
PT3: Fogging of animal houses	inhalation	adult	PAA: 0.5 HP: 2.5	PAA: 0.38 HP: 1.9	PAA: 0.5 HP: 1.25	PAA: higher (76%) HP: higher (152%) Worst case: ventilation, safe re-entry time and no-entry of bystanders should be underlined in the use instructions

Table Appendix IV-4 Secondary exposure – long term (chronic)

Exposure scenario	Exposure route	Species	In-use concentration [%]	Exposure		% NO(A)EC
				Inhalation [mg/m^3]	Oral [mg/kg bw/day]	
PT5: Disinfection of animal drinking water	oral	Farm animals	PAA: 0.0025 HP: 0.0042	Not relevant	PAA: ~ 1/10 of NOAEC[1] HP: ~ 1/100 of NOAEC[2]	PAA: ~ 10[1] HP: ~ 1[2].

[1]: Oral uptake of peracetic acid by farm animals *via* disinfected drinking water corresponds to about 1/10 of the NOAEC determined in studies with experimental animals

[2]: Oral uptake of hydrogen peroxide by farm animals *via* disinfected drinking water corresponds to about 0.88 % of the NOAEC determined in studies with experimental animals