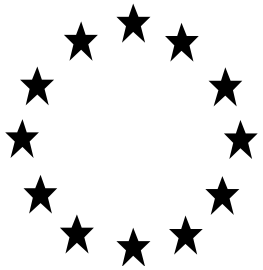
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	A-QUASAN B
Product type(s):	PT 3 (Veterinary hygiene) PT 4 (Food and feed area)
Active ingredient(s):	Benzoic acid
Case No. in R4BP	BC-FG047486-40
Asset No. in R4BP	DE-0020842-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/03.00008 710-05-03-00008-00-00-00-0000
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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the product "A-QUASAN B" with the active substance benzoic acid (9.09 % w/w) is used as a disinfectant in veterinary health care (product-type 3) against the target organisms bacteria and yeast and in food and feed area (product-type 4) against bacteria, yeast and fungi. The product A-QUASAN B is applied in different dilutions in combination with contact times depending on the target organism.
The disinfection of hard surfaces and equipment (e.g. work and storage surfaces, boxes, machine items) in veterinary health care area by spraying or dipping done by the professional user represent safe uses.
In food and feed area (e.g. warehouses, areas in greenhouses where food is processed) the product "A-QUASAN B" is intended to be used for disinfection of hard surfaces for protection against human pathogens by professional user. The application by spraying and dipping is appropriate for disinfection of e.g. work and storage surfaces or small machineries. With the fill up application, inner surfaces of e.g. pipes or tanks in (drinking) water systems can be disinfected.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance benzoic acid including the "elements to be taken into account by Member States when authorising products" as requested by the German CA.
2. The specific provisions from the approval deciscion for the active substance benzoic acid (Commission implementing regulation EU No 1035/2013).

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[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Approval of the active substance

The active substance benzoic acid is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

For products in product type 3 and 4:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following conditions:

(1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

For products in product type 3:

(2) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

For products in product type 4:

(3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(4) Products containing benzoic acid shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of benzoic acid into food or it has been established pursuant to that Regulation that such limits are not necessary.

In the Assessment Report for the approval of the active substance benzoic acid, no specific active substance manufacturer is given. The active substance is only specified with the pharmacopoeia grade.

Composition and formulation

The soluble concentrate “A-QUASAN B” contains the active substance benzoic acid.

Please refer to chapter 2.2 (Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Endocrine disrupting properties:

One co-formulant is included in the PACT-list and is currently under evaluation. Based on the information available to the RefMS at the moment, it is not possible to conclude whether this co-formulant should be

considered to have ED properties or not. This is further assessed in the frame of the REACH Regulation (please find more information in the confidential annex chapter 6.2).
For the other co-formulants and the active substance the assessment of endocrine disrupting properties has shown the following:
Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the product. Therefore, no corresponding regulatory measures are required.

Substances of concern:
The co-formulants propan-1-ol, propan-2-ol, formic acid, and ethane-1,2-diol have been identified as substances of concern. Please refer to chapter 2.2.3 and 5.2.2 for further information.

Physical, chemical and technical properties
The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics
The product has to be classified because of identified physical-chemical hazard(s) (see chapter 2.3). However, this does not lead to an unacceptable risk for end users (please find more information in chapter 3.3).

Methods for detection and identification
Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms
The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health
The solvents propan-1-ol and propan-2-ol, the pH regulator formic acid, and the solubilizer ethane-1,2-diol have been identified as substances of concern.
Accordingly, the human health risk assessment for this product is based on the active substance and substances of concern.

A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1). The post application assessment of secondary exposure for the general public has been carried out for the PT 3 uses (use #1 and use #2).

Additionally a risk assessment for animal health was carried out for those uses (see chapter 3.7).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

The substances Propan-1-ol and Propan-2-ol has been identified as substances of concern. Therefore environmental risk assessment as well as a mixture toxicity assessment is performed for the product "A-QUASAN B" considering the active substance Benzoic acid and the SoCs Propan-1-ol and Propan-2-ol.

Based on the data available at the moment, neither the active substance, nor a coformulant has potential to give the biocidal product endocrine disrupting properties (please find more information in chapter 3.8.5.6 and 6.2).

A risk assessment for the environment has been carried out for professional indoor use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Comparative Assessment

Since no candidate for substitution has been identified (see also chapter 2.2.4) a comparative assessment was not necessary.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

A-QUASAN B

2.1.2 Manufacturer(s) of the product

Name of manufacturer	MENNO CHEMIE-VERTRIEB GMBH
Address of manufacturer	Langer Kamp 104 22850 Norderstedt Germany
Location of manufacturing sites	A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH Otto-Brenner-Straße 16 21337 Lüneburg Germany

2.1.3 Manufacturer(s) of the active substance(s)

Active substance	Benzoic acid
Name of manufacturer	CVH Chemie-Vertrieb GmbH & Co. Hannover KG[a]
Address of manufacturer	Podbielskistraße 22, 30163 Hannover[a]
Location of manufacturing sites	n.a.[a]

[a] In the CAR of the AS it is stated that the applicant himself does not manufacture the AS. Additionally it is stated, that only benzoic acid with specification for pharmaceutical grade is purchased from different suppliers and will be used in biocidal products. It was agreed on TM IV 2011 that pharmaceutical grade with a minimum purity of 99% and no impurity >0.1% was deemed acceptable.
Therefore no specific AS manufacturer and location of manufacturing site can be named. The company who provided the certificate of analysis for the AS is named here instead.

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Benzoic acid	Benzoic acid	Active substance	65-85-0	200-618-2	9.09
n-Propanol	Propan-1-ol	Non-active substance	71-23-8	200-746-9	21.7
2-Propanol	Propan-2-ol	Non-active substance	67-63-0	200-661-7	13
Formic acid	Formic acid	Non-active substance	64-18-6	200-579-1	4.2
Ethylene glycol	Ethane-1,2-diol	Non-active substance	107-21-1	203-473-3	16.01

- Information on the full composition is provided in the confidential[3] annex (see chapter 5).

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

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

[3] Access level: “Restricted” to applicant and authority

2.2.3 Information on the substance(s) of concern

The following substance(s) of concern was/were identified:

- Propan-1-ol (CAS 71-23-8)
- Propan-2-ol (CAS 67-63-0)
- Formic acid (CAS 64-18-6)
- Ethane-1,2-diol (CAS 107-21-1)

➢ (Further) information on the substance(s) of concern is provided in chapter 3.6.2.8. and in the confidential annex (chapter 5.2.2).

2.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.5 Type of formulation

SL - soluble concentrate

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance benzoic acid, the substances of concern propan-2-ol, propan-1-ol, ethane-1,2-diol and formic acid affect the classification of the biocidal product.

The current harmonised classification of the active substance Benzoic acid is based on Commission Regulation (EU) No. 790/2009 (6st ATP):[5]

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

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4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

5 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/22870

Table 2

Classification Hazard classes, Hazard categories	Hazard statements
Flam. Liq. 2	H225
Eye Dam. 1	H318
STOT RE 2 (lung, kidney)	H373
STOT SE 3	H336

Table 3

Labelling	Code	Pictogram / Wording
	GHS02	
	GHS05	
	GHS07	
	GHS08	
Signal word	-	Danger
Hazard statements	H318	Causes serious eye damage.
	H225	Highly flammable liquid and vapour.
	H336	May cause drowsiness or dizziness.
	H373	May cause damage to organs through prolonged or repeated exposure (lung, kidney).
Supplemental hazard information	-	Not required
Supplemental label elements	-	Not required
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.

	P271	Use only outdoors or in a well-ventilated area.
	P273	Avoid release to the environment.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER/doctor/…
	P312	Call a POISON CENTRE/doctor/… if you feel unwell.
	P314	Get medical advice/attention if you feel unwell.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P403 + P235	Store in a wellventilated place. Keep cool.
	P501	Dispose of contents and container according to regional/ national and international regulations.
Note	-	-

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.

It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[6]

2.4.1 Use 1 appropriate for authorisation – Disinfectant of hard surfaces - Professional user - Spraying - Indoor

Product Type(s)	PT 3: Veterinary hygiene
Where relevant, an exact description of the use	Disinfectant of non-porous hard surfaces (e.g. work and storage surfaces, boxes, crates, transport surfaces, tools, machines)
Target organism(s) (including development stage)	Bacteria, Yeast
Field(s) of use	Indoor

6 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

	Disinfection of clean non-porous surfaces in the following areas: • Veterinary health care (Veterinary clinics, veterinary testing laboratories and associated equipment) • Companion animals (animals housing e.g. kennels, hutches and cages, as well as associated equipment)
Application method(s)	Spraying (with low-pressure sprayer or as a foam)
Application rate(s) and frequency	0.4 L/m^2 The product concentration to be used depends on the target organism: Bacteria (10 °C): 3 %, 30 min; 2.5 %, 60 min Bacteria (20 °C): 2.5 %, 30 min, 2 %, 60 min Yeast (10 °C): 4.5 %, 30 min; 3.5 %, 60 min, 3 %, 120 min Yeast (20 °C): 4 %, 30 min; 3.5 %, 60 min, 3 %, 120 min The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s). Applications in veterinary clinics typically occur about once a day but can be more frequent in the operating room when a problem is indicated.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.1.1 Use-specific instructions for use

Only use on clean non-porous surfaces.

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5.2

1) After the recommended treatment time, before the treated surfaces are reused, they have to be rinsed with tap water.
2) Treated surfaces and equipment have to be dried before re-use.
3) No application of the product on surfaces to which cats may have prolonged contact.
4) Use only in well-ventilated areas.

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

5) Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
6) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
7) A protective coverall (type 6, EN 13034 (coated coverall)) shall be worn.
8) Wear suitable protective footwear against chemicals (EN 13832) when applying the product

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.2 Use 2 appropriate for authorisation – Disinfectant of equipment by soaking - Professional user - Dipping - Indoor

Product Type(s)	PT 3: Veterinary hygiene
Where relevant, an exact description of the use	Disinfectant of equipment by soaking (e.g., dishes, cutlery, equipment, small machinery, machine items, crates, boxes)
Target organism(s) (including development stage)	Bacteria, Yeast
Field(s) of use	Indoor Disinfection of clean equipment in the following areas: • Veterinary health care (Veterinary clinics, veterinary testing laboratories and associated equipment) • Companion animals (animals housing e.g. kennels, hutches and cages, as well as associated equipment)
Application method(s)	Open system: dip treatment Equipment are dipped in a fixed vessel filled with the product solution.
Application rate(s) and frequency	The product concentration to be used depends on the target organism: Bacteria (10 °C): 3 %, 30 min; 2.5 %, 60 min Bacteria (20 °C): 2.5 %, 30 min, 2 %, 60 min Yeast (10 °C): 4.5 %, 30 min; 3.5 %, 60 min, 3 %, 120 min Yeast (20 °C): 4 %, 30 min; 3.5 %, 60 min, 3 %, 120 min The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).

	Applications in veterinary clinics typically occur about once a day but can be more frequent in the operating room when a problem is indicated.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.2.1 Use-specific instructions for use

Only use on clean equipment.

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5.2

1) After the recommended treatment time, the treated surfaces have to be rinsed with tap water.
2) Treated surfaces and equipment have to be dried before re-use.
3) No application of the product on surfaces to which cats may have prolonged contact.
4) Use only in well-ventilated areas.

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

5) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.3 Use 3 appropriate for authorisation – Disinfectant of hard surfaces-Professional user - Spraying - Indoor

Product Type(s)	PT 4: Food and feed area
Where relevant, an exact description of the use	Disinfectant of non-porous hard surfaces (e.g., work and storage surfaces, boxes, crates, transport surfaces, tools, machines) for protection against human pathogens
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and areas in greenhouses where food is processed.
Application method(s)	Spraying (with low-pressure sprayer or as a foam)
Application rate(s) and frequency	0.4 L/m^2 The product concentration to be used depends on the target organism: Bacteria (10 °C): 2.5 %, 5 min; 1.5 %, 30 min; 1 %, 60 min

	Bacteria (20 °C): 2 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Yeast (10 °C): 2.5 %, 15 min; 2 %, 30 min Yeast (20 °C): 2.5 %, 15 min; 2 %, 30 min, 1.5 %, 60 min Fungi (20 °C): 6 %, 15 min, 5 %, 30 min; 4 %, 60 min The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.3.1 Use-specific instructions for use

1) Only use on clean surfaces.
2) Use only in greenhouses in which food is processed.
3) Inside greenhouses, use only in areas where food is processed.

2.4.3.2 Use-specific risk mitigation measures

See chapter 2.5.2

1) After the recommended treatment time, before the treated surfaces and equipment are reused, they have to be rinsed with tap water.

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

2) Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). 3) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). 4) A protective coverall (type 6, EN 13034 (coated coverall)) shall be worn. 5) Wear suitable protective footwear against chemicals (EN 13832) when applying the product.

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.4 Use 4 appropriate for authorisation – Disinfectant of equipment by soaking - Professional user - Dipping - Indoor

Product Type(s)	PT 4: Food and feed area
Where relevant, an exact description of the use	Disinfectant of equipment by soaking (e.g., dishes, cutlery, equipment, small machinery, machine items, crates, boxes) for protection against human pathogens
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast

Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and areas in greenhouses where food is processed.
Application method(s)	Open system: dip treatment Equipment are dipped in a fixed vessel filled with the product solution.
Application rate(s) and frequency	The product concentration to be used depends on the target organism: Bacteria (10 °C): 2.5 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Bacteria (20 °C): 2 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Yeast (10 °C): 2.5 %, 15 min; 2 %, 30 min Yeast (20 °C): 2.5 %, 15 min; 2 %, 30 min, 1.5 %, 60 min Fungi (20 °C): 6 %, 15 min, 5 %, 30 min; 4 %, 60 min The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.4.1 Use-specific instructions for use

1) Only use on clean equipment.
2) Use only in greenhouses in which food is processed.
3) Inside greenhouses, use only in areas where food is processed.

2.4.4.2 Use-specific risk mitigation measures

See chapter 2.5.2

1) After the recommended treatment time, before the treated surfaces and equipment are reused, they have to be rinsed with tap water.

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

2) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.5 Use 5 appropriate for authorisation – Disinfectant of inner surfaces without circulation - Professional user - Indoor

Product Type(s)	PT 4: Food and feed area

Where relevant, an exact description of the use	Disinfectant of inner surfaces without circulation (e.g. pipes, tanks, fillers, mixer, other machines which come into contact with food) for protection against human pathogens
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and areas in greenhouses where food is processed.
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Inner surfaces (e.g., pipes) are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water.
Application rate(s) and frequency	The product concentration to be used depends on the target organism. Bacteria (10 °C): 2.5 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Bacteria (20 °C): 2 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Yeast (10 °C): 2.5 %, 15 min; 2 %, 30 min Yeast (20 °C): 2,5 %, 15 min; 2 %, 30 min, 1.5 %, 60 min Fungi (20 °C): 6 %, 15 min, 5 %, 30 min; 4 %, 60 min The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.5.1 Use-specific instructions for use

1) Only use on clean surfaces. 2) The use of a dosing pump for manual loading is required. 3) Use only in greenhouses in which food is processed. 4) Inside greenhouses, use only in areas where food is processed.

2.4.5.2 Use-specific risk mitigation measures

See chapter 2.5.2 After the recommended treatment time, before the treated pipes and machinery are reused, they have to be rinsed with tap water.

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.6 Use 6 appropriate for authorisation – Disinfectant of surfaces in human drinking water systems - Professional user - Indoor

Product Type(s)	PT 4: Food and feed area

Where relevant, an exact description of the use	Disinfectant of surfaces in human drinking water systems (e.g. pipes, tanks, fillers, mixer, other machines which come into contact with food) for protection against human pathogens
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and areas in greenhouses where food is processed.
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Pipe systems are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water.
Application rate(s) and frequency	The product concentration to be used depends on the target organism: Bacteria (10 °C): 2.5 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Bacteria (20 °C): 2 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Yeast (10 °C): 2.5 %, 15 min; 2 %, 30 min Yeast (20 °C): 2.5 %, 15 min; 2 %, 30 min, 1.5 %, 60 min Fungi (20 °C): 6 %, 15 min, 5 %, 30 min; 4 %, 60 min The pipe system is to be filled with the product solution after it has been dosed and mixed as appropriate for the target organism(s). The product solution is to be applied as often as necessary with a maximum of once per day and preferably once per week.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.6.1 Use-specific instructions for use

1) Only use on clean surfaces. 2) The use of a dosing pump for manual loading is required. 3) Use only in greenhouses in which food is processed. 4) Inside greenhouses, use only in areas where food is processed.

2.4.6.2 Use-specific risk mitigation measures

See chapter 2.5.2 After the recommended treatment time, before the treated pipes and machinery are reused, they have to be rinsed with tap water.

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.4.7 Use 7 appropriate for authorisation – Disinfectant of surfaces in veterinary water systems - Professional user - Indoor

Product Type(s)	PT 4: Food and feed area

Where relevant, an exact description of the use	Disinfectant of surfaces in veterinary water systems
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast
Field(s) of use	Indoor • For use in veterinary practices, animal shelters, and animal feeding areas • Animal husbandry (animal houses, market pens, slaughterhouses, etc.)
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Pipe systems are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water
Application rate(s) and frequency	The product concentration to be used depends on the target organism: Bacteria (10 °C): 2.5 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Bacteria (20 °C): 2 %, 5 min; 1.5 %, 30 min; 1 %, 60 min Yeast (10 °C): 2.5 %, 15 min; 2 %, 30 min Yeast (20 °C): 2.5 %, 15 min; 2 %, 30 min, 1.5 %, 60 min Fungi (20 °C): 6 %, 15 min, 5 %, 30 min; 4 %, 60 min The pipe system is to be filled with the product solution after it has been dosed and mixed as appropriate for the target organism(s). The product solution is to be applied as often as necessary with a maximum of once per week.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

2.4.7.1 Use-specific instructions for use

1) Only use on clean surfaces. 2) The use of a dosing pump for manual loading is required.

2.4.7.2 Use-specific risk mitigation measures

See chapter 2.5.2 After the recommended treatment time, before the treated pipes and machinery are reused, they have to be rinsed with tap water.

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

See chapter 2.5.3

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

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

See chapter 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

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2.5.2 Risk mitigation measures

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures:
The use of eye protection during handling of the product is mandatory.

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

IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor/…
Call a POISON CENTRE/doctor/… if you feel unwell.
Get medical advice/attention if you feel unwell.

2.5.4 Instructions for safe disposal of the product and its packaging

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

1) Shelf-life: 5 years
2) Keep away from food, drinks and feeding stuff.

2.5.6 Other information

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2.6 Packaging

Table 4

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of the closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials**
Bottle	1 L	HDPE	screw cap/child safety closure – DIN 25/13 HDPE	Professional	Yes
Bottle with handle	2 L	HDPE	screw cap HDPE	Professional	Yes
Jerry can	10 L	HDPE	screw cap HDPE	Professional	Yes
Jerry can	20 L	HDPE	screw cap HDPE	Professional	Yes
Jerry can	30 L	HDPE	screw cap HDPE	Professional	Yes
Drum	220 L	HDPE	L-Ring drum	Professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – Disinfectant of hard surfaces - Professional user - Spraying - Indoor

Product Type(s)	3
Where relevant, an exact description of the use	Disinfectant of hard surfaces (e.g., work and storage surfaces, boxes, crates, transport surfaces, tools, machines)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor -Veterinary health care (Veterinary clinics, veterinary testing laboratories and associated equipment) -Companion animals (animals housing, e.g. kennels, hutches and cages, as well as associated equipment)
Application method(s)	Spraying (with low-pressure sprayer or as a foam)
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 1.5% and a maximum of 6% concentration may be employed. See the product label for details. The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s). Applications in veterinary clinics typically occur about once a day but can be more frequent in the operating room when a problem is indicated.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.2 Intended use 2 – Disinfectant of equipment by soaking - Professional user - Dipping - Indoor

Product Type(s)	3
Where relevant, an exact description of the use	Disinfectant of equipment by soaking (e.g., dishes, cutlery, equipment, small machinery, machine items, crates, boxes)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor - Veterinary health care (Veterinary clinics, veterinary testing laboratories and associated equipment) - Companion animals (animals housing e.g. kennels, hutches and cages, as well as associated equipment)
Application method(s)	Open system: dip treatment Equipment are dipped in a fixed vessel filled with the product solution.
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 1.5% and a maximum of 6% concentration may be employed. See the product label for details. The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s). Applications in veterinary clinics typically occur about once a day but can be more frequent in the operting room when a problem is indicated.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.3 Intended use 3 – Disinfectant of hard surfaces- Professional user - Spraying - Indoor

Product Type(s)	4

Where relevant, an exact description of the use	Disinfectant of hard surfaces (e.g., work and storage surfaces, boxes, crates, transport surfaces, tools, machines)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and greenhouses
Application method(s)	Spraying (with low-pressure sprayer or as a foam)
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 0.5% and a maximum of 6% concentration may be employed. See the product label for details. The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.4 Intended use 4 – Disinfectant of equipment by soaking - Professional user - Dipping - Indoor

Product Type(s)	4
Where relevant, an exact description of the use	Disinfectant of equipment by soaking (e.g., dishes, cutlery, equipment, small machinery, machine items, crates, boxes)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and greenhouses
Application method(s)	Open system: dip treatment Equipment are dipped in a fixed vessel filled with the product solution.

Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 0.5% and a maximum of 6% concentration may be employed. See the product label for details. The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.5 Intended use 5 – Disinfectant of inner surfaces without circulation - Professional user - Indoor

Product Type(s)	4
Where relevant, an exact description of the use	Disinfectant of inner surfaces without circulation (e.g. pipes, tanks, fillers, mixer, other machines which come into contact with food)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and greenhouses
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Inner surfaces (e.g., pipes) are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water.
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 0.5% and a maximum of 6% concentration may be employed. See the product label for details. The product solution is to be applied as often as necessary. A maximum number of applications each day is restricted by the treatment times recommended for the target organism(s).
Category(ies) of users	Professional user

Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.6 Intended use 6 – Disinfectant of surfaces in human drinking water systems - Professional user - Indoor

Product Type(s)	4
Where relevant, an exact description of the use	Disinfectant of surfaces in human drinking water systems (e.g. pipes, tanks, fillers, mixer, other machines which come into contact with food)
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor For use in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and greenhouses
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Pipe systems are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water.
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 0.5% and a maximum of 6% concentration may be employed. See the product label for details. The pipe system is to be filled with the product solution after it has been dosed and mixed as appropriate for the target organism(s). The product solution is to be applied as often as necessary with a maximum of once per day and preferably once per week.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles

	355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.1.7 Intended use 7 – Disinfectant of surfaces in veterinary water systems - Professional user - Indoor

Product Type(s)	4
Where relevant, an exact description of the use	Disinfectant of surfaces in veterinary water systems
Target organism(s) (including development stage)	Bacteria, Fungus, Yeast, Viruses
Field(s) of use	Indoor • For use in veterinary practices, animal shelters, and animal feeding areas • Animal husbandry (animal houses, market pens, slaughterhouses, etc.)
Application method(s)	Closed system: Fill up (e.g., pipe) system with product solution Pipe systems are filled up with the product solution for the recommended treatment time. After the recommended treatment time is up, the system is to be emptied of the solution and rinsed with tap water
Application rate(s) and frequency	0.4 L/m^2 - The product concentration to be used depends on the target organism. A minimum concentration of 0.5% and a maximum of 6% concentration may be employed. See the product label for details. The pipe system is to be filled with the product solution after it has been dosed and mixed as appropriate for the target organism(s). The product solution is to be applied as often as necessary with a maximum of once per week.
Category(ies) of users	Professional user
Pack sizes and packaging material	Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE Bottle with handle 2 L HDPE screw cap HDPE Jerry can 10 L HDPE screw cap HDPE Jerry can 20 L HDPE screw cap HDPE Jerry can 30 L HDPE screw cap HDPE Drum 220 L HDPE L-Ring drum Outer packaging for 10 x 1 L bottles 355 x 182 x 213 mm (L x W x H) Fibreboard carton Outer packaging for 6 x 2 L bottles 337 x 281 x 256 mm (L x W x H) Fibreboard carton

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	*Visual testing*	MENNO Florades Batch no. 07005 Purity/Specification: 90 g/L	liquid	Kellner G, 2007c (B3.1)
	Visual testing	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	liquid	Bockholt, K., 2015, Report no.: SSL03114
Colour at 20 °C and 101.3 kPa	*Visual testing*	MENNO Florades Batch no. 07005 Purity/Specification: 90 g/L	Clear slightly amber coloured	Kellner G, 2007c (B3.1)
	Visual testing	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	Slightly turbid, light yellow	Bockholt, K., 2015, Report no.: SSL03114
Odour at 20 °C and 101.3 kPa	Olfactory inspection	MENNO Florades Batch no. 07005 Purity/Specification: 90 g/L	The odour is dominated by the formulants (organic solvents and acids) and is slightly alcoholic and acidic. Benzoic acid itself is almost odourless. None of	Kellner G, 2007c (B3.1)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			the ingredients has an intense odour.	
	Olfactory inspection	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	Alcoholic odour	Bockholt, K., 2015, Report no.: SSL03114
Acidity / alkalinity	*CIPAC MT 191*	MENNO Florades Batch no. 07005 Purity/Specification: 90 g/L	Acidity 5.69 %	Fieseler A, 2008c
	pH: *CIPAC MT 75.3* *Acidity: CIPAC MT 191*	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	**pH:** **Before acc. storage** pH = 3.0 (1%) diluted solution **After acc. storage** pH = 3.0 (1%) diluted solution Acidity: **Before acc. storage** 6.0% calculated as H_2SO_4 **After acc. storage** 5.89% calculated as H_2SO_4	Bockholt, K., 2015, Report no.: SSL03114
Relative density / bulk density	EC A.3	MENNO Florades Batch no. 07005 Purity/Specification:	$D_4^{20} = 0.999$	Fieseler A, 2008, Report no.: 43962182

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		90 g/L		
	OECD 109 (oscillating density meter)	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	D^{20}= 0.9996 g/mL	Bockholt, K., 2015, Report no.: SSL03114
Storage stability test – **accelerated storage**	CIPAC MT 46.3	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	The product is stable after storing for eight weeks at 40°C. Active substance content: 9.24% before storage 9.25% after storage Appearance, pH/acidity, dilution stability and packaging did not change significantly during storage (values see individual endpoints).	Bockholt, K., 2015, Report no.: SSL03114
Storage stability test – **long term storage at ambient temperature**	GIFAP Technical Monograph no.17	MENNO Florades Batch no.: 9601 For dilution stability on aged product: A-QUASAN, Batch-No.: 15011	Active substance content: T = 0: 9.17% T = 27 months: 9.02% (loss of 1.6%) T = 68 months: 8.88% (loss of 3.2%) The change of the following properties were investigated during stability test:	Kellner, G., 2005, „Shelf Life Following Storage at Ambient Temperature over 65 resp. 68 months with MENNO Florades", Report no.: CC05D04 For dilution stability on aged product: Müllewitz, M. 2020, Study no.: Mo6832

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Appearance: No change was observed after 27 and 68 months. pH-values: T = 0: pH: 2.5 T = 27 months: pH: 2.5 T = 68 months: pH: 2.5 Density: T = 0: D_4^{20}=0.999 T = 27 months: D_4^{20}= 1.0 T = 68 months: D_4^{20}= 1.0 Refractive index n_D^{20} T = 0: n_D^{20}= 1.413 T = 27 months: n_D^{20}= 1.413 T = 68 months: n_D^{20}= 1.413	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Dilution stability on product after 63 months: Highest in use concentration: 6% (v/v) dilution: 6mL test item was diluted to 100 mL. After 30 min at 30°C 15mL solid separation (crystals) were observed at the bottom. After 24 h at 30°C 10 mL solid separation (crystals) were observed at the bottom as well as 40mL of turbid liquid at the top.Because of these observations a wet sieving test in accordance with CIPAC MT 185 was conducted. No residue was observed after pouring the test solution through a 75µm sieve.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 7 days 0°C	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	Small traces of sediment were observed after 7 days storage at 0°C. The amount was quantified to 0.40 mL/100 mL equivalent to 0.4 % v/v.	Bockholt, K., 2015, Report no.: SSL03114

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Two similar samples kept at ambient temperature for 24 h afforded 0.55 mL of sediment that could be re-homogenized by shaking. The formation of sediment was a typical property of the test item. Storage at 0°C appeared to have no influence on the formation of sediments.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver.		The formulation is packaged in a HDPE container which protects it from exposure to direct sunlight during storage.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Humidity: No significant effect expected as the product contains water. Temperature: The product is stable at 40°C for 8 weeks. For more information see accelerated storage study.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging material is sufficient.	Dangerous Goods Database http://www.dgg.bam.de/en/

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Wettability	Waiver.		Not applicable. Data is only required for solid preparations which are to be dispersed in water. The product is a liquid formulation used as soluble concentrate.	
Suspensibility, spontaneity and dispersion stability	Waiver.		Not applicable. Data is required only for solid preparations and suspensions which are to be dispersed/diluted in water. The product is a liquid formulation used as soluble concentrate.	
Wet sieve analysis and dry sieve test	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Emulsifiability, re-emulsifiability and emulsion stability	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Disintegration time	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Particle size distribution, content of dust/fines, attrition, friability	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Persistent foaming	CIPAC MT 47.2	MENNO Florades	1% (v/v) dilution:	Bockholt, K., 2015, Report no.: SSL03114

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Batch no.: 14010 Purity/Specification: 90 g/L	Foam after: 10 sec: 34 ml 1 min: 21 ml 3 min: 6 ml 12 min: 0 ml 4% (v/v) dilution: Foam after: 10 sec: 60 ml 1 min: 57 ml 3 min: 55 ml 12 min: 53 ml	
	CIPAC MT 47.2	A-Quasan Batch no.: 19019 Purity/Specification: 9 %	Lowest in use concentration 0.5% (v/v) dilution: Foam after: 10 sec: 50 ml 1 min: 38 ml 3 min: 8 ml 12 min: 2 ml Highest in use concentration: 6% (v/v) dilution: Foam after: 10 sec: >120 ml	Manka, S., 2109, "Determination of physico-chemical Properties for A-QUASAN", Report no.: Mo6532

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			1 min: >110 ml 3 min: >110 ml 12 min: 80 ml (The measured foam was limited by the stopper and therefore limited the determination of its volume. The difference in the limiting volume is caused by a rising surface level of the solution.)	
Flowability/Pourability/Dustability	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Burning rate — smoke generators	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Burning completeness — smoke generators	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Composition of smoke — smoke generators	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate.	
Spraying pattern — aerosols	Waiver.		Not applicable. Data is not required for a liquid formulation used as soluble concentrate and is not sold in spray cans.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical compatibility	Waiver.		The biocidal product is not recommended and intended to be used with other products.	
Chemical compatibility	Waiver.		The biocidal product is not recommended and intended to be used with other products.	
Degree of dissolution and dilution stability	CIPAC MT 41	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	Solutions of the test item as received and after 8 weeks storage at 40°C afforded slightly turbid solutions with traces of sediment (1 %m/v) and turbid solutions with sediments (4 %m/v) by visual inspection. The amount of separated material in the test item solution of 1 %v/v in standard water D was 0.016 %m/m before and 0.031 %m/m after storage for 8 weeks at 40°C. The amount of separated material in the test item solution of 4 %v/v in standard water D was 0.082 %m/m before and 0.037 %m/m after storage for 8 weeks at 40°C. Sediments <0.1% were considered as traces and	Bockholt, K., 2015, Report no.: SSL03114

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			therefore the results were considered acceptable, especially since the amount of sediment decreased for the 4% test solution after storage at 40°C.	
	CIPAC MT 41	A-Quasan Batch no.: 19019 Purity/Specification: 9 %	Highest in use concentration: 6% (v/v) dilution: The test was conducted with a total volume of 6 mL. After 18h a solid separation at the bottom of 1 mL was observed.	Manka, S., 2109, "Determination of physico-chemical Properties for A-QUASAN", Report no.: Mo6532
Surface tension	EU method A.5 (Ring method)	MENNO Florades Batch no.: 9903 Purity/Specification: 90 g/L	53.4 mN/m at 20°C, (c = 0 1g/L ≙ 0.1% (w/w))	Schulz, H., 2000, Report no.: IF-100/22588-00
	EU method A.5 (Ring method)	MENNO Florades Batch no.: 14010 Purity/Specification: 90 g/L	27.2 mN/m at 25°C for neat product	Bockholt, K., 2015, Report no.: SSL03114
Viscosity	OECD 114 (rotary viscometer)	MENNO Florades Batch no.: 07005 Purity/Specification: 90 g/L	Dependence of shear rates were measured in the range of 500 - 2000 s^{-1} The test item was a Newtonian liquid. 8.0 mPas at 20°C ± 0.1°C: (1000 s^{-1})	Fieseler, A., 2008, Report no.: 43963196

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			5.5 mPas at 40°C ± 0.1°C: (1000 s^{-1})	
	OECD 114 (rotary viscometer)	MENNO Florades Batch no.: 07005 Purity/Specification: 90 g/L	Dependence of shear rates were measured in the range of 1 - 250 s^{-1} The test item was a non-Newtonian liquid. 25°C dynamic viscosity [mPas] = 132.73 * (shear rate [s^{-1}]) -0.675 (range 1.03 s^{-1} to 258 s^{-1}) 40°C: dynamic viscosity [mPas] = 223.6 * (shear rate [s^{-1}]) -0.812 (range 1.03 s^{-1} to 258 s^{-1}) The minimum viscosities observed were: 25°C: 5.7 mPas (258 s^{-1}) 40°C: 3.9 mPas (258 s^{-1})	Bockholt, K., 2015, Report no.: SSL03114

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant were acceptable. The physical and chemical properties of the biocidal product were conducted on the product “Menno Florades”. More information on “Menno Florades” is in the confidential annex. Read across between “Menno Florades” and “A-QUASAN B” is acceptable. The product is a clear slightly amber to slightly turbid, light yellow liquid solution with an alcoholic odour. These observations mirror the property of the product to form little amounts of sediments, especially after dilution. The pH of an 1% aqueous dilution of the product was 3.0 before and after accelerated storage at 40°C for 8 weeks. The acidity amounts to 6.0% before and 5.9% after accelrated storage calculated as H_2SO_4. The relative density of the product is 0.999. The accelerated storage test showed that the product is stable for 8 weeks at 40°C. No significant change in active substance concentration, appearance, pH/acidity, dilution stability and packaging was observed. The long term storage test showed a shelf life of 5 years (60 months). No significant changes in active substance concentration, appearance, density, pH-value, acidity and refractive index were observed after storage. The low temperature stability test did not have an influence on the product. The slight amount of sediment that was detected after storing the product at 0°C for 7 days was also observed after storing the product at room temperature. Homogenization of the product is obtained by shaking. The test for persistent foaming showed decreasing amount of foam from 50 mL after 10 sec. to 38 mL after 1 min for the lowest in use concentration. For the highest in use concentratoin the amount of foam exceeded with >120 mL after 10 sec to >110 mL after 1 min the threshold of 60 mL. Dilution stablility The surface tension is 53.4 mN/m at 20°C for a 1g/L aqueous dilution of the and 27.2 mN/m at 25°C for the neat product. The viscosity tests showed a newtonian behaviour of the liquid at shear rates bewteen 500-2000 s^{-1} and non-newtonian behaviour at shear rates bewteen 1 – 250 $s^{-^}$. At 1000 s^{-1} the viscosity is 8.0 mPas at 20°C and 5.5 mPas at 40°C. Between shear rates of 1 - 250 s^{-1} the dynamic viscosity can be described by the following equation at 25 °C [mPas] = 132.73 * (shear rate [s^{-1}]) $^{-0.675}$ and at 40°C by [mPas] = 223.6 * (shear rate [s^{-1}]) $^{-0.812}$.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties	IUCLID[7]
Flammable gases	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Flammable aerosols	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Oxidising gases	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Gases under pressure	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Flammable liquids	ISO 3679	MENNO Florades Batch no.: 14010	Flash point: 19.2 °C	Flammable liquid, Category 2 based on GHS/CLP criteria.	Bockholt, K., 2015, Report no.: SSL03114

[7] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		Purity/Specification: 90 g/L			
Flammable solids	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID[7]
Pyrophoric liquids	study scientifically not necessary			Waiver: Experience in manufacture and handling shows that the formulation does not ignite spontaneously on coming into contact with air at normal temperatures.	IUCLID[7]
Pyrophoric solids	study scientifically unjustified			Not applicable Not performed because the formulation is a liquid and not a solid.	IUCLID[7]
Self-heating substances and mixtures	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Substances and mixtures which in contact with water emit	study scientifically not necessary			Waiver: The formulation is a soluble concentrate. Experience in production or handling shows that the formulation does not react with water.	IUCLID[7]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
flammable gases					
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.	IUCLID[7]
Oxidising solids	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID[7]
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	A-QUASAN Batch-no.: 18024	Corrosion rate: negative Type of material: Aluminium Plates 7075-T6 Corrosion rate: negative Type of material: Steel S235JR+CR	Not classified based on GHS/CLP criteria.	Dreisch, S., 2020, Report no.: CSL-20-0137.01

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Auto-ignition temperature (liquids and gases)	DIN 51794	MENNO Florades Lot no.: 14010 Purity/Specification: 90 g/L	Auto-ignition temperature: 435 °C		Angly, H., 2000, Report no.: 2000.4048.AFG
Relative self-ignition temperature for solids	study scientifically unjustified			Not applicable The study does not need to be conducted because the formulation is a liquid and not a solid.	IUCLID[7]
Dust explosion hazard	study scientifically unjustified			Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[7]

Table 8

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Experimental data on flash point (19.2 °C), auto-ignition temperature (435 °C) and corrosive to metals (no classification) were provided for the product. The Biocidal product is not expected to have any explosive or oxidising properties. Based on experience in production and handling it can be concluded that the product is not pyrophoric, does not evolve flammable gases in contact with water. Therefore, the biocidal product is classified as Flammable liquid, Category 2 based on GHS/CLP criteria.

3.4 Methods for detection and identification

Table 9

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Benzoic acid (active substance)	HPLC-DAD	No interference for target analyte was found.	10 to 100 mg analyte/L 10 to 250 mg analyte/L At each fortification level, 5 independent replicates and two untreated control samples were made. Regression coefficient always ≥ 0.9996	Fortification levels: 1 % benzoic acid in the blank formulation 5 % benzoic acid in the blank formulation 10 % benzoic acid in the blank formulation Each fortification level was analysed fivefold.	97-98%	LEVELS 97 at 1% level 98 at 5% level 98 at 10% level OVERALL 98% (n=3)	LEVELS 0.9 at 1% level 0.8 at 5% level 0.4 at 10% level OVERALL All values ≤1.4% which demonstrates reliability of the injection.	0.45 mg/L *Quantification Limit:* *A content of 1 % benzoic acid in the formulation can be determined with sufficient precision and accuracy*	Meinerling, M. and Mollandin, G., 2008, *report no.: 43964101*

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected		AR PT3,4; LoEP; 09/2013
Drinking water	benzoic acid	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	benzoic acid	2.5 mg/L	$PNEC_{water}$ AR PT3,4; 2.2.2.2.; 09/2013
Air	benzoic acid	1.5 mg/m³	AEL: 5 mg/kg bw/d AR PT3,4; LoEP; 09/2013
Animal and human body fluids and tissues	benzoic acid	0.1 mg/kg (tissues) 0.05 mg/L (fluids)	classified as toxic (STOT RE 1) to be submitted at product authorisation; AR PT3,4; LoEP; 09/2013
Food of plant origin	no relevant residues expected		AR PT3,4; LoEP; 09/2013
Food of animal origin	no relevant residues expected		AR PT3,4; LoEP; 09/2013

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
benzoic-1-^{13}C acid determined as 4-benzamidobenzene sulfonic acid	LC-MS/MS, Acquity UPLC BEH C18, ESI+, m/z 279→106, 279→208	blanks: 0.056 – 0.075 µg/L two transitions	using matrix-matched standards 0.04-2 ng/mL, that corres-	m/z 279→106 0.1 µg/L / 5 1 µg/L / 5 m/z 279→208	 87 - 115 95 - 107	 98 101	 10 5	0.1 µg/L	Buttler, 2014

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
			ponds to 0.08-4 µg/L R^2: 0.999823 – 0.999625	0.1 µg/L / 5 1 µg/L / 5	77 - 92 89 - 105	82 98	8.5 6.1		

Table 12:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Benzoic acid (active substance)	Ion chromatography-UV	--	--	--	--	--	--	LOQ: 0.1 mg/m^3	Benzoic acid PT3 and PT4 Assessment Reports, September 2013
Benzoic acid (active substance)	LC-MS/MS Nucleodur C18, ESI-, m/z 121→77 (quantification)	blanks: < 1.1 % LOQ 1.5 mg/m^3 /5 15 mg/m^3 /5 Ctrl. /2	using solvent standards 50 - 1600 µg/mL y = 1764.59 x – 48.6453 r^2 = 0.997525	1.5 mg/m^3 / 5 15 mg/m^3 / 5 Sufficiently proven	79-83 85-93	80 90	2.5 3.0	LOQ: 1.5 mg/m^3	Buttler, O., 2014a

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Benzoic acid (active substance)	HPLC-DAD RP18, 235 nm (confirmation)	blanks: < 1.1 % LOQ 1.5 mg/m³ /5 15 mg/m³ /5 Ctrl. /2	using solvent standards 50 - 1600 µg/mL y = 1178.47 x + 4.40·105 r^2 = 0.999979	1.5 mg/m³ / 5 15 mg/m³ / 5 Sufficiently proven	82-88 85-91	84 88	2.4 3.0	LOQ: 1.5 mg/m³	Buttler, O., 2014a
Propan-1-ol	GC-FID								The MAK-Collection Volume 1 Issue 3. July 2016: W. Schneider, D. Breuer, R. Hebisch A. Hartwig, MAK Commission: Solvent mixtures [Air Monitoring Methods, 2014b]
Propan-2-ol	2-Propanol present in air is collected on adsorption tubes (Anasorb ® 747).								Alcohol Task Force (2015) Validation Report - Determination of 2-Propanol

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	GC-MS								in DMF/CS2 by GC/MS. Fraunhofer Institute for Toxicology and Experimental Medicine, Fraunhofer ITEM Validation Study No.: 15V15201, Report Date: 30th July 2015. CAR Propan-2-ol

Table 13

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
benzoic acid	HPLC-UV, RP18, 245 nm	blanks: < 30 % LOQ	using solvent standards	Test water, isomedium				0.75 mg/L	Meinerling & Hermann, 2004 CAR for PT 3

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
			0.25 – 2.5 µg/mL, that corres-ponds to 0.25 - 20 mg/L 2 – .5 µg/mL, that corres-ponds to - 200 mg/L R^2: 0.999823 – 0.999625	0.75 mg/L / 5 1 mg/L / 10 2 mg/L / 10 12.5 mg/L / 5 150 mg/L / 5 Test water, Elendt 0.75 mg/L / 5 1 mg/L / 10 2 mg/L / 10 12.5 mg/L / 5 150 mg/L / 5	93 - 105 85 – 107 78 - 91 100– 107 101 - 106 87 - 111 84 – 91 76 - 95 99 – 105 103 - 106	100 93 83 102 103 102 88 85 102 104	5 9 4 3 2 10 3 7 2 1		and PT4 Doc III A 4.2.03; 02/2008

Table 14

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
benzoic acid determined as 4-benzamidobenzene sulfonic acid for liver and as 4-benzamidobenzene sulfonic acid (deuterated) for blood	LC-MS/MS, Acquity UPLC BEH C18, ESI+, liver m/z 278→162, 278→105 blood m/z 283→167, 283→110	blanks: < 30 % LOQ two transitions	using matrix-matched standards liver: 1 - 50 ng/mL, that corres-ponds to 0.01 -0.5 mg/kg blood: 1 - 20 ng/mL, that corres-ponds to 0.017 - 0.333 mg/L R^2: 0.9968 – 0.9992	Liver m/z 278→162 0.1 mg/kg / 5 m/z 278→105 0.1 mg/kg / 5 Blood m/z 283→105 0.05 mg/L / 5 m/z 283→110 0.05 mg/L / 5	71 - 87 71 – 80 101-115 99 - 111	76 75 111 106	8.5 4.4 5.1 4.0	Liver 0.1 mg/kg Blood 0.05 mg/L	Buttler, 2014

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product 2. 5.2.1. Soil 3. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[8]
Justification	See justification(s)/annotation(s) in IUCLID dossier 1. According to chapter III, section 3.4.2 of the Guidance on the Biocidal Products Regulation, Volume I, Identity/physico-chemical properties/analytical methodology, Part A, Information Requirements (version 1.1, Nov. 2014), in cases where the SoC or relevant impurity cannot possibly increase on manufacture or storage of the biocidal product then they do not need to be included in the storage stability/shelf-life study. A suitable justification was submitted from the applicant 2. Analytical methods for monitoring purposes in soil are not necessary. Due to the many sources and the ubiquitous occurrence of benzoic acid it is not possible to distinguish between contamination by using benzoic acid as biocidal product and natural or industrial background levels. 3. Analytical methods for monitoring purposes in/on food of plant and animal origin or feeding stuffs are not necessary since no relevant residues of benzoic acid are expected due to the biocidal application.

Table 16

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance and substances of concern were acceptable. The methods provided regarding residues were acceptable. Sufficiently validated analytical methods are available for the determination of residues of benzoic acid in drinking and surface water, in air and in body fluids and tissues. Methods regarding residues of substances of concern were not necessary.

[8] Not necessary if neither the active substance nor the material treated with it come into contact with food-producing animals, food of plant and animal origin or feeding stuffs

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The biocidal product is a concentrate based on the active substance benzoic acid that is diluted prior to use.
A-QUASAN B is intended to be used for the disinfection of clean non-porous surfaces and equipment in the veterinary area (e.g. veterinary health care (veterinary clinics, veterinary testing laboratories and associated equipment) and companion animals (animals housing e.g. kennels, hutches and cages, as well as associated equipment)).
In PT4 the product is intended to be used for the disinfection of clean non-porous surfaces and equipment as well as inner surfaces of pipelines in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and areas of greenhouses where food is processed.

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

The product is intended to have bactericidal and yeasticidal activity in PT 3 as well as PT 4. In PT 4 an additional fungicidal activity is intended.
A fungicidal and virucidal activity in PT 3 was claimed by the applicant but withdrawn in course of the evaluation. Furthermore, in PT 4 the applicant withdrew an initially intended virucidal claim (including bacteriophages) as well as a specific claim against *Legionella pneumophila* during evaluation.

3.5.3 Effects on target organisms, including unacceptable suffering

Application of the product leads to irreversible inactivation of bacterial cells, yeast and fungi.

3.5.4 Mode of action, including time delay

Benzoic acid is described as non-specific inhibitor. In solution, benzoic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cells membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the benzoic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported: Decrease of the membrane permeability for amino acids,

organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the citric acid cycle is observed. There is no time delay.

3.5.5 Efficacy data

As the product is intended to be applied for disinfection, the product was tested in a tiered approach with phase 2, step 1 tests (quantitative suspension tests) and phase 2, step 2 tests (quantitative surface tests) where available. All studies have been performed based on available EN standards.

Bactericidal efficacy (PT 3 and PT 4)

Phase 2, step 1 tests (EN 1656, EN 1276) and phase 2, step 2 tests (EN 14349, EN 13697) have been submitted to prove bactericidal efficacy of the product.
In all studies efficacy of the product under clean conditions has been assessed at either 10 or 20 °C.

Yeasticidal efficacy (PT 3 and PT 4)

Phase 2, step 1 tests (EN 1657, EN 1650) and phase 2, step 2 tests (EN 16438, EN 13697) have been submitted to prove yeasticidal efficacy of the product.
In all studies efficacy of the product under clean conditions has been assessed at either 10 or 20 °C.

Fungicidal activity (PT 4)

Phase 2, step 1 tests (EN 1650) and phase 2, step 2 tests (EN 13697) have been submitted to prove fungicidal efficacy of the product. In all studies efficacy of the product under clean conditions has been assessed at 20 °C.

Table 17

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT 3 bactericidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 1656:2009 (A1:2010)	Quantitative suspension test 10 °C, Clean conditions (3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75 % product concentration 30 min, 60 min contact time	Results showed a >5 log reduction for bacteria at 3 % product concentration in 30 min and 2.5 % product concentration in 60 min under clean conditions. All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-005
PT 3 bactericidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 1656:2009 (A1:2010)	Quantitative suspension test 20 °C, Clean conditions (3 g/l BSA) 2.5, 2, 1.5, 1, 0.75, 0.5, 0.25 % product concentration 30 min, 60 min contact time	Results showed a >5 log reduction for bacteria at 2.5 % product concentration in 30 min and 2 % product concentration in 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-006
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 1657:2005 (A1:2007)	Quantitative suspension test 20 °C, Clean conditions (3 g/l BSA) 4, 3.5, 3, 2.5, 2 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >4 log reduction for yeast at 3.5 % product concentration in 30 min and 60 min and 3 % product concentration in 120 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-007 and 6.7-009
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 1657:2005 (A1:2007)	Quantitative suspension test 10 °C, Clean conditions (3 g/l BSA) 5, 4.5, 4, 3.5, 3, 2.5, 2 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >4 log reduction for yeast at 4 % product concentration in 30 min and 60 min and 3 % product concentration in 120 min under clean conditions	Hunsinger (2015) 6.7-008

						All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 20009)	*Candida albicans ATCC 10231*	EN 1657:2016	Quantitative suspension test 10 °C, Clean conditions (3 g/l BSA) 4.5, 4, 3.5, 3, 2.5 % product concentration 60 min	Results showed a >4 log reduction for yeast at 3.5 % product concentration in 60 min All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2020) 6.7-050
PT 3 bactericidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 14349:2012	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >4 log reduction for bacteria at 3 % product concentration in 30 min and 2.5 % product concentration in 60 and 120 min under clean conditions All controls were valid.	Hunsinger (2015) 6.7-010 and 6.7-040
PT 3 bactericidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 14349:2012	Quantitative surface test 20 °C, Clean conditions (3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >4 log reduction for bacteria at 2.5 % product concentration in 30 min and 2 % product concentration in 60 and 120 min under clean conditions All controls were valid.	Hunsinger (2015) 6.7-011
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 16438:2014	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 6, 5, 4.5, 4, 3.5, 3, 2.5, 2 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >3 log reduction for yeast at 4.5 % product concentration in 30 min, at 3.5 % in 60 min and at 3 % product concentration in 120 min under clean conditions All controls were valid.	Hunsinger (2015) 6.7-012 and 6.7-041
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 16438:2014	Quantitative surface test 20 °C, Clean conditions (3 g/l BSA) 5, 4.5, 4, 3.5, 3, 2.5, 2 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >3 log reduction for yeast at 4 % product concentration in 30 min, at 3.5 % in 60 min and at 3 % product concentration in 120 min under clean conditions All controls were valid.	Hunsinger (2015) 6.7-013
PT 4 Bactericidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538	EN 1276:2009 (A1:2010)	Quantitative suspension test 10 °C,	Results showed a >5 log reduction for bacteria at 1.5 % product concentration in 5 min	Hunsinger (2015) 6.7-016

			Enterococcus hirae ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536*		Clean conditions (0.3 g/l BSA) 2, 1.5, 1, 0.75, 0.5, 0.25, 0.1 % product concentration 5 min, 30 min, 60 min contact time	and 30 min and 1 % product concentration in 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	
PT 4 Bactericidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536*	EN 1276:2009 (A1:2010)	Quantitative suspension test 20 °C, Clean conditions (0.3 g/l BSA) 2, 1.5, 1, 0.75, 0.5, 0.25, 0.1 % product concentration 5 min, 30 min, 60 min contact time	Results showed a >5 log reduction for bacteria at 1.5 % product concentration in 5 min and 1 % product concentration in 30 min and 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-017
PT 4 Yeasticidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 1650:2008+A1:2013	Quantitative suspension test 10 °C, Clean conditions (0.3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 15 min, 30 min, 60 min contact time	Results showed a >4 log reduction for yeast at 2.5 % product concentration in 15 min and 2 % product concentration in 30 and 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-018 and 6.7-020
PT 4 Yeasticidal Fungicidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231* *Aspergillus brasiliensis ATCC 16404*	EN 1650:2008+A1:2013	Quantitative suspension test 20 °C, Clean conditions (0.3 g/l BSA) 10, 8, 6, 5, 4, 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 15 min, 30 min, 60 min contact time	Results showed a >4 log reduction for yeast at 2 % product concentration in 15 min and 1.5 % product concentration in 30 and 60 min under clean conditions Results showed a >4 log reduction for fungi at 6 % product concentration in 15 min and 5 % product concentration in 30 min and 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2015) 6.7-019 and 6.7-021

PT 4 Yeasticidal Fungicidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 20009)	*Candida albicans ATCC 10231* *Aspergillus brasiliensis ATCC 16404*	EN 1650:2019	Quantitative suspension test 20 °C, Clean conditions (0.3 g/l BSA) 5, 4.5, 4, 3.5, 3, 2.5, 2, 1.5, 1 % product concentration 60 min contact time	Results showed a >4 log reduction for yeast at 1.5 % product concentration in 60 min under clean conditions Results showed a >4 log reduction for fungi at 4 % product concentration in 60 min under clean conditions All controls were valid. Additional controls demonstrated that precipitation did not affect test results.	Hunsinger (2020) 6.7-051
PT 4 Bactericidal Yeasticidal Fungicidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536* *Candida albicans ATCC 10231* *Aspergillus brasiliensis ATCC 16404*	EN 13697:2001 (modified according to prEN 13697:2012 and *A. brasiliensis* spore preparation according to EN 1650:2008+A1:2013)	Quantitative surface test 20 °C, Clean conditions (0.3 g/l BSA) 6, 5, 4, 3.5, 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 15 min, 30 min, 60 min contact time	Results showed a > 4 log reduction for bacteria at 2 % product concentration in 5 min, at 1.5 % in 30 min and at 1 % in 60 min. Results showed a > 3 log reduction for yeast at 2.5 % product concentration in 15 min, at 2 % in 30 min and at 1.5 % in 60 min. Results showed a > 3 log reduction for fungi at 6 % product concentration in 15 min, at 5 % in 30 min and at 4 % in 60 min. All controls were valid.	Hunsinger (2015) 6.7-022 and 6.7-024, 6.7-025, 6.7-027, 6.7-039
PT 4 Bactericidal	(Inner) Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536*	EN 13697:2001 (modified according to prEN 13697:2012)	Quantitative surface test 10 °C, Clean conditions (0.3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 30 min, 60 min contact time	Results showed a > 4 log reduction for bacteria at 2.5 % product concentration in 5 min, at 1.5 % in 30 min and at 1 % in 60 min. All controls were valid.	Hunsinger (2015) 6.7-023
PT 4 Yeasticidal	(Inner Surface disinfection/ Dipping	A-QUASAN (Batch-No. 14004)	*Candida albicans ATCC 10231*	EN 13697:2001 (modified according to prEN 13697:2012)	Quantitative surface test 10 °C, Clean conditions (0.3 g/l BSA) 3, 2.5, 2, 1.5, 1, 0.75 % product concentration 15 min, 30 min, 60 min contact time	Results showed a > 3 log reduction for yeast at 2.5 % product concentration in 15 min, at 2 % in 30 min and at 2 % in 60 min. All controls were valid.	Hunsinger (2015) 6.7-026

PT 4 Bactericidal Yeasticidal Fungicidal	Surface disinfection/ Dipping	A-QUASAN without benzoic acid (Lab sample 19.01.2016)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536* *Candida albicans ATCC 10231*	EN 13697:2015	Quantitative surface test 20 °C, Clean conditions (0.3 g/l BSA/8.5 g/L skimmed milk (*P. aeruginosa*)) 6, 5, 4, 3.5, 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 5 min, 15, 30 min contact time	Results showed a >4 log reduction for bacteria at 3 % product concentration in 30 min. The product was not efficacious at 1.5 % in 30 min. Results showed a >3 log reduction for yeast at 8 % product concentration in 15 min. The product was not efficacious at 5 % in 15 min.	Supportive data Hunsinger (2016) 6.7-042
PT 3 Bactericidal	Surface disinfection/ Dipping	A-QUASAN without benzoic acid (Lab sample 19.01.2016)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 14349:2012	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 15, 10, 9, 8, 7, 6, 5, 4, 3, 2 % product concentration 30 min contact time	Results showed a >4 log reduction for bacteria at 8 % product concentration in 30 min under clean conditions. The product was not efficacious at 6 % in 30 min. All controls were valid.	Supportive data Hunsinger (2016) 6.7-043
PT 3 Yeasticidal	Surface disinfection/ Dipping	A-QUASAN without benzoic acid (Lab sample 19.01.2016)	*Candida albicans ATCC 10231*	EN 16438:2014	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 20, 15, 12.5, 10, 9, 8 % product concentration 30 min, 60 min contact time	Results showed a >3 log reduction for yeast at 15 % product concentration in 30 min and 12,5 % product concentration in 60 min under clean conditions. The product was not efficacious at 8 % in 30 min or 60 min. All controls were valid.	Supportive data Hunsinger (2016) 6.7-044
PT 4 Bactericidal Yeasticidal Fungicidal	Surface disinfection/ Dipping	Formic acid (Fluka, Art. 06440)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536* *Candida albicans ATCC 10231* *Aspergillus brasiliensis ATCC 16404*	EN 13697:2001 (modified according to prEN 13697:2012 and *A. brasiliensis* spore preparation according to EN 1650:2008+A1:2013)	Quantitative surface test 20 °C, Clean conditions (0.3 g/l BSA) 6, 5, 4, 3.5, 3, 2.5, 2, 1.5, 1, 0.75, 0.5 % product concentration 5 min, 15 min, 30 min, 60 min contact time	Results showed a >4 log reduction for bacteria at 2 % product concentration in 5 min, at 1.5 % product concentration in 30 min and at 1 % product concentration in 60 min. Results showed a >3 log reduction for yeast at 2.5 % product concentration in 15 min, at 2 % product concentration in 30 min and at 1.5 % product concentration in 60 min. Results showed a >3 log reduction for fungi at 3 % product concentration in 15 min, at 2 % product concentration in 30 min	Supportive data Hunsinger (2015) 6.7-045

						and 60 min. All controls were valid.	
PT 3 Bactericidal	Surface disinfection/ Dipping	Formic acid (Fluka, Art. 06440)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *P. vulgaris ATCC 13315*	EN 14349:2012	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 3.5, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 % product concentration 30 min, 60 min, 120 min contact time	Results showed a >4 log reduction for bacteria at 3 % product concentration in 30 min, at 2.5 % product concentration in 60 min and at 2% product concentration in 120 min under clean conditions. Formic acid was not efficacious at 0.5 % in 30 min. All controls were valid.	Supportive data Hunsinger (2015) 6.7-046
PT 3 Yeasticidal	Surface disinfection/ Dipping	Formic acid (Fluka, Art. 06440)	*Candida albicans ATCC 10231*	EN 16438:2014	Quantitative surface test 10 °C, Clean conditions (3 g/l BSA) 20, 15, 12.5, 10, 9, 8 % product concentration 30 min, 60 min contact time	Results showed a >3 log reduction for yeast at 3 % product concentration in 30 min and 2 % product concentration in 60 min under clean conditions. Formic acid was not efficacious at 1 % in 30 min. All controls were valid.	Supportive data Hunsinger (2015) 6.7-047
comparision control B	Surface disinfection/ Dipping	A-QUASAN (batch-no. 20009)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli NCTC 10538*	EN 1656:2019/EN 13727:2012+A2:2015	Quantitative suspension test, 20 °C, only comparision of control B	For all test organisms comparable results were achieved in control B, independent whether control B was performed according to EN 1656 or EN 13727.	Supportive data Hunsinger (2020) 6.7-048
PT 3 Bactericidal	Surface disinfection/ Dipping	A-QUASAN (batch-no. 20009)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli NCTC 10538*	EN 13727:2012+A2:2015	Quantitative suspension test, 20 °C, clean conditions (0.3 g/L BSA) 2, 1.5, 1, 0.75, 0.5 % product concentration 5 min, 30 min contact time	Results showed a >5 log reduction at 1 % product concentration in 5 min and at 0.75 % in 30 min.	Supportive data Hunsinger (2020) 6.7-049

Separate contact times for mandatory target organisms

As bacteria and yeast are considered as mandatory organisms for the intended uses, normally a product needs to be at least efficacious against those two groups of organisms at the intended use concentrations and contact times. However, the applicant provided a justification why separate product concentration/contact times should be applied for the target organisms in this case.

The reasons are: The product is only intended for professional use. A professional user optimizes the use of disinfection products in regards to occupational and environmental safety. The professional user is able to differentiate which microbiological hazard is present at what time point and needs to be handled. Bacteria and yeast can occur in different numbers depending on use area and soiling. Especially in moist environments a massive bacteria infestation can occur, whereas yeast will not be quantifiable there. In order to control disinfecting measures by professional users the surfaces are examined at regular intervals by contact slides so that a specific application of the biocidal product is given. Therefore, separate contact times/in use product concentrations were accepted for this product for the mandatory target organisms.

Formic acid as non-active co-formulant

The product contains benzoic acid (active substance) and formic acid (see product composition, chapter 2.2.1). Formic acid is evaluated as an existing active substance in accordance with the Regulation (EU) No. 1062/2014. According to the applicant, formic acid is not acting as an active substance in the product but serves as a pH regulator (see 6.7-036 and 6.7-037). In order to prove that formic acid is not acting as an active substance, the applicant provided additional phase 2, step 2 tests (EN 13697, EN 14349, EN 16438) against bacteria and yeast with product without benzoic acid (dummy product) and formic acid alone (see Table 17, 6.7-042-6.7-047). Thereby, the efficacy of the product with and without benzoic acid as well as formic acid alone were compared after the different contact times claimed for the biocidal product (5, 15, 30 and 60 min). A reduction of > 4 log for the most resistant strain *E. hirae* was shown in e.g. EN 13697 for the fully formulated product at 1.5 % product concentration in 30 min. The dummy product without benzoic acid only showed a log reduction of lg R 2.77 at that concentration and contact time. Formic acid alone showed a reduction of 1.4 log or less for *E. hirae* at the lowest concentrations tested (0.5 %, which was higher than the formic acid concentration in the fully formulated product at in use concentration (0.063 %)). Therefore, it was considered that formic acid is not acting as an active substance in the BP but serves rather as pH regulator and increases the amount of benzoic acid in undissociated efficacious form.

Precipitation in phase 2, step 1 tests

In the submitted phase 2, step 1 tests (EN 1656, EN 1650, EN 1276) precipitation occurred at test procedures >15 min and product concentrations ≥ 1.5 %. The applicant provided additional justifications and controls so that the validity of the studies could be proven. The additional controls included membrane filtration of the complete test mixture after sample taking (1 ml) for plating and additional

plating of the membrane filter on agar plates to exclude microbial growth in the precipitate while no growth could be observed in the normal sample. The data have been included in the efficacy test reports and additional information can be found in IUCLID.

Use in veterinary healthcare

The applicant provided additional studies (EN 13727, 6.7-049) as well as comparisons of control B (toxicity of the neutralisation medium) according to EN 1656 and EN 13727 (6.7-048) in order to prove that bridging of PT 3 study results to PT 2 study results (for use area veterinary healthcare) is possible.

Summary on efficacy

In general, sufficient bactericidal and yeasticidal activity (PT 3 and 4) at 10 and 20 °C as well as fungicidal activity (PT 4) at 20 °C has been proven for disinfection of clean, non-porous surfaces (PT 3 and 4) as well as inner surfaces (PT 4).

3.5.6 Occurrence of resistance and resistance management

Many publications are available that report about resistance of micro-organisms against benzoic acid, mainly in the context of food spoilage (Davidson, PM and Harrison, MA, 2002;[9] Brul, S and Coote, P, 1999[10]). A number of yeasts are known to be resistant to benzoates. It is suggested that the mechanism by which yeasts develop resistance to weak acidic antimicrobials, including benzoic acids, is related to membrane permeability and the ability of the cells to continuously pump antimicrobials out of the cell. Some micro-organisms on the other hand have innate resistance to benzoates because they metabolize the compounds. These bacteria and molds degrade benzoic acid through either the ortho or the meta cleavage pathway. Few studies examine the potential for acquired resistance to benzoic acid in yeasts previously exposed to sub-inhibitory concentrations of benzoic acid. Pre-exposure to benzoic acid caused a 1.4 to 2.2 fold increase in MIC. The proposed resistance mechanism was increased cellular efflux (Warth, AD, 1988[11]). There was neither any evidence of indicating increased resistance due to mutation nor any evidence that the resistance was stable. Further, there is little or no evidence in the literature of acquired bacterial resistance to benzoic acid.

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9 Davidson, PM and Harrison, MA (2002) Resistance and Adaption to Food Antimicrobials, Sanitizers, and Other Process Controls. Food technology 56 (11): 69-78

10 Brul, S and Coote, P (1999) Preservative Agents in Foods. International Journal of Food Microbiology 50: 1-17

11 Warth, AD (1988) Effect of Benzoic acid on Growth Yield and Yeasts Differing in Their Resistance to Preservatives. Applied and Environmental Microbiology 54(8): 2091-2095

Considering the length of time that benzoic acid has been applied to food products it would seem, however, that the development of acquired resistance by spoilage and pathogenic micro-organisms is very rare or non-existent.

3.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of the disinfectant BP.

3.5.8 Evaluation of the label claims

The following biocidal label claims are supported by the efficacy data provided (non-biocidal label claims have not been evaluated):

All uses:

- For disinfection of clean, non-porous surfaces

Use #1-2

- Effective against bacteria and yeast

Use #3-7

- Effective against bacteria, yeast and fungi

To ensure the efficacy of the products, the following use conditions have to be indicated on the product label:

- Only use on clean surfaces.

Contact times should be stated on the product label.

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

The product is not intended to be authorized for use in combination with other biocidal products.

3.5.10 Data waiving and conclusion

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 19

Conclusion on the efficacy
Efficacy tests were conducted on the product A-QUASAN B. The diluted product demonstrated bactericidal and yeasticidal efficacy under test conditions defined for disinfection of clean non-porous surfaces in veterinary, veterinary hospital and food area by spraying, soaking and dipping. Furthermore, fungicidal efficacy was shown for food area disinfection. **Use 1 & Use 2** ***For use at 10°C*** Bactericidal – 3 %, contact time 30 min – 2.5 %, contact time 60 min Yeasticidal – 4.5 %, contact time 30 min – 3.5 %, contact time 60 min – 3 %, contact time 120 min *For use at 20°C (e.g. in veterinary hospitals)* Bactericidal – 2.5 %, contact time 30 min – 2 %, contact time 60 min Yeasticidal – 4 %, contact time 30 min – 3.5 %, contact time 60 min – 3 %, contact time 120 min **Use 3-7** *For use at 10°C* Bactericidal – 2.5 %, contact time 5 min – 1.5 %, contact time 30 min – 1 %, contact time 60 min Yeasticidal – 2.5 %, contact time 15 min – 2 %, contact time 30 min *For use at 20°C* Bactericidal – 2 %, contact time 5 min – 1.5 %, contact time 30 min

Conclusion on the efficacy
– 1 %, contact time 60 min Yeasticidal – 2.5 %, contact time 15 min – 2 %, contact time 30 min – 1.5 %, contact time 60 min Fungicidal – 6 %, contact time 15 min – 5 %, contact time 30 min – 4 %, contact time 60 min It is concluded that the product is expected to be efficacious if used in accordance with the use instructions proposed in the SPC. Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of the BP have been met. To ensure the efficacy of the products, the following use conditions have to be indicated on the product label: Only use on clean surfaces / equipment

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 20

Benzoic acid	Value	Study	Safety factor
ADI (acceptable daily intake, external long-term reference dose)	5 mg/kg bw [1]	Rat, subchronic, carcinogenicity studies	100
AOEL-S (Operator Exposure)	5 mg/kg bw [1]	Rat, subacute, subchronic, reproductive and developmental studies	100
ARfD (acute reference dose)	Not allocated, not necessary [1]		

[1] Based on Assessment-Reports (PT3 & 4) (RMS DEU (2013))

Table 21

Benzoic acid	Value	Reference
Oral absorption	nearly complete: excretion >80 % [1]	Rapid: peak plasma concentration within 1-2 h, based on urinary excretion, human data
Dermal absorption	See chapter 3.6.2.7	

[1] Based on Assessment-Reports (PT3 & 4) (RMS DEU (2013))

3.6.2 Assessment of effects of the product on human health

The *in vivo* studies submitted by the applicant have been conducted with the biocidal product A-QUASAN B, which was referred to as MENNO FLORADES and equals the representative product in the active substance evaluation of benzoic acid (PT3 and PT4) under Regulation (EU) No. 528/2012. MENNO FLORADES is also a plant protection product with the same formulation, authorised under Regulation (EC) No 1107/2009.

3.6.2.1 Skin corrosion and irritation

Table 22

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration(of exposure**	**Results**	**Remarks (e.g. major deviations)**	**Reference**
OECD TG 404 (17.07.1992), GLP compliant, Reliability: 1	Rabbit, White New Zealands, unspecified sex, 3 animals	Benzoic acid (9.0 %; purity: 100 %, according to the study protocol), formic acid (4.2 %; purity: 98-100 %) 0.5 mL of test article, exposure for 4 h	Average score erythema: Animal No. 1: 0.0 Animal No. 2: 1.0 Animal No. 3: 2.0 Average score oedema: Animal No. 1: 0.0 Animal No. 2: 0.0 Animal No. 3: 1.0 Very slight to well-defined redness of the skin was observed in all animals. Very slight swelling was seen in one animal at 24, 48 and 72 h p.a. These observed findings were reversible within 6 days p.a.	Sex of animals was not given.	8.1. Report no. 10-03-0862/00-94

Table 23

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to the skin.
Justification for the value/conclusion	Based on an *in vivo* animal study.
Classification of the product according to CLP	Classification for skin corrosion and irritation is not required.

3.6.2.2 Eye irritation

Table 24

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** **Average score (24, 48, 72h)/ Observations and time point of onset, Reversibility**	**Remarks (e.g. major deviations**	**Reference**
OECD TG 405 (24.02.1987), GLP compliant, Reliability: 1	Rabbit, White New Zealands, unspecified sex, 3 animals	Benzoic acid (9.0 %; purity: 100 %, according to the study protocol), formic acid (4.2 %; purity: 98-100 %), 0.1 g of test article, single dose	Animal No. 1: No evaluation due to adhesion of the eyelids caused by severe ocular secretion Average score Cornea: Animal No. 2: 3.67 Animal No. 3: 2.0 Average score Iris: Animal No. 2: evaluation not possible Animal No. 3: 1.0 (hyperemia) Average score Conjunctivae (redness): Animal No. 2: 3.0 Animal No. 3: 3.0	Sex of animals was not given	Report no. 10-03-0861/00-94

			Average score Conjunctivae (chemosis): Animal No. 2: 3.67 (ocular secretion) Animal No. 3: 3.33 Corneal opacity, hyperemia of the iris, redness and chemosis of the conjunctivae and ocular secretion were each observed in all animals. Although an assessment of the treated eye in the first animal was not possible at 48 and 72 h p.a., it is expected that severe ocular lesions (ocular secretion) occured. In two animals corneal opacity was not fully reversible within 21 days p.a. appeared, comparable to those findings observed in the other animals. In all animals there were long-lasting severe findings. The strength of effects and the irreversibility of some effects in 2 of 3 animals indicate that the biocidal product causes severe eye damage.		

Table 25

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	Damaging to the eye.
Justification for the value/conclusion	Based on an *in vivo* animal study.
Classification of the product according to CLP	Eye Dam. 1, H318

3.6.2.3 Respiratory tract irritation

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.10 Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008.

Table 27

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory tract irritation.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 28

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, Duration of exposure, Route of exposure**	**Results** **Proportion of sensitised animals at induction dose); evidence for local or systemic toxicity (time**	**Remarks** **(e.g. major deviations)**	**Reference**

			course of onset)		
Method: Magnusson & Kligman maximisation test Guidelines: OECD 406; 96/54/EEC, Annex V, Test B.6; EPA OPPTS 870.2600 GLP: yes Reliability: 2	Guinea pig, Pirbright White Crl:HA, <u>Range Finding Test</u> 1 m, 1 f <u>Main Test</u> 10 test animals (5 m, 5 f) 5 control animals (2 m, 3 f) <u>Rechallenge</u> 10 test animals from main test 5 control animals (3 m, 2 f)	Benzoic acid (9.0 %; purity: 100 %, according to the study protocol), formic acid (4.2 %; purity: 98-100 %), 0.1 g of test article, single dose	<u>Range Finding Test</u> No skin reactions 48 h after intradermal injection of 5 % test material and dermal application of undiluted test material. <u>Main Test</u> No skin reactions after dermal application in induction phase Test group – 24 h after challenge exposure: *Erythema* 100 % test substance – m: 1/1/1/0/1, f: 0/1/1/1/1 Vehicle – all 0 *Oedema* 100 % test substance – m: 1/1/1/0/1, f: 0/1/1/1/1 Vehicle – all 0 Reaction rate: 80 % Test group – 48 h after challenge exposure: *Erythema* 100 % test substance – m: 2/**/2/2/2, f: **/2/2/2/2 Vehicle – all 0 *Oedema* 100 % test substance – m: 1*/0/1*/1*/1*, f: 0/1*/1*/1*/1* Vehicle – all 0 Reaction rate: 100 % Control group – 24 h after challenge exposure: *Erythema*	The test was performed with only 10 test animals. The OECD guideline 406 strongly recommends carrying out a study with 20 animals. Only if a clear sensitising effect can be demonstrated 10 animals are sufficient. However, since the result after the rechallenge was clearly negative in 10 of 10 animals the study is considered acceptable. Both treated animals and control animals show skin reaction after challenge at a dose level of 100 %. Therefore, it was considered justified to perform a re-challenge with lower concentrations (e.g. 50 %)	Report no. 10-5-0202-02

			100 % test substance – m: 1/1, f: 1/0/1 Vehicle – all 0 *Oedema* 100 % test substance – m: 1/1, f: 1/0/1 Vehicle – all 0 Reaction rate: 80 % Control group – 48 h after challenge exposure: *Erythema* 100 % test substance – m: 2/2, f: 2/2/2 Vehicle – all 0 *Oedema* 100 % test substance – m: 1*/1*, f: 1*/1*/1* Vehicle – all 0 Reaction rate: 100 % <u>Rechallenge</u> Test group – 24 h and 48 h after rechallenge exposure: *Erythema* 50 %, 25 %, 10 % of test substance – all 0 Vehicle – all 0 *Oedema* 50 %, 25 %, 10 % of test substance – all 0 Vehicle – all 0 Reaction rate (50 %, 25 % or 10 %): 0 % Control group - 24h and 48h after rechallenge exposure: *Erythema* 50 %, 25 %, 10 % of test substance – all 0 Vehicle – all 0 *Oedema*		

			50 %, 25 %, 10 % of test substance – all 0 Vehicle – all 0 Reaction rate (50 %, 25 % or 10 %): 0 % The biocidal product MENNO Florades is considered not to be sensitising to the skin. (** slight eschar formation, * hardening of treated area)		

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Based on an *in vivo* animal study.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product family or their components are not available.

Table 31

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components that are known to have sensitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.

Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 32

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Type of administration**	**Signs of toxicity *(nature, onset, duration, severity, reversibility)***	**Value LD50**	**Remarks *(e.g. major deviations)***	**Reference**
OECD TG 401 (24.02.1987), GLP compliant, Reliability: 1	Rat, Hsd/Win:WU, 5 male and 5 female rats	Benzoic acid (9.0 %; purity: 100 %, according to the study protocol), formic acid (4.2 %; purity: 98-100 %), application of a single dose of 2000 mg/kg bw by gavage (1.98 mL/kg)	No findings	LD_{50} (male and female) > 2000 mg/kg No animals died during the study.	-	Report no. 10-04-0859/00-94

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	Non-toxic via the oral route.
Justification for the selected value	Based on an *in vivo* animal study.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation

Data waiving was acceptable for the following information requirements	
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indications on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 35

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (dusts and mists): > 5 mg/L
Justification for the selected value	The LC_{50} (dusts and mists) is calculated from the acute inhalation toxicity data of the single components.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 36

Summary table of animal studies on acute dermal toxicity						
Method, Guide-line, GLP status, Reliabi-lity	**Species, strain, Sex, No / group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity (nature, onset, duration, severity, reversibility)**	**LD50**	**Remarks (e.g. major deviations)**	**Refe-rence**
OECD TG 402 (24.02.1987), GLP complia	Rat, Hsd/Win: WU, 5 male and 5 female rats	Benzoic acid (9.0 %; purity: 100 %, according to the study	No abnormal clinical signs, no animal died during the study In 3 female animals erythema was seen	LD50 (male and female) > 2000 mg/kg	The test was perfor-med with female ani-mals with a weigt range	10-04-0860/00-94

Summary table of animal studies on acute dermal toxicity						
Method, Guide-line, GLP status, Reliabi-lity	**Species, strain, Sex, No / group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity (nature, onset, duration, severity, reversibility)**	**LD50**	**Remarks (e.g. major deviations)**	**Refe-rence**
nt, Reliabilit y: 1		protocol), formic acid (4.2 %; purity: 98-100 %), single dermal administratio n of 2000 mg/kg bw (1.98 mL/kg)	until day 4 p.a. In 2 females it was associated with slight fissuration which was still apparent in one female until day 7 p.a. Weight gains were reduced in 4 of 5 male animals as well as in 4 of 5 female animals during the entire observation period.		at study initiation of 177-221 g. According to OECD guideline 402 the test should be conducted with young adults with a size. which facilitates the conduct of the test (200-300 g). However, since the result was clearly ne-gative the study is considered acceptable.	

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Non-toxic via the dermal route.
Justification for the selected value	Based on an *in vivo* animal study.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	In the absence of reliable dermal absorption data with the biocidal product or comparable formulations, default values according to EFSA Guidance on Dermal Absorption (2017) can be applied for the soluble concentrate and the dilution.

Table 39

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenario(s)	Benzoic acid (concentrate)	Benzoic acid (dilution)
Value(s)	10 %	50 %
Justification for the selected value(s)	Default for water-based/dispersed soluble concentrate and dilutions (EFSA Guidance on dermal absorption (2017))	

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

3.6.2.8.1 Propan-2-ol (CAS-No.: 67-63-0)

Threshold Limits and other Values for Human Health Risk Assessment

	Value	Source	AF
Dermal absorption	10 % 50 %	Default value for the soluble concentrate and Default value for dilution	
AEL acute / medium-term / long term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Human volunteer study (Sethre et al. 2000a)	6.4
AEL acute / medium term / long term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Human volunteer study (Sethre et al. 2000a)	3.8
ADI	Not necessary, no residues in food expected		
ARfD	Not necessary, no residues in food expected		

Classification	
Harmonised Annex VI (1272/2008/EC)	Eye Irrit. 2, H319 STOT SE 3, H336,
Proposed classification and labelling with regard to toxicological data according to the criteria in Reg. 1272/2008 based on Assessment-Report (RMS DE (2017))	Eye Irrit. 2, H319 STOT SE 3, H336, EUH066*

3.6.2.8.2 Propan-1-ol (CAS-No.: 71-23-8)

Threshold Limits and other Values for Human Health Risk Assessment

Table 23

Summary			
	Value	Source	AF
$AEL_{long\text{-}term}$	9.2 mg/kg bw/d	Overall NOAEL from rat 13-week rat inhalation study (impairment in male fertility parameters)	200 (In addition to default AF of 100, application of separate AF of 2 for extrapolation from medium-term to long-term systemic toxicity)
$AEL_{medium\text{-}term}$	18.3 mg/kg bw/d	Overall NOAEL from rat 13-week inhalation study (impairment of male fertility parameters), Assessment-Report (RMS DE (2019))	100
AEL_{acute}	27.6 mg/kg bw/d	Rat inhalation developmental toxicity studies (foetal skeletal malformations), Assessment-Report (RMS DE (2019))	100
Oral absorption	Nearly 100 %	based on *in vivo* rat study, Assessment-Report (RMS DE (2019))	
Dermal absorption	10 % 50 %	Default value for the soluble concentrate and Default value for dilution	
Inhalation absorption	100 % default value	No absorption studies available. Physical chemical parameters and blood:air partition coefficients are indicative for a complete absorption comparable to propan-2-ol, Assessment-Report (RMS DE (2019))	

Classification

Summary			
	Value	Source	AF
Proposed classification and labelling with regard to toxicological data according to the criteria in Reg. 1272/2008 based on Assessment-Report (RMS DE (2019))		Eye Dam. 1, H318 STOT SE 3, H336, EUH066	

3.6.2.8.3 Ethane-1,2-diol (CAS-No.: 107-21-1)

Data for WORKERS

INHALATION Exposure	**Threshold**	**Most sensitive study**
Local Effects		
European OEL (IOELV)	52 mg/m³ (8h-TWA) 104 mg/m³ (STEL (15 mins))	Irritation (mucosae) in human volunteers

Data for the GENERAL POPULATION

INHALATION Exposure	**Threshold**	**Most sensitive study**
Local Effects		
DNEL Long-term:	7 mg/m³	skin irritation/corrosion
	Threshold	**Most sensitive study**
DERMAL Exposure,		
DNEL Long-term:	53 mg/kg bw/day	repeated dose toxicity

Classification	
Harmonised Annex VI (1272/2008/EC)	Acute Tox. 4; H302 STOT RE 2; H373

3.6.2.8.4 Formic acid (CAS-No.: 64-18-6)

Data for WORKERS

INHALATION Exposure	**Threshold**	**Most sensitive study**
Local Effects		
European OEL (IOELV)	9 mg/m³ (8h-TWA)	irritation (respiratory tract)
DERMAL Exposure, ORAL Exposure, EYE Exposure		
High hazard (no threshold derived)		

Data for the GENERAL POPULATION

INHALATION Exposure	**Threshold**	**Most sensitive study**
Local Effects		
DNEL Long-term:	3 mg/m³	irritation (respiratory tract)

DERMAL Exposure, ORAL Exposure, EYE Exposure
High hazard (no threshold derived)

Classification	
Harmonised Annex VI (1272/2008/EC)	Skin Corr. 1A H314

Based on the available toxicological information for the single components, the biocidal product is classified with STOT RE 2 (lung, kidney), H373 and STOT SE 3, H336.
For details refer to the confidential annex 5.2.2 Information on the substance(s) of concern in the product.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not available.

3.6.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on an *in vivo* study, the biocidal product is considered as not corrosive or irritating to the skin.
Eye irritation	Based on an *in vivo* study, the biocidal product is classified with Eye Dam. 1, H318.
Respiratory tract irritation	Based on the available toxicological information for the single components, the biocidal product is not classified for respiratory tract irritation.
Skin sensitisation	Based on an *in vivo* study, the biocidal product is not classified for skin sensitisation.
Respiratory sensitization (ADS)	Based on the available toxicological information for the single components, the biocidal product is not classified for respiratory sensitisation.
Acute toxicity by oral route	Based on an *in vivo* study, the biocidal product is not classified for acute oral toxicity.
Acute toxicity by inhalation	Based on the available toxicological information for the single components, the biocidal product is not classified for acute inhalation toxicity.
Acute toxicity by dermal route	Based on an *in vivo* study, the biocidal product is not classified for acute dermal toxicity.

Endpoint	Brief description
Information on dermal absorption	10 % for concentrate (default value for soluble concentrates, EFSA Guidance 2017) 50 % for dilution (default value for aqueous dilutions, EFSA Guidance 2017) Refer to the Confidential Annex.
Available toxicological data relating to non-active substance(s)	Based on the available toxicological information for the single components, the biocidal product is classified with STOT RE 2 (lung, kidney), H373 and STOT SE 3, H336. For details refer to the Confidential Annex.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not available.

3.6.3 Exposure assessment

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

Table 41

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

List of scenarios

Table 42

	Summary table: scenarios			
Scenario number	Use	Scenario	Primary or secondary exposure Description of scenario	Exposed group

		(e.g. mixing/ loading)		**(e.g. professionals, non-professionals, bystanders)**
1a	1	PT03 - Disinfectant of hard surfaces - Professional user - Spraying – Indoor	Primary exposure of workers resulting from dilution and application of the b.p. using a hand-held manual medium/high pressure spraying/foaming device (4-7 bar) to disinfect 100 small rooms (kennels) and cleaning of equipment. Secondary exposure was considered to be re-entry of the treated area for rinsing (Scenario 2a).	professionals
1b	3	PT04 - Disinfectant of hard surfaces - Professional user - Spraying – Indoor	Primary exposure of workers resulting from dilution and application of the b.p. using a hand-held manual medium/high pressure spraying/foaming device (4-7 bar) indoors and cleaning of the equipment. Secondary exposure was considered to be re-entry of the treated area for rinsing (Scenario 2b).	professionals
2a	1	PT03 - Secondary exposure – spray treatment (re-entry of treated location)	Secondary inhalation/dermal exposure of workers resulting from re-entry of treated facility (100 dog kennels) after contact time to rinse off the treated surfaces.	professionals
2b	3	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Secondary inhalation/dermal exposure of workers resulting from re-entry of treated facility (canteen / kitchen) after contact time to rinse off the treated surfaces.	professionals
3a	2	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Primary exposure of workers resulting from dilution and application of the b.p during disinfection of equipment by soaking followed by placing the treated equipment on storage location. (e.g. dishes, cutlery, equipment, small machinery, machine items, crates, boxes)	professionals
3b	4	PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Primary exposure of workers resulting from dilution and application of the b.p during the disinfection of equipment by soaking followed by placing treated equipment on storage location. (e.g. dishes, cutlery, equipment, small machinery, machine items, crates, boxes)	professionals
4	5, 6, 7	PT04 - Disinfectant of inner surfaces without circulation -	Primary exposure of workers during cleaning in place, closed system Only contact under particular circumstances (contamination during maintenance of equipment)	professionals

		Professional user - Indoor		
5	1,2	PT3 - Post-application	Secondary exposure – Entering treated room and touching dried disinfected surface.	General Public

3.6.3.1.1 Professional exposure

A-QUASAN B is a water-based concentrate for surface disinfection in the veterinary sector as well as in the food and feed sector. It is applied by spraying (foaming), dipping or by filling of pipelines for disinfection of closed systems.

It is a concentrate disinfectant containing benzoic acid (CAS-No.: 65-85-0, 9.09 %) as active substance. The biocidal product also contains the substance of concern (SoC) propan-1-ol (CAS-No.: 71-23-8), propan-2-ol (CAS-No.: 67-63-0), ethane-1,2-diol (CAS-No.: 107-21-1) and formic acid (CAS-No.: 64-18-6).

The biocidal product is marketed in different package sizes: Bottle 1 L HDPE screw cap/child safety closure – DIN 25/13 HDPE, bottle with 1,2handle 2 L HDPE screw cap HDPE, jerry can 10 L HDPE screw cap HDPE, jerry can 20 L HDPE screw cap HDPE, jerry can 30 L HDPE screw cap HDPE, drum 220 L HDPE L-Ring drum.

Exposure to the a.s./SoC is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. The assessment is usually based on the harmonized document “Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated, where relevant, by corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

In Annex 4.3.1, the details of the exposure calculations to the a.s./SoC for the professional user are laid out.

Scenario 1 - Disinfectant of hard surfaces - Professional user - Spraying – Indoor

Manual medium pressure spray/foam treatment (4-7 bar)

Description

The exposure assessment of the manual medium pressure spray/foam treatment is based on model data described in detail in the Biocides Human Health Exposure Methodology document (October 2015, version 1).

A-QUASAN B is a water-soluble liquid concentrate that has to be diluted prior to application. Subsequently, the application liquid is sprayed/foamed using hand-held manual medium pressure devices (4-7 bar) to disinfect hard surfaces in veterinary sector and food processing facilities.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During application process, exposure via skin is likely, mainly due to deposition of the generated aerosol on work clothing and the hands of the operator and through contact with contaminated surfaces (e.g. treated surfaces, equipment). For the application method of medium pressure spraying/foaming, dermal exposure is assessed using “Spraying model 2” (Biocides Human Health Exposure Methodology Document Version 1 (October 2015)). It already contains mixing and loading of liquids in compression sprayers. Therefore, a separate calculation for this phase has not been performed.

In addition, exposure of hands during cleaning of the equipment has to be considered, although it represents a minor part of total dermal exposure. This post-application phase is assessed using the model presented in the “Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure: Cleaning of spray/foam equipment in antifouling use (PT 21)”. However, the assessor assumes that a thorough cleaning for 20 minutes as considered in the above mentioned document for PT 21 is not needed in case of low concentrated water-based application solutions; instead, a figure of 5 min seems to be appropriate here.

Inhalation exposure

Exposure to aerosols is not expected for the post-application phase, but occurs during mixing and loading as well as during application phase (spraying/foaming) and is calculated for the a.s. using the values from “Spraying model 2”. In addition, inhalation exposure to vapour is calculated for the volatile SoC’s propan-1-ol, propan-2-ol and ethane-1,2-diol by using ConsExpo Web.

Exposure to the eyes

During mixing and loading and application phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Calculations for Scenario 1

The detailed description of scenario 1a is summarised in Table 43 and of scenario 1b in Table 45.
The results of calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) of scenario 1a are summarised in Table 44 and of scenario 1b in Table 46.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on Scenario 1

Additionally, during spraying of the application liquid in downward direction, exposure to the feet is expected. Thus, footwear protective against chemicals (EN 13832) is required.

Table 43

Description of Scenario 1a **PT03 - Disinfectant of hard surfaces - Professional user - Spraying**		
Scenario 1a represents the exposure assessment of a disinfection application by foaming in the veterinary sector; here: small animal houses (100 dog kennels, worst-case assumption of the applicant). This scenario constitutes of a worst-case scenario with regard to dermal exposure while foaming and especially to inhalation exposure to the volatile SoC contained in the product. The following parameters were used for the evaluation. *Secondary exposure* See scenario 2a.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	4.5%
	Application rate	400 ml/m²
	Application duration	2 min
	Exposure duration	2 min
	Frequency	100 events/day
	Room volume	8 m³
	Ventilation rate	1.3 h^{-1}
	Release area	20 m²
Tier 2	Protection factor respiratory tract: Half mask + gas filter (EN 529, table C.1)	10
	Protection factor body: type 6, EN 13034 (coated coverall)	10%
	Protection factor hands: protective gloves (EN 374, HEEG opinion 9)	10% (Post-Application) indicative value (M&L + Applic.)

Table 44

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 1a	Tier 1: No PPE	Benzoic acid: 0.130	Benzoic acid: 203.61
		Propan-1-ol: 7.81	Propan-1-ol: 486.06
		Propan-2-ol: 9.769	Propan-2-ol: 291.19
		Ethane-1,2-diol: 0.63	Ethane-1,2-diol: 715.23
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: $1.3*10^{-2}$	Benzoic acid: 9.26
		Propan-1-ol: 0.781	Propan-1-ol: 22.10
		Propan-2-ol: 2.81	Propan-2-ol: 13.24
		Ethane-1,2-diol: $6.31*10^{-2}$	Ethane-1,2-diol: 32.30

Table 45

Description of Scenario 1b **PT04 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor**		
Scenario 1b represents the exposure assessment of a disinfection application using foaming in a food processing plant (canteen kitchen). The following parameters were used for the evaluation. *Secondary exposure* See scenario 2b.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	6%
	Application rate	400 ml/m²
	Application duration	120 min
	Exposure duration	240 min
	Frequency	1 event/day
	Room volume	2400 m³
	Ventilation rate	1.3 h^{-1}
	Release area	2000 m²
Tier 2	Protection factor respiratory tract: Half mask + gas filter (EN 529, table C.1)	10
	Protection factor body: type 6, EN 13034 (coated coverall)	10%
	Protection factor hands: protective gloves (HEEG opinion 9)	10% (Post-Application) indicative value (M&L + App)

Table 46

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 1b	Tier 1: No PPE	Benzoic acid: 0.104	Benzoic acid: 325.47
		Propan-1-ol: 9.747	Propan-1-ol: 776.98
		Propan-2-ol: 8.648	Propan-2-ol: 465.47
		Ethane-1,2-diol: 0.730	Ethane-1,2-diol: 573.25
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: $1.04*10^{-2}$	Benzoic acid: 19.79
		Propan-1-ol: 0.975	Propan-1-ol: 47.23
		Propan-2-ol: 0.865	Propan-2-ol: 28.30
		Ethane-1,2-diol: $7.30*10^{-2}$	Ethane-1,2-diol: 34.85

Scenario 2 - Secondary exposure – spray treatment (re-entry of treated location for rinsing)

Description

This scenario assesses dermal and inhalation exposure to the biocidal product when re-entering the treated rooms to rinse the disinfectant with water.
Secondary dermal exposure of workers due to contact with treated surfaces in animal housings cannot be excluded. Additionally, inhalation exposure to volatile SoCs of the b.p. may be possible during re-entry of the treated facilities.

Dermal exposure
It is expected that dermal exposure of a professional user is possible when treated surfaces are touched. Compared to primary exposure, secondary exposure is only a small part of total exposure.

Inhalation exposure

For the re-entry into the treated facilitiy, inhalation exposure to vapour is expected and calculated for the volatile SoC. propan-1-ol, propan-2-ol, ethane-1,2-diol and the sublimating active substance benzoic acid by using ConsExpo Web.

Exposure to the eyes

During rinsing of the disinfectant with water, splashes are likely to occur. Eye contact in consequence of splashes to the non-volatile substances highly diluted in the rinsing water cannot be excluded.

Calculations for Scenario 2

The detailed description of scenario 2a is summarised in Table 47 and of scenario 2b in Table 49. The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) of scenario 2a are summarised in Table 48 and of scenario 2b in Table 50. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on scenario 2

Additionally, when rinsing the disinfectant, exposure of the feet to the non-volatile substances highly diluted in the rinsing water is expected. Thus, footwear protective against chemicals (EN 13832) is required.

Table 47

Description of Scenario 2a **PT03 - Secondary exposure – spray treatment (re-entry of treated location)**		
Scenario 2a represents the exposure assessment of rinsing of many small animal houses (100 dog kennels, worst-case assumption of the applicant) with water after a previous disinfection application by foaming. The following parameters were used for the evaluation. For estimation of inhalation exposure to the volatile substances, the mean event concentration of the respective substances after 30 minutes-contact time was determined using the ConsExpo model; this corresponds to the average value between minute 32 and minute 34 after the start of application.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	4.5%
	Application rate	400 ml/m²
	Application duration	2 min (after 2 minutes Application + 30 minutes-contact time)
	Exposure duration	2 min
	Frequency	100 events/day
	Room volume	8 m³
	Ventilation rate	15 h^{-1}
	Release area	20 m²
	Exposure model (ConsExpo)	vapour / evaporation / (mean event concentration between minute 32 and minute 34 after start of application)
Tier 2	Protection factor respiratory tract: Half mask+gas filter	10
	Protection factor body: type 6, EN 13034 (coated coverall)	10%
	Protection factor hands: protective gloves	10% (Post-Application) indicative value (M&L + App)

Table 48

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 2a	Tier 1: No PPE	Benzoic acid: $8.71*10^{-3}$	Benzoic acid: 67.08
		Propan-1-ol: 55.00	Propan-1-ol: 160.15
		Propan-2-ol: 63.33	Propan-2-ol: 95.94
		Ethane-1,2-diol: 0.483	Ethane-1,2-diol: 118.15
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: $8.71*10^{-4}$	Benzoic acid: 6.71
		Propan-1-ol: 5.50	Propan-1-ol: 16.01
		Propan-2-ol: 6.33	Propan-2-ol: 9.59
		Ethane-1,2-diol: $4.83*10^{-2}$	Ethane-1,2-diol: 11.82

Table 49

Description of Scenario 2b **PT04 - Secondary exposure – spray treatment (re-entry of treated location)**		
Scenario 2b represents the exposure assessment of rinsing a food processing plant (canteen kitchen) with water after a previous disinfection application by foaming. The following parameters were used for evaluation.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	6%
	Application rate	400 ml/m²
	Application duration	200 min
	Exposure duration	200 min
	Frequency	1 event/day
	Room volume	2400 m³
	Ventilation rate	15 h^{-1}
	Applied amount	800,000 g
	Exposure model (ConsExpo)	vapour / instantaneous release
Tier 2	Protection factor respiratory tract: Half mask + gas filter (EN 529, table C.1)	10
	Protection factor body: type 6, EN 13034 (coated coverall)	10%
	Protection factor hands: protective gloves (HEEG opinion 9)	10% (Post-Application) indicative value (M&L + App)

Table 50

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 2b	Tier 1: No PPE	Benzoic acid: 1.46	Benzoic acid: 89.45
		Propan-1-ol: 36.25	Propan-1-ol: 213.53
		Propan-2-ol: 21.67	Propan-2-ol: 127.92
		Ethane-1,2-diol: 120.00	Ethane-1,2-diol: 157.54
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: 0.15	Benzoic acid: 16.01
		Propan-1-ol: 3.63	Propan-1-ol: not applicable.
		Propan-2-ol: 2.17	Propan-2-ol: not applicable
		Ethane-1,2-diol: 12.00	Ethane-1,2-diol: 28.36

Scenario 3 - Disinfectant of equipment by soaking - Professional user - Dipping – Indoor

Dip treatment (manual dipping)

Description

A harmonised approach for exposure assessment of dip treatment is described in the Biocides Human Health Exposure Methodology document (October 2015, version 1). The assessment laid out in this PAR follows this approach.

A-QUASAN B is a concentrated disinfectant which has to be diluted prior to application. In case of manual dipping, the application liquid is either mixed directly inside the dipping tank or it is prepared in a mixing bin faced beside the dipping tank using an automatic dosage system in case of large packaging units. In this case the freshly prepared liquid has to be pumped into the dipping tank but in case of smaller packaging units manual addition of product cannot be excluded.

The application phase consists of dipping the equipment to be disinfected into the treatment solution for a period of time (minutes to hours, usually 30 to 120 minutes). The dipping process is carried out manually and followed by placing the treated equipment on the storage place to drip off.

Dermal exposure
Exposure to skin is considered to occur during all phases of handling.

Due to the process of dilution, exposure to hands is expected for the mixing and loading phase during connecting of transfer lines of the IBC to the automatic dosing system. An appropriate model is recommended by Human Exposure Expert Group (HEEG) and is used to calculate hand exposure. This phase has minor impact on total dermal exposure.

The application phase covers different steps of handling: manual dipping of equipment in a tank followed by manual removing the treated equipment for storage. Exposure to hand and body is considered to occur and is calculated using “Dipping model 1” (TNsG on Human Exposure) taking into account a duration of 30 minutes per day according to the Human Exposure Expert Group (HEEG) opinion on “Defaults and appropriate models to assess human exposure for dipping processes (PT8)”. The model provides measurement data of potential body and actual hand exposure (measurements of hand exposure inside gloves) and is recommended by the harmonized document “Biocides Human Health Exposure Methodology (October 2015, version 1)”. The application process significantly contributes to total dermal exposure.

Additionally, exposure to hand and body during cleaning of the dipping tank has to be considered. Since no suitable generic model for exposure assessment of the post-application phase exists, dermal exposure is estimated on the basis of expert judgement. Due to the extensive cleaning operation, the indicative values for hand and body exposure of “Dipping model 1” for one cycle are used. As a worst case assumption daily cleaning of the dipping tank is assumed.

Exposure by inhalation
Inhalation exposure may occur when leaning over the open tank to immerse and rotate the equipment. Therefore, inhalation exposure to aerosol of the active substance for the application phase has been calculated using indicative values of “Dipping model 1”. Inhalation exposure to vapour of the volatile SoC propan-1-ol, propan-2-ol and ethane-1,2-diol for the application phase has been assessed using the consumer exposure model ConsExpo which is applicable to estimate the volatile substance.

Exposure to the eyes
During the mixing and loading and application phase of the b.p. splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Calculations for Scenario 3

The detailed description of scenario 3a is summarised in Table 51 and of scenario 3b in Table 53. The results of the calculations for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) of scenario 3a are summarised in Table 52 and of scenario 3b in Table 54. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Table 51

Description of Scenario 3a **PT03 - Disinfectant of equipment by soaking - Professional user - Dipping – Indoor**		
Scenario 3a represents the exposure assessment of a disinfection application by soaking of equipment used in the veterinary sector. The following parameters were used for evaluation.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	4.5%
	Application rate	400 ml/m²
	Application duration	30 min
	Exposure duration	240 min
	Frequency	1 event/day
	Room volume	300 m³
	Ventilation rate	2 h^{-1}
	Applied amount	40000 g
	Release area	100 m²
	Exposure Model (ConsExpo)	Vapour/evaporation/increasing area
Tier 2	Protection factor respiratory tract: Improved ventilation (cross ventilation providing an air exchange rate of 5 /h)	air exchange rate of 5/h considered in ConsExpo (instead of 2/h)
	Protection factor body: type 6 EN 13034 (coated coverall)	20%
	Protection factor hands: protective gloves (HEEG opinion 9)	10% (Post-Application) indicative value (M&L + App)

Table 52

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 3a	Tier 1: - protective gloves (EN 374)	Benzoic acid: $5.11*10^{-5}$	Benzoic acid: 50.83
		Propan-1-ol: $1.05*10^{-2}$	Propan-1-ol: 121.34
		Propan-2-ol: $1.30*10^{-2}$	Propan-2-ol: 72.69
		Ethane-1,2-diol: $9.10*10^{-5}$	Ethane-1,2-diol: 89.53
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - improved ventilation - Footwear protective against chemicals (EN 13832)	Benzoic acid: $5.11*10^{-5}$	Benzoic acid: 15.13
		Propan-1-ol: $4.50*10^{-3}$	Propan-1-ol: 36.12
		Propan-2-ol: $5.50*10^{-3}$	Propan-2-ol: 21.64
		Ethane-1,2-diol: $4.00*10^{-5}$	Ethane-1,2-diol: 26.65

Table 53

Description of Scenario 3b **PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor**		
Scenario 3b represents the exposure assessment of a disinfection application by soaking of equipment used in the food processing sector. The following parameters were used for evaluation.		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	6%
	Application rate	400 ml/m²
	Application duration	30 min
	Exposure duration	240 min
	Frequency	1 event/day
	Room volume	300 m³
	Ventilation rate	2 h^{-1}
	Applied amount	40000 g
	Release area	100 m²
	Exposure Model (ConsExpo)	Vapour/evaporation/increasing area
Tier 2	Protection factor respiratory tract: Improved ventilation (cross ventilation providing an air exchange rate of 5 /h)	air exchange rate of 5/h considered in ConsExpo (instead of 2/h)
	Protection factor body: type 6 EN 13034 (coated coverall)	20%
	Protection factor hands: protective gloves (HEEG opinion 9)	10% (Post-Application) indicative value (M&L + App)

Table 54

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 3b	Tier 1: - protective gloves (EN 374)	Benzoic acid: $6.82*10^{-5}$	Benzoic acid: 66.71
		Propan-1-ol: $1.35*10^{-2}$	Propan-1-ol: 161.13
		Propan-2-ol: $1.70*10^{-2}$	Propan-2-ol: 96.53
		Ethane-1,2-diol: $1.20*10^{-4}$	Ethane-1,2-diol: 118.88
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - improved ventilation - Footwear protective against chemicals (EN 13832)	Benzoic acid: $6.82*10^{-5}$	Benzoic acid: 20.06
		Propan-1-ol: $6.00*10^{-3}$	Propan-1-ol: 48.09
		Propan-2-ol: $7.50*10^{-3}$	Propan-2-ol: 28.81
		Ethane-1,2-diol: $6.00*10^{-5}$	Ethane-1,2-diol: 25.22

Scenario 4 - PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor

Cleaning in place

Description

In this use, the inner surface of pipelines in the food and feed sector is disinfected. For this purpose, the application solution is mixed in a tank and automatically pumped into the pipe. Significant exposure is expected only for the mixing phase and during connecting of lines. A harmonised approach for exposure assessment of tasks including connecting of transfer lines is described in the Biocides Human Health Exposure Methodology document (October 2015, version 1). The assessment laid out in this PAR follows this approach.

A-QUASAN B is a concentrated disinfectant that has to be diluted prior to application. For disinfection of inner surfaces, the application liquid is either mixed directly in a tank which is integrated in the pipeline system (for adding medical or feed supplements) or is prepared in a mixing bin faced beside the tank

using an automatic dosage system in case of large packaging units. The freshly prepared liquid has to be pumped into the pipe system.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

For mixing and loading, exposure of hands is expected due to the dilution process and during connecting transfer lines of the IBC and/or mixing tank to the automatic dosing system. An appropriate model is recommended by Human Exposure Expert Group (HEEG) and used to calculate hand exposure. During application and post-application phase, no significant dermal exposure is expected.

Exposure by inhalation

Significant exposure to aerosols and vapours of the volatile SoC during mixing/loading is calculated with the *advanced reach tool model (ART).* During application and post-application phase, no significant inhalation exposure is expected.

Exposure to the eyes

During mixing and loading phase of the b.p., splashes are likely to occur. Eye contact in consequence of splashes cannot be excluded.

Table 55

Description of Scenario 4 **Disinfectant of inner surfaces without circulation - Professional user - Indoor**		
The following parameters were used for the evaluation		
	Parameters	Value
Tier 1	Concentration of the a.s. benzoic acid in the b.p.	9.09%
	Concentration of the soc propan-1-ol in the b.p.	21.70%
	Concentration of the soc propan-2-ol in the b.p.	13.00%
	Concentration of the soc ethane-1,2-diol in the b.p.	16.01%
	Concentration of the b.p. in the application liquid	6%
	Application rate	400 ml/m²
	Application duration	30 min
	Exposure duration	240 min
	Frequency	1 event/day
	Room volume	300 m³
	Ventilation rate	2 h^{-1}
	Applied amount	40000 g
	Release area	100 m²
	Exposure Model (ART)	Falling liquids Transfer of liquid product with flow of 10 – 100 l/minute (see Annex 4.3)
Tier 2	Protection factor respiratory tract: Half mask + gas filter (EN 529, table C.1)	1
	Protection factor body: type 3 or 4, EN 14605 (impermeable coverall)	100%
	Protection factor hands: protective gloves (HEEG opinion 9)	10%

Calculations for Scenario 4

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) of scenario 4 are summarised in Table 56.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.

For risk characterisation, see chapter 3.6.4.5.

Table 56

Summary table: estimated exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenario 4	Tier 1: No PPE	Benzoic acid: not applicable	Benzoic acid: $5.02*10^{-2}$
		Propan-1-ol: 1.70	Propan-1-ol: 0.12
		Propan-2-ol: 0.90	Propan-2-ol: $7.18*10^{-2}$
		Ethane-1,2-diol: 5.00	Ethane-1,2-diol: $2.32*10^{-2}$
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: not applicable	Benzoic acid: $5.02*10^{-3}$
		Propan-1-ol: $4.00*10^{-3}$	Propan-1-ol: $1.20*10^{-2}$
		Propan-2-ol: 0.21	Propan-2-ol: $7.18*10^{-3}$
		Ethane-1,2-diol: 1.20	Ethane-1,2-diol: $2.32*10^{-3}$

- **<u>Combined scenarios</u>**

Table 57

Summary table: combined systemic exposure from professional uses			
Scenarios combined	**Tier/PPE**	**Estimated inhalation exposure [mg/m³]**	**Estimated dermal exposure [mg/day]**
Scenarios [1a+2a]	Tier 1: No PPE	Benzoic acid: 0.14	Benzoic acid: 270.69
		Propan-1-ol: 62.81	Propan-1-ol: 646.21
		Propan-2-ol: 73.10	Propan-2-ol: 387.13
		Ethane-1,2-diol: 1.11	Ethane-1,2-diol: 833.39
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: $1.38*10^{-2}$	Benzoic acid: 15.97
		Propan-1-ol: 6.28	Propan-1-ol: 22.10
		Propan-2-ol: 9.14	Propan-2-ol: 13.24
		Ethane-1,2-diol: 0.11	Ethane-1,2-diol: 44.11
Scenarios [1b+2b]	Tier 1: No PPE	Benzoic acid: 1.56	Benzoic acid: 414.92
		Propan-1-ol: 46.00	Propan-1-ol: 990.51
		Propan-2-ol: 30.31	Propan-2-ol: 593.39
		Ethane-1,2-diol: 120.73	Ethane-1,2-diol: 730.78
	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832)	Benzoic acid: 0.16	Benzoic acid: 35.89
		Propan-1-ol: 4.60	Propan-1-ol: 47.23
		Propan-2-ol: 3.03	Propan-2-ol: 28.30
		Ethane-1,2-diol: 12.07	Ethane-1,2-diol: 63.20

3.6.3.1.2 Non-professional exposure

Not relevant. The biocidal product is not intended for non-professional use.

3.6.3.1.3 Secondary exposure of the general public

- **Scenario 5**

Table 58

Description of Scenario 5 – PT3 Post-application		
Secondary exposure – Entering treated room and touching dried disinfected surface. The biocidal product is intended for the PT3 application in veterinary health care (e.g. veterinary clinics) and for animal housings of companion animals. Hence, visiting pet owners may get in contact with treated surfaces of animal housings and cages in veterinary clinics occasionally (acute exposure). Exposure of smaller children or toddler is not assessed. It is expected that only children ≥ 6 years may be taken by their parents to veterinary clinics. The biocidal product is intended for spraying application of hard surfaces (Use #1). According to the applicant, the maximum in-use concentration for PT3 applications is 18 g biocidal product/m^2. The application rate of this dilution is 400 mL/m^2 and the density is assumed to be 1 g/cm^3. It is assumed that adults or children touch treated surfaces with the palm of one hand. According to the applicant, treated surfaces should be dried before re-use. Hence, a transfer coefficient of 55 % for white smooth glazed tiles is used as worst-case default. Oral exposure may occur if persons lick their hands after dermal contact. Under the given conditions oral exposure is considered unlikely. As a worst case it can be assumed that a person licks some fingertips after dermal contact. It is assumed that the licked surface of the fingertips, for both children and adults, is about one tenth of the palm. According to the applicant, the product should only be used in well-ventilated areas and treated surfaces should be dried before re-use. Therefore, assessment of inhalation exposure is considered not relevant for potential secondary exposure of the general public after PT3 spraying application.		
	Parameters	Value
Tier 1	Concentration of a.s. in b.p. (Applicant)	9.09 %
	Application frequency of b.p. (Applicant)	1 d^{-1}
	Concentration of b.p. in dilution (Applicant)	4.5 %
	Application rate of b.p. (Applicant)	400 mL/m^2
	Concentration of a.s. in dilution (Applicant)	0.40905 %
	Maximum surface residue level of a.s.	0.16362 mg a.s./cm^2
	Body weight adult (HEAd hoc Recommendation 14)	60 kg
	Body weight child (HEAd hoc Recommendation 14)	23.9 kg
	Surface of palm of one hand, adult (based on surface of palms and backs of both hands: 820 cm^2, HEAd hoc Recommendation 14)	205 cm^2
	Surface of palm of one hand, child (based on surface of palms and backs of both hands: 427.8 cm^2, HEAd hoc Recommendation 14)	107 cm^2
	Surface of licked fingertips (= 1/10 of palm of one hand; expert judgement)	Adult: 20.5 cm^2 Child: 10.7 cm^2
	Transfer coefficient for dislodgeable residues	Dried fluid: 55 %

	(Default smooth glazed tiles, Biocides Human Health Exposure Methodology, 2015)	
	Transfer coefficient hand-to-mouth (Default)	100 %
	Dermal absorption for dilution (EFSA Guidance on Dermal Absorption 2017)	50 %
	Oral absorption (CAR, 2013)	100 %

Calculations for Scenario 5 – Tier 1

Dermal exposure

Systemic dermal exposure = surface residue level of a.s. x surface hand palm x transfer coefficient dislodgeable residues x dermal absorption / body weight

Adult

Systemic dermal exposure = 0.16362 mg/cm^2 x 205 cm^2 x 55 % x 50 % / 60 kg
= 0.1537 mg/kg bw

Child

Systemic dermal exposure = 0.16362 mg/cm^2 x 107 cm^2 x 55 % x 50 % / 23.9 kg
= 0.2014 mg/kg bw

Oral exposure

Systemic oral exposure = surface residue level of a.s. x surface fingertips x transfer coefficient dislodgeable residues x transfer coefficient hand-to-mouth x oral absorption / body weight

Adult

Systemic oral exposure = 0.16362 mg/cm^2 x 20.5 cm^2 x 55 % x 100 % x 100 % / 60 kg
= 0.0307 mg/kg bw

Child

Systemic oral exposure = 0.16362 mg/cm^2 x 10.7 cm^2 x 55 % x 100 % x 100 % / 23.9 kg
= 0.0403 mg/kg bw

Total systemic exposure - Tier 1

Adult

Total systemic exposure = 0.1844 mg/kg bw

Child

Total systemic exposure = 0.2417 mg/kg bw

Further information and considerations on scenario 5

Dilutions of the biocidal product for PT3 applications (max. 4.5 %) do not require classification for human health hazards. Therefore, no human health risk is expected. In addition, all identified substances of concern (SoC) in the biocidal product have a high vapour pressure (for details refer to table 'Summary table on dietary risk assessment of substances of concern (SoC)') and are assumed to evaporate promptly from treated surfaces. Therefore, exposure of the general public to SoCs by touching dried surfaces after application is not expected. Hence, secondary exposure of the general public is limited to the active substance benzoic acid and a quantitative or qualitative exposure assessment for SoCs is not required.

Table 59

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5 - Touching dried disinfected surfaces – PT3 (Adult)	Tier 1	n.a.	0.1537	0.0307	0.1844
Scenario 5 – Touching dried disinfected surfaces – PT3 (Child)	Tier 1	n.a.	0.2014	0.0403	0.2417

- **Combined scenarios**

Not applicable.

3.6.3.2 Dietary exposure

Table 60

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Benzoic acid
Type of formulation	soluble concentrate
Substance(s) of concern	SoC1: propan-1-ol SoC2: propan-2-ol SoC3: formic acid SoC4: ethane-1,2-diol (ethylene glycol)
Field(s) of use	PT 3: Disinfectant in veterinary health care - Use #1: Disinfectant of hard surfaces by spraying (indoor) - Use #2: Disinfectant of equipment by soaking (indoor) PT 4: Disinfectant in food production facilities, beverage production facilities, warehouses, refrigerated warehouses, and greenhouses - Use #3: Disinfectant of hard surfaces by spraying - Use #4: Disinfectant of equipment by soaking - Use #5: Disinfectant of inner surfaces without circulation (indoor)

Intended use(s) (critical application with regard to dietary exposure)	
	- Use #6: Disinfectant of surfaces in human drinking water systems (indoor) PT 4: Desinfectant in veterinary practices, animal shelters, animal feeding areas, and animal husbandry - Use #7: Disinfectant of surfaces in veterinary water systems (indoor)
Target organism(s)	Bacteria, Fungus, Yeast, Viruses
Application rate(s) and frequency	Application rate: - 0.4 L biocidal product/m^2 (6 % bp in diluted solution) - a.s. concentration: in undiluted bp 9 % (90 g/L), in diluted bp (in-use) 0.54 % (5.4 g/L), 2.16 g/m^2 Frequency: - Use #1-5: as often as necessary, typically once a day - Use # 6-7: as often as necessary, max. once per day
Category(ies) of users	Professional user
Waiting periods after treatment	/
Further information	/

Conclusion

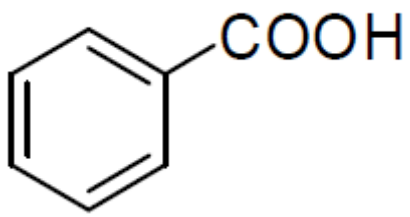
The biocidal product is to be used for the disinfection of surfaces and equipment in the area of veterinary hygiene (PT3) and food and feed production (PT4), as well as for the disinfection of surfaces of human drinking water systems and veterinary water systems (PT4). Therefore, direct contact of the biocidal product with food or feed cannot be excluded. Nevertheless, according to the CARs of benzoic acid for PT3 and PT4 uses (both 2013, eCA: DE), consumer exposure to benzoic acid residues in food or feed items via biocidal products will be much lower compared to consumer exposure to benzoic acid occurring as a natural food ingredient and from use as a registered food additive and authorised feeding stuff additive.

However, to avoid contact with food or feed, the applicant proposed use-specific risk mitigation measures:

- Treated surfaces and equipment need to be dried before re-use. (Use #1, 2)
- After application of the biocidal product rinse treated surfaces and equipment with drinking water. (Use #3, 4)
- After application of the biocidal product rinse treated pipes and machinery with drinking water. (Use #5-7)
- Keep away from food, drinks and feeding stuff. (Conditions of storage)

3.6.3.2.1 General information on active substance(s)

Table 61

Active substance (Common Name)	Benzoic Acid
CAS number	65-85-0
Chemical structure	
Molecular formular	$C_7H_6O_2$
Molar mass	122,12 g/mol
Log Po/w	1.87 (20°C) (unionised molecule)
Active substance approval	PT: 3, 4 RMS: DE
Restrictions	CAR PT3 and 4 (DE, 2013): For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (CAR PT3 and 4, DE, 2013)
Current regulations on MRLs	No MRLs required (substance included in Annex IV of Reg. (EC) No 396/2005 without prejudice to Regulation (EC) No 1333/2008 on food additives) Product has additional non-biocidal uses for which in part maximal concentration levels have been set for benzoic acid (see summary table of other (non-biocidal) uses).

3.6.3.2.1.1 Information of non-biocidal use of the active substance

- Information on the residue definitions is provided in chapter 3.6.4.2 (Maximum residue limits or equivalent).

Table 62

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Food and feed additive	- Approved food additive (E210) - Feed additive: Authorised as a zootechnical additive for weaned piglets and pigs for fattening and as a chemically defined flavouring for all animal species (E210)	- Food Additive: 150 – 2000 mg/kg for various food commodities *(Re. (EU) 2015/538)* - Feed additive: max. inclusion level of 10,000 mg/kg *(EFSA FEEDAP Panel, 2019. EFSA Journal 2019;17(1):5527, 12 pp. doi: 10.2903/j.efsa.2019.5527)*
2.	Plant Protection Products	Approved as pesticide in rooms, buildings and on equipment in floriculture, horticulture and agriculture	no MRL required, ADI of 5 mg/kg bw *(Reg. (EU) 2017/1113, Reg. (EC) 396/2005)*
3.	Human and veterinary medicine	Therapeutic substances (0.15 - 6 %) e.g. as anti-fungal cream or as antiseptic	No MRL required *(Reg. (EU) 37/2010 Calcium benzoate)* ADI of 0 - 5 mg/kg bw *(SCCP (Scientific Committee on Consumer Products) Opinion on Benzoic Acid and Sodium Benzoate. 2005)*
4.	Cosmetics	Preservative	Max. Concentration 0.5 – 2.5 % *(EU. Allowed Preservatives: Annex V, Regulation 1223/2009/EC on Cosmetic Products, as amended by Regulation 2019/1966/EU)*

3.6.3.2.2 Dietary exposure to substances of concern

Four substances of concern have been identified for the biocidal product “A-QUASAN-B”:
(1) Propan-1-ol (CAS-Nr. 71-23-8),
(2) Propan-2-ol (CAS-Nr. 67-63-0),
(3) Formic acid (CAS-Nr. 64-18-6) and
(4) Ethan-1,2-diol (CAS-Nr. 107-21-1).

For an overview and a qualitative residue evaluation for these substances please see the Table 63 below. All substances of concern have a high vapour pressure and are expected to evaporite rapidly from treated surfaces and equipment. Moreover, as RMM it is foreseen that treated surfaces and equipment used for food and feed production/processing (PT 4 use #3 - #6) are rinsed with water after treatment with A-QUASAN-B. Due to the good water solubility and high vapour pressure of all substances of concern, the efficiency of rinsing is expected to be high. Therefore, a transfer of any of the substances of concern into food stuff is expected to be low.
Additionally, exposure of livestock animals with any of the substances of concern via PT 3 uses of A-QUASAN-B (use #1 and #2) is expected to be negligible, as the biocidal product is only intended for the application in veterinary health care (e.g. veterinary clinics) and for animal houses of companion animals, but not for the use in livestock farming.

In conclusion relevant residues of the substances of concern in food or feed and in food of animal origin from the intended uses of A-QUASAN-B are not expected.

Table 63

Summary table on dietary risk assessment of substances of concern (SoC)			
SoC Name (CAS-No.)	**Classification of BP due to classified SoC**	**Band (acc. to Guidance on BPR[a])**	**Relevant data for evaluation of SoC**
Propan-1-ol (71-23-8)	Eye Dam 1, H318 STOT SE 3, H336	B	- Vapour pressure: 2820 Pa at 25 °C[b] - Water solubility: miscible at any ratio (1000 g/L at 20 °C)[b]
Propan-2-ol (67-63-0)	approved biocidal active substance PT1, 2, 4	/	- Vapour pressure: 5780 Pa, 25 °C[c] - Water solubility: miscible at any ratio[d] (1000 g/L at 25 °C)[c]
Formic acid (64-18-6)	Eye Dam 1, H318	B	- Vapour pressure: 4271 Pa, 20 °C[e] - Water solubility: miscible at any ratio (1000 g/L at 20 °C)[e]
Ethan-1,2-diol (107-21-1)	STOT RE 2 (kidney) H373	C	Although the classification of ethan-1,2-diol would require a quantitative assessment, a qualitative assessment is considered sufficient because of the intended uses of the biocidal product and the physicochemical properties of ethan-1,2-diol. - Vapour pressure: 12.3 Pa, 25 °C[f] - Water solubility: miscible at any ratio (1000 g/L at 20 °C)[f]

[a] Guidance on the BPR: Vol. III Parts B+C, Version 4.0, December 2017, Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products
[b] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14586/1
[c] CAR Propan-2-ol PT1, 2014, RMS: DE
[d] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15339/1
[e] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15127/1
[f] https://www.echa.europa.eu/sl/web/guest/registration-dossier/-/registered-dossier/15973/1

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

Exposure during production, formulation and disposal of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Summary of exposure assessment

Table 64

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake** [mg/kg bw/d]
1a	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.08 Propan-1-ol: 0.31 Propan-2-ol: 0.58 Ethane-1,2-diol: not calculated
2a	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.06 Propan-1-ol: 0.92 Propan-2-ol:1.06 Ethane-1,2-diol: not calculated
1a + 2a	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.14 Propan-1-ol: 1.23 Propan-2-ol: 1.63 Ethane-1,2-diol not calculated
1b	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.17 Propan-1-ol: 0.56 Propan-2-ol:0.38 Ethane-1,2-diol: not calculated
2b	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.16 Propan-1-ol: 0.60 Propan-2-ol: 0.36 Ethane-1,2-diol: not calculated
1b + 2b	professionals	Tier 2: - protective gloves (EN 374) - coated coverall (type 6, EN 13034) - Half mask + gas filter (EN 529, table C.1) - Footwear protective against chemicals (EN 13832) - Eye protection	Benzoic acid: 0.33 Propan-1-ol: 1.16 Propan-2-ol: 0.74 Ethane-1,2-diol: not calculated

3a	professionals	Tier 1: - protective gloves (EN 374) - Eye protection	Benzoic acid: 0.42 Propan-1-ol: 1.01 Propan-2-ol: 0.61 Ethane-1,2-diol: not calculated
3b	professionals	Tier 1: - protective gloves (EN 374) - Eye protection	Benzoic acid: 0.56 Propan-1-ol: 1.34 Propan-2-ol: 0.81 Ethane-1,2-diol: not calculated
4	professionals	Tier 1: - Eye protection	Benzoic acid: $4.2x10^{-4}$ Propan-1-ol: 0.28 Propan-2-ol: 0.15 Ethane-1,2-diol: not calculated
5	General public	Tier 1/ no PPE	Adult Benzoic acid: 0.1844 Child Benzoic acid: 0.2417

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in chapter 3.6.1 Assessment of effects of the active substance on human health

3.6.4.2 Maximum residue limits or equivalent

No MRLs are required

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product A-QUASAN B takes into account systemic and local effects of the active substance benzoic acid, systemic and local effects of the substances of concern propan-1-ol, propan-2-ol and ethane-1,2-diol (ethylene glycol) as well as local effects of the substance of concern formic acid.

The occupational risk assessment for systemic effects of the active substance benzoic acid and the substances of concern propan-1-ol and propan-2-ol is based on the internal reference value (AEL). This reference value is compared with the estimated total uptake of benzoic acid, propan-1-ol and propan-2-ol, respectively.

Furthermore, for the substance of concern ethane-1,2-diol the european occupational exposure limit (OEL) is the basis for risk characterisation. This reference value is compared with external inhalation exposure values for ethane-1,2-diol.

Systemic effects

Benzoic acid

The primary toxic effects of the active substance benzoic acid are neurotoxic and hepatotoxic effects and mortalities following subacute and subchronic exposure as well as the maternal toxicity and the reduced 8-week offspring survival in a teratogenicity study, both in rats.

The risk characterisation for systemic effects of benzoic acid is performed with the AEL approach that compares total internal body burden (total uptake) with the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to benzoic acid resulting from use of the biocidal product A-QUASAN B.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{long\text{-}term}$ of 5 mg benzoic acid/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for the active substance benzoic acid.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available for the concentrated and the diluted product. Therefore, the default value of 10 % for water-based concentrates and 50 % for diluted solutions (according to the EFSA Guidance on Dermal Absorption, 2017) has to be taken into consideration for risk assessment.

The inhalation uptake and dermal uptake referring to the active substance benzoic acid resulting from use of the biocidal product A-QUASAN B are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to benzoic acid (mg/m^3) x 10 m^3/d breathing volume / 60 kg body weight x 100 %-inhalation absorption / 100 %
>
> Dermal uptake (mg/kg bw/d) = dermal exposure to benzoic acid (mg/kg bw/d) x 10 or 50 %-dermal absorption / 100 %

Dermal exposure to benzoic acid given in mg/kg bw/d is calculated from dermal exposure to benzoic acid given in mg/person through division by 60 kg/person.

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the active substance benzoic acid resulting from the use of the biocidal product A-QUASAN B is unlikely if the AEL exhaustion (%) for each scenario/combined scenario is below the value of 100 %. Table 65 gives a detailed overview of the risk assessment results referring to the active substance benzoic acid in the biocidal product A-QUASAN B. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 65. However, the underlying calculations are based on unrounded values. As shown in Table 65, for all scenarios a risk for the professional user is unlikely already in TIER 1.

Table 65: Overview of detailed risk assessment results referring to the active substance benzoic acid in the biocidal product A-QUASAN B

Scenario			$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Inhalation uptake / AEL %	Estimated dermal uptake mg/kg bw/d	Dermal uptake / AEL %	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL AEL exhaustion %	Acceptable (yes/no)	HQ
1a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	5	0.02	0.43	1.70	34	1.72	34	**yes**	0.34
		Tier 2	5	$2.16x10^{-3}$	0.04	0.08	2	0.08	1.6	yes	$1.6x10^{-2}$
1b	PT04 – Disinfectant of hard surfaces- Professional user – Spraying – Indoor	Tier 1	5	0.02	0.35	2.71	54	2.73	55	**yes**	0.55
		Tier 2	5	$1.73x10^{-3}$	0.03	0.16	3	0.17	3.3	yes	$3.3x10^{-2}$
2a	PT03 – Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	5	$1.45x10^{-3}$	0.03	0.56	11	0.56	11	**yes**	0.11
		Tier 2	5	$1.45x10^{-4}$	< 0.01	0.06	1.1	0.06	1.1	yes	$1.1x10^{-2}$
2b	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	5	0.24	5	0.75	15	0.99	20	**yes**	0.20
		Tier 2	5	0.02	0.5	0.13	2.7	0.16	3.2	yes	$3.2x10^{-2}$
3a	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	5	$8.52x10^{-6}$	< 0.01	0.42	8	0.42	8.5	**yes**	$8.5x10^{-2}$
		Tier 2	5	$8.52x10^{-6}$	< 0.01	0.13	3	0.13	2.5	yes	0.03
3b	PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	5	$1.14x10^{-5}$	< 0.01	0.56	11	0.56	11	**yes**	0.11
		Tier 2	5	$1.14x10^{-5}$	< 0.01	0.17	3	0.17	3.3	yes	$3.3x10^{-2}$
4		Tier 1	5	Not applicable		$4.18x10^{-4}$	$8.36x10^{-3}$	$4.18x10^{-4}$	$8.36x10^{-3}$	**yes**	$8.36x10^{-5}$

	PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor	Tier 2	5			$4.18x10^{-5}$	$8.36x10^{-4}$	$4.18x10^{-5}$	$8.36x10^{-4}$	yes	$8.36x10^{-6}$
	Combined Scenarios										
1a + 2a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	5	0.02	0.46	2.26	45	2.28	46	**yes**	0.46
		Tier 2	5	$2.30x10^{-3}$	0.05	0.13	2.7	0.14	2.7	yes	$2.7x10^{-2}$
1b + 2b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	5	0.26	5.2	3.46	69	3.72	74	**yes**	0.74
		Tier 2	5	0.03	0.52	0.30	6.0	0.33	6.5	yes	$6.5x10^{-2}$

HQ: Hazard Quotient

Conclusion

Based on the risk assessment of the active substance benzoic acid via the inhalation and dermal route, a risk for professional users resulting from all uses with the biocidal product A-QUASAN B is unlikely already after TIER 1 consideration.

Propan-1-ol

The primary toxic effect of the substance of concern propan-1-ol is impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies. The risk characterisation for systemic effects of propan-1-ol is performed with the AEL approach that compares total internal body burden (total uptake) to the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-1-ol resulting from use of the biocidal product A-QUASAN B.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{long\text{-}term}$ of 9.2 mg propan-1-ol/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for propan-1-ol.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available for the concentrated and the diluted product. Therefore, the default value of 10 % for water-based concentrates and 50 % for diluted solutions (according to the EFSA Guidance on Dermal Absorption, 2017) has to be taken into consideration for risk assessment.

The inhalation uptake and dermal uptake referring to the active substance propan-1-ol resulting from use of the biocidal product A-QUASAN B are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-1-ol (mg/m^3) x 10 m^3 / 60 kg x %-inhalation absorption / 100 %.
>
> Internal dermal exposure (mg(kg bw/d) = dermal exposure to propan-1-ol (mg/d) / 60 kg x 10 or 50 %-dermal absorption / 100 %

The summation of inhalation and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the active substance propan-1-ol resulting from the use of the biocidal product A-QUASAN B is unlikely if the AEL exhaustion (%) for each scenario/combined scenario is below the value of 100 %. Table 66 gives a detailed overview of the risk assessment results referring

to the substance of concern propan-1-ol in the biocidal product A-QUASAN B. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 66. However, the underlying calculations are based on unrounded values. As shown in Table 66, for the scenarios 1a, 1b, 2b, 3a, 3b and 4 a risk for the professional user is unlikely already in Tier 1. For the scenarios 2a, 1a + 2a and 1b + 2b inacceptable risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely in TIER 2.

Table 66: Overview of detailed risk assessment results referring to the substance of concern propan-1-ol in the biocidal product A-QUASAN B

Scenario			$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Inhalation uptake / AEL %	Estimated dermal uptake mg/kg bw/d	Dermal uptake / AEL %	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL AEL exhaustion %	Acceptable (yes/no)	HQ
1a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	9.2	1.30	14.2	4.05	44	5.35	58	**yes**	0.58
		Tier 2	9.2	0.13	1.4	0.18	2.0	0.31	3	yes	$3.42x10^{-2}$
1b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	9.2	1.62	17.7	6.47	70	8.10	88	**yes**	0.88
		Tier 2	9.2	0.16	1.8	0.39	4	0.56	6	yes	$6.04x10^{-2}$
2a	PT03 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	9.2	9.17	99.6	1.33	15	10.50	114	no	1.14
		Tier 2	9.2	0.92	9.96	0.13	1.5	0.92	10	**yes**	0.10
2b	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	9.2	6.04	65.7	1.78	19	7.82	85	**yes**	0.85
		Tier 2	9.2	0.60	6.6	Not applicable		0.60	7	yes	$6.57x10^{-2}$
3a	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	9.2	$1.75x10^{-3}$	0.02	1.01	11	1.01	11	**yes**	0.11
		Tier 2	9.2	$7.5x10^{-4}$	0	0.30	3	0.30	3	yes	$3.28x10^{-2}$
3b	PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	9.2	$2.25x10^{-3}$	0.02	1.34	15	1.34	15	**yes**	0.15
		Tier 2	9.2	$1.00x10^{-3}$	0.01	0.40	4	0.40	4	yes	$4.37x10^{-2}$
4		Tier 1	9.2	0.28	3.1	$9.98x10^{-4}$	0.01	0.28	3	**yes**	$3.09x10^{-2}$

	PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor	Tier 2	9.2	$6.67x10^{-4}$	0.01	$9.98x10^{-5}$	< 0.01	$7.66x10^{-4}$	< 0.01	yes	$8.33x10^{-5}$
Combined Scenarios											
1a + 2a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	9.2	10.47	113.78	5.39	59	15.85	172	no	1.72
		Tier 2	9.2	1.05	11.38	0.18	2.0	1.23	13	**yes**	0.13
1b + 2b	PT04 – Disinfectant of hard surfaces- Professional user – Spraying – Indoor	Tier 1	9.2	7.67	83.33	8.25	90	15.92	173	no	1.73
		Tier 2	9.2	0.77	8.33	0.39	4.3	1.16	13	**yes**	0.13

HQ: Hazard Quotient

Conclusion

Based on the systemic risk assessment of the substance of concern propan-1-ol via the inhalation and dermal route, a risk for professional users resulting from all intended uses is unlikely at the latest after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

Propan-2-ol

The primary toxic effect of the substance of concern propan-2-ol is acute central nervous system (CNS) depression. The risk characterisation for systemic effects of propan-2-ol is performed with the AEL approach that compares total internal body burden (total uptake) to the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the biocidal product A-QUASAN B.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{acute/medium-/long-term}$ of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for propan-2-ol.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available for the concentrated and the diluted product. Therefore, the default value of 10 % for water-based concentrates and 50 % for diluted solutions (according to the EFSA Guidance on Dermal Absorption, 2017) has to be taken into consideration for risk assessment.

The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal product A-QUASAN B are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m^3) x 10 m^3 / 60 kg x %-inhalation absorption / 100 %.
>
> Internal dermal exposure (mg(kg bw/d) = dermal exposure to propan-2-ol (mg/d) / 60 kg x 100 %-dermal absorption / 100 %

The summation of inhalation and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the substance of concern propan-2-ol resulting from the use of the biocidal product A-QUASAN B is acceptable if the AEL exhaustion (%) for each scenario is below the value of 100 %. Table 67 gives a detailed overview of the risk assessment results referring to the

substance of concern propan-2-ol in the biocidal product A-QUASAN B. It is noted that for clarity reasons all values are rounded to two decimal places in Table 67. However, the underlying calculations are based on unrounded values. As shown in Table 67, for all scenarios a risk for the professional user is unlikely already in TIER 1.

Table 67: Overview of detailed risk assessment results referring to the substance of concern propan-2-ol in the biocidal product A-QUASAN B

Scenario			$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Inhalation uptake / AEL %	Estimated dermal uptake mg/kg bw/d	Dermal uptake / AEL %	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL AEL exhaustion %	Acceptable (yes/no)	HQ
1a	PT03 – Disinfectant of hard surfaces – Professional user – Spraying – Indoor	Tier 1	17.9	1.63	9.10	2.43	14	4.05	23	**yes**	0.23
		Tier 2	17.9	0.47	2.6	0.11	0.6	0.58	3.2	yes	0.03
1b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	17.9	1.44	8.1	3.88	22	5.32	30	**yes**	0.30
		Tier 2	17.9	0.14	0.81	0.24	1.3	0.38	2.1	yes	2.12×10^{-2}
2a	PT03 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	17.9	10.56	58.97	0.80	4.5	11.36	63	**yes**	0.63
		Tier 2	17.9	1.06	5.90	0.08	0.4	1.06	5.9	yes	0.06
2b	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	17.9	3.61	20.2	1.07	6.0	4.68	26	**yes**	0.26
		Tier 2	17.9	0.36	2.0	Not applicable		0.36	2.0	yes	2.02×10^{-2}
3a	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	17.9	2.17×10^{-3}	0.01	0.61	3.4	0.61	3.4	**yes**	3.40×10^{-2}
		Tier 2	17.9	9.17×10^{-4}	< 0.01	0.18	1.0	0.18	1.0	yes	1.01×10^{-2}
3b	PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	17.9	2.83×10^{-3}	0.02	0.80	4.5	0.81	4.5	**yes**	4.51×10^{-2}
		Tier 2	17.9	1.25×10^{-3}	< 0.01	0.24	1.3	0.24	1.3	yes	1.35×10^{-2}
4		Tier 1	17.9	0.15	0.84	5.98×10^{-4}	3.34×10^{-3}	0.15	0.8	**yes**	8.41×10^{-3}

	PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor	Tier 2	17.9	$3.50x10^{-2}$	0.20	$5.98x10^{-5}$	$3.34x10^{-4}$	0.04	0.2	yes	$1.96x10^{-3}$
Combined Scenarios											
1a + 2a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	17.9	12.18	68.1	3.23	18	15.41	86	**yes**	0.86
		Tier 2	17.9	1.52	8.5	0.11	0.6	1.63	9.1	yes	$9.13x10^{-2}$
1b + 2b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	17.9	5.05	28.2	4.94	28	10.00	56	**yes**	0.56
		Tier 2	17.9	0.51	2.8	0.24	1.3	0.74	4.1	yes	$4.14x10^{-2}$

HQ: Hazard Quotient

Conclusion

Based on the systemic risk assessment of the substance of concern propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from all intended uses is unlikely after TIER 1 consideration.

Ethane-1,2-diol

The systemic toxicity profile of the substance of concern ethane-1,2-diol is considered. This substance contributes to the classification of the biocidal product A-QUASAN B with H373 (kidney) (May cause damage to organs through prolonged or repeated exposure).

Quantitative risk characterisation

For the substance of concern ethane-1,2-diol impact on the kidney is considered as primary toxic effect. As no other reliable reference value exists the quantitative risk characterisation for professional user for inhalation exposure is carried out with the EU occupational exposure level (OEL) of 52 mg/m^3 for ethane-1,2-diol.

Details of risk characterisation

Reference values

For the purpose of risk characterisation exposure of professional users to ethane-1,2-diol from the biocidal product A-QUASAN B, inhalation exposure to ethane-1,2-diol is assessed. For this, the EU OEL (52 mg/m^3; 8 h TWA) of ethane-1,2-diol is used as external inhalation reference value and directly compared with airborne concentrations of ethane-1,2-diol.

Calculation of OEL exhaustion (%)

The substance specific exposure-to-OEL ratio (%) referring to the substance of concern ethane-1,2-diol resulting from use of the biocidal product A-QUASAN B is determined according to the following equations:

> Exposure-to-OEL ratio (%) = inhalation exposure to ethane-1,2-diol (in mg/m^3) / EU OEL of ethane-1,2-diol (in mg/m^3).

A risk for professional users referring to the substance of concern ethane-1,2-diol resulting from the use of the biocidal product A-QUASAN B is acceptable if the OEL exhaustion (%) for each scenario is below the value of 100 %. For the scenarios 2b as well as 1b + 2b inacceptable risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely in TIER 2

Table 68 gives a detailed overview of the local risk assessment results for inhalation route referring to the substance of concern ethane-1,2-diol in the biocidal product A-QUASAN B. It is noted that for clarity

reasons all values are rounded to two decimal places in Table 68. However, the underlying calculations are based on unrounded values. As shown in Table 68 for the scenarios 1a, 1b, 2a, 3a, 3b, 4 and 1a + 2a a risk for professional users is unlikely already in TIER 1. For the scenarios 2b as well as 1b + 2b inacceptable risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely in TIER 2

Table 68: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern ethane-1,2-diol in the biocidal product A-QUASAN B

Scenario			**Reference value inhalative OEL** mg/m³ **TWA**	**Estimated inhalation exposure** mg/m³	**Estimated inhalation exposure / OEL** OEL exhaustion **%** **TWA**	**Acceptable** (yes/no) **TWA**
1a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	52	0.63	1.2	**yes**
		Tier 2	52	0.06	0.12	yes
1b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	52	0.73	1.40	**yes**
		Tier 2	52	7.30×10^{-2}	0.14	yes
2a	PT03 – Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	52	0.48	0.93	**yes**
		Tier 2	52	4.8×10^{-2}	0.09	yes
2b	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	52	120	231	no
		Tier 2	52	12	23	**yes**
3a	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	52	9.1×10^{-2}	< 0.01	**yes**
		Tier 2	52	4.0×10^{-5}	< 0.01	yes
3b	PT04 – Disinfectant of equipment by soaking – Professional user – Dipping – Indoor	Tier 1	52	1.2×10^{-4}	< 0.01	**yes**
		Tier 2	52	6.0×10^{-5}	< 0.01	yes
4	PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor	Tier 1	52	5.0	9.6	**yes**
		Tier 2	52	1.2	2.3	yes
Combined Scenarios						
1a + 2a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	52	1.1	2.1	**yes**
		Tier 2	52	0.11	0.21	yes

1b + 2b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	52	120	232	no
		Tier 2	52	12	23	**yes**

Conclusion

Based on the risk assessment of the substance of concern ethane-1,2-diol via the inhalation route, a risk for professional users resulting from all intended uses is unlikely at the latest after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

Qualitative local risk characterisation

The local toxicity profiles of the active substance benzoic acid as well as of the substances of concern propan-1-ol, propan-2-ol, ethane-1,2-diol and formic acid are considered. Benzoic acid and formic acid contribute to the classification of the biocidal product A-QUASAN B with H318 (Causes serious eye damage) and H372 (May cause damage to organs (lung) through prolonged or repeated exposure). Therefore a qualitative risk assessment for local effects regarding contact with eye and respiratory tract is necessary. The qualitative local risk assessment takes into account the concentrated biocidal product as well as the different dilutions thereof. Table 69 gives an overview of the relevant classifications for the qualitative local risk assessment of biocidal product A-QUASAN B. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 69: Relevant classification and resulting hazard categories A-QUASAN B

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100	Eye Dam. 1, H318 STOT-RE 2 (lung), H373	high
6	Eye Irrit. 1, H319	low

For the concentrated biocidal product local risk assessment is triggered by the eye damage (Eye Dam. 1, H318) as this classification is allocated to the hazard category “high” (Table 69). The classification for respiratory tract effects (STOT-RE 2, H373 (lung) is allocated to the hazard category “low” (Table 69).
For b.p. concentration in application solution of 6 %, local risk assessment is triggered by eye irritation (Eye Irrit. 1, H319) as this classification is allocated to the hazard category “low” (Table 69).

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part

B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the eye and respiratory tract of the biocidal product A-QUASAN B. With the proposed risk mitigation measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses (Table 70 to

Table 72).

Table 70: Summary of qualitative conclusions for local risk assessment for the scenario 'Disinfectant of hard surfaces - Professional user - Spraying - Indoor + Secondary exposure – spray treatment (re-entry of treated location)'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability	
Mixing & Loading: Dilution of b.p. and loading into a sprayer	100%	Eye Dam. 1, H318 STOT-RE 2 (lung), H373	High	10 min/day	EYES: Incidental contact to eyes possible	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable**	+ Used for short duration + Professionals using appropriate PPE
Application: Foam application	6%	Eye Irrit. 2, H319	Low	200 min/day	EYES: Contact to eyes expected	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable**	+ professionals using appropriate PPE
Post-Application: Cleaning of foam equipment	6%	Eye Irrit. 2, H319	Low	5 min/day	EYES: Incidental contact to eyes possible	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable**	+ Used for short duration + Professionals using appropriate PPE
Secondary exposure: re-entry of treated location for rinsing	dried application solution on surfaces & volatile substances of b.p. in air	-	-	200 min/day	EYES: contact to eyes unlikely as b.p. is dried	-/-	**Acceptable**	+ Professionals using appropriate PPE

Table 71: Summary of qualitative conclusions for local risk assessment for the scenario 'Disinfectant of equipment by soaking - Professional user - Dipping - Indoor'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing & Loading: Dilution of b.p. and loading into a fixed vessle	100%	Eye Dam. 1, H318 STOT-RE 2 (lung), H373	High	10 min/day	EYES: Incidental contact to eyes possible	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable** + Used for short duration + Professionals using appropriate PPE
Application: Dipping	6%	Eye Irrit. 2, H319	Low	30 min/day	EYES: Contact to eyes expected	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable** + professionals using appropriate PPE
Post-Application: Cleaning of equipment	6%	Eye Irrit. 2, H319	Low	30 min/day	EYES: Incidental contact to eyes possible	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable** + Used for short duration + Professionals using appropriate PPE

Table 72: Summary of qualitative conclusions for local risk assessment for the scenario 'Disinfectant of inner surfaces without circulation - Professional user – Indoor'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing & Loading: Dilution of b.p. and loading into a pipe system	100%	Eye Dam. 1, H318 STOT-RE 2 (lung), H373	High	10 min/day	EYES: Incidental contact to eyes possible	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **- Eye protection**	**Acceptable** + Used for short duration + Professionals using appropriate PPE
Application: closed system	6%	Eye Irrit. 2, H319	Low	30 min/day	EYES: Contact to eyes not expected	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **-/-**	**Acceptable** closed system
Post-Application: closed system	6%	Eye Irrit. 2, H319	Low	30 min/day	EYES: Contact to eyes not expected	**Technical Measure:** -/- **Organisation:** At the workplace a good standard of occupational hygiene is assumed **PPE:** **-/-**	**Acceptable** closed system

Conclusion

Concerning the irritating properties and the effects on the respiratory tract/lung of the biocidal product A-QUASAN B, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, a risk for professional users resulting from all intended uses with the biocidal product A-QUASAN B is unlikely.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product A-QUASAN B is unlikely for all intended uses. Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure a safe use of the biocidal product A-QUASAN B.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

For the component 'Leuna-Alkansulfonat 95' contained in the biocidal product A-QUASAN B the composition is not fully known. The risk assessment is based on the assumption that the biocidal product contains no further substances relevant for the evaluation.

3.6.4.6 Risk for non-professional users

Not relevant. The biocidal product is not intended for non-professional use.

3.6.4.7 Risk for the general public

Table 73: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [5] - Touching dried disinfected surfaces – PT3 (Adult)	1	500	5	0.1844	3.69	yes
Scenario [5] – Touching dried disinfected surfaces – PT3 (Child)	1	500	5	0.2417	4.83	yes

- **Local effects**

Dilutions of the biocidal product for PT3 applications (max. 4.5 %) do not require classification for human health hazards. Therefore, no human health risk from local effects is expected.

Cumulative exposure assessment

The biocidal product is not intended for non-professional use. The product contains only one active substance (benzoic acid, CAS-No. 65-85-0). A quantitative risk assessment for the substances of concern (propan-2-ol, CAS-No. 67-63-0; propan-1-ol, CAS-No. 71-23-8; ethan-1,2-diol, CAS-No. 107-21-1; formic acid, CAS-No. 64-18-6) is not required for exposure of the general public (refer to 3.6.3.1.3 - Further information). Therefore, no cumulative exposure estimate is performed.

Conclusion

The biocidal product is intended for the PT3 application in veterinary health care and for animal housings of companion animals. Therefore, contact of the general public with treated surfaces of animal housings and cages, e.g. in veterinary clinics, cannot be excluded.
No human health risk was identified for secondary exposure of the general public when touching surfaces, professionally treated with the biocidal product, after they have dried. However, the requirement of sufficient ventilation and drying of treated surfaces before re-use has to be implemented in the use-specific risk mitigation measures for all PT3 applications.

3.6.4.8 Risk for consumers via residues in food

Residues in food or feed from biocidal uses are expected to be very low compared to other sources (see section 3.6.3.2 Dietary exposure). The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

3.6.4.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Professional user

Risk characterisation for professional users from combined exposure takes into account the dermal and inhalation exposure of the active substance and the SoCs with systemic effects in the biocidal product A-QUASAN B. Thus, the risk characterisation considers the active substance benzoic acid and the SoCs Propan-1-ol as well as propan-2-ol in the biocidal product A-QUASAN B.

First, each substance is assessed individually for all scenarios relevant to the biocidal products use (Tier 1). Secondly, the combined exposure of the active substances is assessed by considering the effects used to establish the AELs as dose-additive regardless of the specific target organs or mode of actions (Tier 2). If necessary, Tier 3 is carried out which further refines the assessment by either confirming or refuting the assumption of dose-additivity of Tier 2.

Tier 1: Risk assessment of substance by substance of the mixture/the biocidal product

The hazard quotients (HQs) and the conclusions for the risk assessment substance by substance are presented in chapter 3.6.4.5 (**Table 65**, **Table 66**, **Table 67**).

Tier 2: Risk assessment of combined exposure to the mixture/the biocidal product by dose addition

Calculation of the Hazard Index (HI) for each scenario: The HI is the sum of the HQs.

A risk for professional users resulting from the use of the biocidal product A-QUASAN B is unlikely if the HI for each scenario is below or equal to the value of 1. If the HI for a scenario exceeds the value of 1, the risk related to the mixture will be considered unacceptable and further refinement is needed. The refinement may consider further risk mitigation measures beyond the Tier 1 assessment or a Tier 3 assessment.

As shown in Table 74, for the scenarios 1a, 1b, 2a, 2b, 1a + 2a and 1b + 2b the exposure estimates/HQs for all active substances were refined in Tier 1. Therefore, only when additional risk mitigation measures are implemented a risk for the professional user from the combined exposure to the active substance benzoic acid and the SoCs propan-1-ol and propan-2-ol is unlikely because the HI of the Tier 2 assessment is below the value of 1.

Table 74: Combined exposure to the mixture of benzoic acid, propan-1-ol and propan-2-ol in the biocidal product A-QUASAN B by dose addition

Scenario			**HI**[1]	**acceptable** (yes/no)
1a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	1.2	no
		Tier 2	0.08	**yes**
1b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	1.7	no
		Tier 2	0.11	**yes**
2a	PT03 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	1.9	no
		Tier 2	0.17	**yes**

2b	PT04 - Secondary exposure – spray treatment (re-entry of treated location)	Tier 1	1.3	no
		Tier 2	0.12	**yes**
3a	PT03 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	0.23	**yes**
		Tier 2	$6.8x10^{-2}$	yes
3b	PT04 - Disinfectant of equipment by soaking - Professional user - Dipping - Indoor	Tier 1	0.30	**yes**
		Tier 2	$9.1x10^{-2}$	yes
4	PT04 - Disinfectant of inner surfaces without circulation - Professional user - Indoor	Tier 1	$3.9x10^{-2}$	**yes**
		Tier 2	$2.1x10^{-3}$	yes
Combined scenarios				
1a + 2a	PT03 - Disinfectant of hard surfaces - Professional user - Spraying - Indoor	Tier 1	3.0	no
		Tier 2	0.25	**yes**
1b + 2b	PT04 - Disinfectant of hard surfaces- Professional user - Spraying - Indoor	Tier 1	3.0	no
		Tier 2	0.23	**yes**

[1]Sum of the HQs (Hazard Quotients) for each substance. HQ: estimation of internal exposure/AEL. Acceptable: HI≤1

Tier 3: Confirmation or refutation of dose addition

A refinement of the cumulative Tier 2 assessment is not necessary as a risk for the professional user is unlikely, represented by the HI < 1 after implementation of additional risk mitigation measures.

Overall conclusion

Based on the risk assessment of combined exposure to the mixture of the active substance benzoic acid and the SoCs propan-1-ol and propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from all uses with the biocidal product A-QUASAN B is unlikely at the latest when RMMs are applied. Regarding occupational safety, there are no objections against the uses taking into account the provisions described in chapter 2.5.2 of this PAR.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product A-QUASAN B is unlikely for all intended uses (Table 74). Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure a safe use of the biocidal product A-QUASAN B.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant. The biocidal product is not intended for non-professional use.

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 75

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario 5 - Touching dried disinfected surfaces – PT3 (Adult), Tier 1	5	0.1844	3.69	yes
Scenario 5 – Touching dried disinfected surfaces – PT3 (Child), Tier 1	5	0.2417	4.83	yes

3.7 Risk assessment for animal health[12]

The biocidal product is intended for the application in veterinary health care (e.g. veterinary clinics) and for animal housings of companion animals (PT3: Use #1 - Spraying of hard surfaces and Use #2 - Dipping of equipment). Hence, exposure of different types of companion animals to treated surfaces is to be expected.

The toxicological information submitted by the applicant, the Competent Authority Report (CAR) and the Assessment Report (AR), as well as the current scientific literature was evaluated with regard to indications for increased susceptibility of relevant animal species to the active substance.

Doc II of the CAR states, that cats represent a particularly sensitive mammalian species towards the active substance benzoic acid, due to their deficiency in the metabolic pathway of glucuronic acid conjugation. Consequently, benzoic acid will build up to toxic levels when glycine conjugation to hippuric acid is saturated. Therefore, secondary exposure and risk assessment for companion animals is performed, by using cats as worst-case example species. Though cats may be exposed via different pathways, oral exposure from licking the fur after contact with treated surfaces is considered the worst-case exposure scenario.

Oral exposure:

[12] Pets and domestic animals.

Description of Scenario [1]		
Oral exposure of cats by licking the fur after contact with treated surfaces. The scenario assumes a cat lying in a treated animal housing/cage, i.e. in a veterinary clinic. According to the applicant, the maximum in-use concentration for PT3 applications is 18 g biocidal product/m^2. Oral exposure may occur when cats lick their fur. The licking behaviours of cats is very particular, as they tend to thoroughly clean their whole body at least once a day. Hence, it is assumed that half of the body surface of a cat comes into contact with a treated surface and the whole fraction of active substance, which is transferred to the fur, will be available for oral uptake. According to the applicant, the product application needs to be dried before re-use of the treated surfaces. Therefore, a transfer coefficient of 55 % is used as worst-case default. Tier 2 calculations assume contact with a dried surface that has been rinsed with plenty of water after product application. Due to the good water solubility of benzoic acid, the efficiency of rinsing is expected to be high. The assumption of 90 % reduction in a.s. residue level is based on a dilution factor of 1/10 after rinsing, set for household detergents and cleaning products (HERA guidance document Methodology, February 2005). Since cats of various ages may be present in veterinary clinics, the exposure and risk assessment is performed for small cats (kittens), as well as for adult cats.		
	Parameters	Value
Tier 1	Concentration of a.s. in b.p. (Applicant)	9.09 %
	Application frequency of b.p. (Applicant)	1 d^{-1}
	Concentration of b.p. in solution (Applicant)	4.5 %
	Application rate of b.p. (Applicant)	0.4 L/m^2 (=18 g b.p./m^2)
	Concentration of a.s. in solution (Applicant)	0.40905 %
	Maximum surface residue level of a.s.	0.16362 mg a.s./cm^2
	Body weight cat (BW) [1-3]	Kitten (9 weeks): 1 kg Adult cat: 5 kg
	Body surface area cat (BSA) [1-3]	Kitten (9 weeks): 0.1 m^2 Adult cat: 0.29 m^2
	50 % of BSA coming in contact with treated surface (expert judgement)	Kitten (9 weeks): 0.05 m^2 = 500 cm^2 Adult cat: 0.145 m^2 = 1450 cm^2
	Transfer coefficient for dislodgeable residues (Default smooth glazed tiles, Biocides Human Health Exposure Methodology, 2015)	Dried fluid: 55 %
	Oral absorption (default)	100 %
Tier 2 - Rinsing with water	Surface residue level of a.s. after rinsing with water (assumed reduction by 90%)	0.016362 mg a.s./cm^2
	For other parameters refer to Tier 1	

1) Hill R.C. and Scott K.C. *Energy requirements and body surface area of cats and dogs*; JAVMA, Vol 225, No. 5, 2004.
Equation for calculation of BSA: BSA (for cats ≤ 2.5kg) = 0.110 m^2/kg of $BW^{0.67}$; BSA (for cats > 2.5kg) = 0.143 m^2/kg of $BW^{0.4}$

2) Kresken, J-G.; Wendt, R.T.; Modler, P.: *Kardiologie bei Hund und Katze*; 1. Auflage Thieme Verlagsgruppe, 2017
Equation for calculation of BSA: BSA in m^2 = K × (BW in $g^{2/3}$) × 10^{-4}; K = 10.0 (constant for cats)

3) Mealey S. W.: Pharmacotherapeutics for Veterinary Dispensing - *Appendix H: Canine and Feline Body Surface Area Conversion Tables*; First Edition John Wiley & Sons, Inc. 2019

Calculations for Scenario [1] – Tier 1

Systemic oral exposure = Surface residue level of a.s. x application frequency x fraction of BSA coming in contact with treated surfaces x transfer coefficient x oral absorption / body weight

Small cat (kitten) = 0.16362 mg a.s./cm^2 x 1/d x 500 cm^2 x 55 % x 100 % / 1 kg

= **45 mg/kg bw/d**

Adult cat = 0.16362 mg a.s./cm^2 x 1/d x 1450 cm^2 x 55 % x 100 % / 5 kg

= **26 mg/kg bw/d**

Calculations for Scenario [1] – Tier 2

Systemic oral exposure = Surface residue level of a.s. x application frequency x fraction of BSA coming in contact with treated surfaces x transfer coefficient x oral absorption / body weight

Small cat (kitten) = 0.016362 mg a.s./cm^2 x 1/d x 500 cm^2 x 55 % x 100 % / 1 kg

= **4.5 mg/kg bw/d**

Adult cat = 0.016362 mg a.s./cm^2 x 1/d x 1450 cm^2 x 55 % x 100 % / 5 kg

= **2.6 mg/kg bw/d**

There are case reports in the public literature describing adverse effects in cats after exposure to benzoic acid in meat (Bedford and Clarke 1971, 1972). In the supposedly subacute feeding study with cats, a NOAEL/LOAEL of 200/340 mg/kg bw/d was reported (Bedford and Clarke, 1972). However, essential details on study design and the reporting of the effects are lacking. Longtime or teratogenicity studies with cats are currently not available. Therefore, the ADI derived for humans will be used with an additional assessment factor of 10 for derivation of guidance values for cats, resulting in a provisional ADI/AEL of 0.5 mg/kg bw for acute and chronic exposure scenarios.

Since only cats are known to be poor metabolizers of benzoic acid, risk characterisation for other possibly exposed companion animals is assessed by comparing exposure data of cats to human AEL_{acute} of 5 mg/kg bw. This is still assumed to be worst-case, for none of the other companion animals display such intense licking and cleaning behavior.

Table 76 Risk characterisation for cats

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d[1)]	Estimated uptake mg/kg bw/d	Margin of Exposure (MOE)	AEL mg/kg bw/d[2)]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary exposure - licking the fur (kitten)	1	200	45	4.44	0.5	9000	no
	2	200	4.5	44.4	0.5	900	no
Secondary exposure - licking the fur (adult cat)	1	200	26	7.69	0.5	5219	no
	2	200	2.6	76.9	0.5	522	no

1) Bedford & Clarke, 1972

2) Expert judgement

Table 77 Risk characterisation for other companion animals

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Margin of Exposure (MOE)	AEL mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary exposure - licking the fur (kitten)	1	500	45	11.1	5	900	no
	2	500	4.5	111	5	90	yes
Secondary exposure - licking the fur (adult cat)	1	500	26	19.2	5	520	no
	2	500	2.6	192	5	52	yes

Table 78

Conclusion on risk assessment for animal health
Due to their metabolic sensitivity to benzoic acid, a health risk for cats for PT3 surface applications of the biocidal product cannot be excluded. Hence, the product should not be applied on surfaces to which cats may have prolonged contact. This has to be ensured by a use-specific risk mitigation measure. Potential health risk for other companion animals, as well as for the general public, can be minimized by rinsing of the treated surfaces after application of the biocidal product. The active substance benzoic acid and all other co-formulants of the biocidal product are readily soluble in water. Hence, rinsing with plenty of water will effectively reduce surface residue levels. This has to be ensured by assigning a use-specific risk mitigation measure.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product “A-QUASAN B”, a soluble concentrate containing the active substance Benzoic acid, is applied as a disinfectant to be used indoor for disinfection of hard surfaces and equipment to ensure veterinary hygiene (PT3). Moreover, the biocidal product is used in PT 4 for disinfection of hard surfaces, equipment and inner surfaces (CIP) in the food and feed industry (PT 4). One more use is the disinfection of surfaces in veterinary water systems in veterinary practices, animal shelters, animal feeding areas and animal husbandry (animal houses, market pens, slaughterhouses, etc.).

The product “A-QUASAN B” was the representative product in the CAR/Assessment Report for benzoic acid (PT3 and PT4) under Regulation (EU) No 528/2012. The product was referred to by the name MENNO FLORADES. The product studies were conducted on the product under the names MENNO FLORADES and “A-QUASAN”. The name MENNO FLORADES is still used for a plant protection product with the same formulation that is authorised under Regulation (EC) No 1107/2009.

3.8.2 Effects assessment

Effects assessment for the product „A-QUASAN B“ is performed for the active substance Benzoic acid and the identified SoCs Propan-1-ol and Propan-2-ol.

The evaluation is adapted from the Benzoic acid assessment reports in PT3 and PT4 (CAR 2013; Rapporteur: Germany). For the substance of concern Propan-2-ol, the effects assessment is based on the Assessment Reports (2014) in PT1, PT2 and PT4. For the substance of concern Propan-1-ol, the effects assessment is based on Assessment Reports (2017) in PT1, PT2 and PT4.The Assessment Reports of the active substances Propan-2-ol and Propan-1-ol provide detailed information on ecotoxicity data, the PNEC derivation and PNEC values and the environmental risk assessment. A summary is included in the chapters below.

3.8.2.1 Mixture toxicity

The product „A-QUASAN B“ consists of one active substance. Besides several other co-formulants two non–active substances (Propan-1-ol and Propan-2-ol) are included for which a Competent Authority Report (CAR, with an agreed risk assessment) is available. Those substances are regarded as SoCs because they potentially affect environmental organisms due to their intrinsic biological activity and are present in the biocidal product at a concentration ≥ 0.1%.
Moreover, the product contains Formic acid, which is also applied for as biocidal active substance in PT 2 - 6. However, for Formic acid a draft final Competent Authority Report is not available and consequently, this substance is not treated as SoC in the further assessment.
Therefore, an environmental risk assessment as well as a mixture toxicity assessment is performed for the product “A-QUASAN B” considering the active substance Benzoic acid and the SoCs Propan-1-ol and Propan-2-ol. For further details please refer to the confidential annex in chapter 5.

Screening step

- **Screening Step 1:**

The biocidal product affects both, aquatic and terrestrial environment. For further information on the release pathway and the relevant compartments for the assessment of the product, see chapter 3.8.4.3.

- **Screening Step 2:**

As explained above, the product contains the biocidal active substance Benzoic acid as well as the identified SoCs Propan-1-ol and Propan-2-ol.

- **Screening Step 3: Screen on synergistic interactions**

There is no information on synergistic effects between any of the components in the product.

Table 79

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

Conclusion:

Mixture toxicity assessment is required, as three ecotoxicologically relevant components were identified. The assessment will be provided in the subsequent sections.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Aquatic toxicity**

No aquatic toxicity data are available for the product "„A-QUASAN B" itself. The effects assessment is therefore based on data for the active substance Benzoic acid as well as the data for the 2 SoCs Propan-2-ol and Propan-1-ol. Detailed data on the environmental effect assessment and PNEC derivation for the active substance Benzoic acid can be found in the respective CARs for PT3 and PT4 (2013) and the assessment reports for Propan-1-ol (AR 2017) and Propan-2-ol (AR 2014).

Benzoic acid

For surface water, a $PNEC_{water}$ of 2.5 mg/L was derived based on the NOEC of 25 mg/L from a long-term study with *Daphnia manga* by applying an assessment factor of 10. No studies with benthic organisms are available for Benzoic acid. Therefore, the PNEC for the sediment was derived from the $PNEC_{water}$ using the equilibrium partitioning method (CAR for PT3 (2013)), resulting in a $PNEC_{sediment}$ of 3.4 mg/kg ww.

Propan-2-ol

The $PNEC_{water}$ for Propan-2-ol is 2.82 mg/L, based on the NOEC of 141 mg/L from a long-term test with *Daphnia magna* by applying an assessment factor of 50 (AR 2014). For the sediment compartment, a PNEC of 2.41 mg/kg ww was calculated using the equilibrium partitioning method.

Propan-1-ol

For Propan-1-ol, the $PNEC_{water}$ was derived from a 96h-EC_{50} of 2300 mg/L for the copepod *Nitocra spinipes*. As only short-term effect values are available, the application of an assessment factor of 1000 results in a $PNEC_{water}$ of 2.3 mg/L AR (DE, 2017). By using the equilibrium partitioning method (EPM) a $PNEC_{sediment}$ of 1.998 mg/kg ww was estimated.

- **Inhibition of microbial activity (aquatic)**

Benzoic acid

For the active substance its effect on activated sludge was assessed according to OECD 209. For risk assessment an EC50 value of 1000 mg/L was agreed. The $PNEC_{microorganisms}$ (STP) of 10 mg/L was derived by considering an assessment factor of 100 (AR 2013).

Propan-1-ol and Propan-2-ol

The $PNEC_{STP}$ for Propan-2-ol and Propan-1-ol is 10 mg a.s./L according to AR (DE, 2014 and 2017).

3.8.2.3 Terrestrial compartment (including groundwater)

Regarding terrestrial toxicity no data are available for the product "„A-QUASAN B" itself.

Benzoic acid

A $PNEC_{soil}$ of 1.5 mg/kg ww (CAR 2013) was derived from $PNEC_{water}$ using the equilibrium partitioning method, as no test with terrestrial organisms are available for Benzoic acid. For further details please refer to CAR (2013).

Propan-2-ol

$PNEC_{soil}$ for Propan-2-ol is 0.496 mg/kg ww based on EPM, according to AR (DE, 2014).

Propan-1-ol

$PNEC_{soil}$ for Propan-1-ol is 0.4362 mg/kg ww based on EPM, according to AR (DE, 2017).

Atmosphere

Benzoic acid is not considered to be used as fumigant. The vapour pressure of Benzoic acid is 4×10^{-2} to 7×10^{-2} Pa at 20°C. The Henry's constant is 4.6×10^{-3} to 2.2×10^{-2} Pa m^3 mol^{-1} at 20°C. According to a classification scheme after LYMAN et al. (1983) the Henry's law constant indicates moderate volatility from water. The half-life and chemical lifetime of Benzoic acid in the troposphere were estimated to 12.9 and 18.6 days, respectively. Thus, Benzoic acid has a potential for long-range environmental transport regarding the half-life in air (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004, revised in 2017): "… a chemical that migrates significantly through the air, its half-life in air should be greater than two days …"). On the other hand, according to the BPR guidance Vol IV part B + C (2017) effects on stratospheric ozone and acidification are not expected because Benzoic acid does not contain halogens, nitrogen or sulphur substituent. The potential for global warming cannot be characterised because there is no information available in the absorption spectrum in the range from 800 to 1200 nm.

Propan-1-ol has a relatively high vapour pressure, direct evaporation is expected. Nevertheless, the Henry's Law constant indicates that Propan-1-ol is moderately volatile. The DT_{50} in the atmosphere is estimated to be 2.8 d.

Propan-2-ol has a relatively high vapour pressure, direct evaporation is expected. Nevertheless, the Henry's Law constant indicates that Propan-2-ol is moderately volatile. The DT_{50} in the atmosphere is estimated to be 3.1 d. Available effect values from inhalation studies for Propan-2-ol were above the environmental concentration in air according to the AR (DE, 2014). Consequently, adverse effects on terrestrial (air-breathing) organisms were not expected.

3.8.2.4 Non-compartment specific effects

3.8.2.4.1 Further ecotoxicological studies

Benzoic acid

An assessment of secondary poisoning has to be performed if a substance has a potential for bioaccumulation. According to the CAR (2013), Benzoic acid does not have any potential for bioaccumulation and thus, no further assessment of secondary poisoning is considered necessary.

Propan-1-ol and Propan-2-ol

Propan-1-ol and Propan-2-ol were found to have a low bioaccumulation potential and thus, secondary poisoning is considered negligible for those substances according to AR (DE, 2014 and 2017).

3.8.2.5 Summary of effects assessment

The PNEC values for Benzoic acid and the environmental SoCs Propan-1-ol and Propan-2-ol according to the respective Assessment Reports are summarised in the following table.

Table 80: Summary table on calculated PNEC values

Summary table on calculated PNEC values			
Compartment	**Benzoic acid**	**Propan-2-ol (AR, 2014)**	**Propan-1-ol (AR, 2017)**
STP	10 mg/L	10 mg/L	10 mg/L
Surface water	2.5 mg/L	2.82 mg/L	2.3 mg/L
Sediment	3.4 mg/kg ww	2.41 mg/kg ww	1.998 mg/kg ww
Soil	1.5 mg/kg ww	0.496 mg/kg ww	0.4362 mg/kg ww

3.8.3 Fate and behaviour

3.8.3.1 Biodegradation

The a.s. Benzoic acid was regarded as “readily biodegradable within the 10-day window”. This is based on a weight of evidence approach, considering a test on ready biodegradability according to OECD 301 C (“MITI-I test”), the averaged results of 128 tests performed according to either OECD 301 B, or OECD 301 D, or OECD 301 E, and the fact that sodium salt of Benzoic acid is one of the recommended reference compounds proposed in the OECD 301 test guideline.

An anaerobic biodegradation test shows that more than 75% of theoretical gas production is achieved within 60 days of incubation, which means that complete anaerobic biodegradation can be assumed for Benzoic acid.

Propan-1-ol and Propan-2-ol are classified as readily biodegradable, 10-day window fulfilled. For Propan-1-ol and Propan-2-ol no data on biodegradation in soil, water/sediment or sewage treatment plants are available as in light of the screening test results no further studies were deemed necessary. The environmental exposure assessment is based on default assumptions as provided by the Guidance on the BPR, Vol. IV, Part B+C (2017).

3.8.3.2 Abiotic Degradation

Benzoic acid as an aromatic monocarboxylic acid possesses no hydrolysable functional groups. For this reason, hydrolysis under environmental conditions is not expected. In real life samples the microbial population will rapidly degrade Benzoic acid and compared with biodegradation processes, hydrolysis in surface waters will not be relevant. In conclusion, Benzoic acid is stable in pure and sterile water.
Benzoic acid has two absorption bands at wavelength of 228 nm and 274 nm. Thus, a direct photodegradation does not occur for Benzoic acid as chemicals with UV/absorption maximum of < 290 nm cannot undergo direct photolysis in sunlight.
In air Benzoic acid will be degraded by indirect photodegradation, the half-life was calculated to 12.9 d, which corresponds to a value of 18.6 d for the chemical lifetime in the troposphere.

Propan-1-ol is stable to hydrolysis and photolysis in water is not applicable due to no absorption maximum above 290 nm. The DT_{50} in the atmosphere is estimated to be 2.8 d. For further details, please refer to CAR and AR on Propan-1-ol, (2017).

Propan-2-ol is stable to hydrolysis and photolysis in water is not applicable due to no absorption maximum above 290 nm. The DT_{50} in the atmosphere is estimated to be 3.1 d. For further details, please refer to CAR and AR on Propan-2-ol, (2014).

3.8.3.3 Distribution

Based on log Pow of Benzoic acid, the log Koc was estimated to 1.4 by application of QSAR models (Sabljic and Güsten in EU TGD on Risk Assessment (2003), Part III, Chapter 4.3, Table 4) and calculations based on the generally accepted model PCKOCWIN v1.66 (ref. to CAR 2013). The value was used for classification of Benzoic acid as substance with high mobility in soil and for the environmental exposure assessment. The Koc value for Benzoic acid is dependent on pH variation and solubility. The predicted Koc for the Benzoic acid decreases slightly with pH-value, i.e. from the non-ionised molecule to the gradually ionised molecule. In conclusion, Benzoic acid is regarded to be a highly mobile substance in soil at environmentally relevant pH values and Benzoic acid mobility was positively correlated with soil pH, and negatively correlated with Al- and Fe-contents.

Based on a log K_{OW} of 0.25 and the QSAR for alcohols, the K_{OC} for Propan-1-ol was estimated as 3.96 L/kg. Therefore, Propan-1-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of Propan-1-ol in soil and a very low geo-accumulation potential.

Based on a log K_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} for Propan-2-ol was estimated as 3.3 L/kg. Therefore, Propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of Propan-2-ol in soil and a very low geo-accumulation potential.

3.8.3.4 Bioconcentration

Benzoic acid

The calculated bioconcentration factors (BCFs) for Benzoic acid in fish is 7.75 L/kg_{ww} and for earthworm 1.73 L/kg ww based on the experimentally derived log K_{OW} of 1.87. Hence, the aquatic and terrestrial bioaccumulation potential of Benzoic acid was assumed as low according to the CAR for PT3 (2013).

Propan-1-ol and Propan-2-ol

The calculated bioconcentration factor for Propan-1-ol in fish is 0.33 L/kg_{ww} and for earthworm 0.86 L/kg_{ww} according to the active substance AR (DE, 2017). The calculated BCF for Propan-2-ol is 0.22 L/kg_{ww} for fish and 0.85 L/kg_{ww} for earthworm according to the active substance AR (DE, 2014). Correspondingly, a low bioaccumulation potential of both substances was assumed.

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product “A-QUASAN B” is a soluble concentrate containing Benzoic acid (9.09 % w/w) as active substance as well as Propan-1-ol (21.7 % w/w) and Propan-2-ol (13 % w/w) as substances of concern.

The biocidal product is intended to be used indoor for disinfection of hard surfaces and equipment to ensure veterinary hygiene (PT3). The applicant describes the uses more specific as disinfection of hard surfaces by spraying (e.g. work and storage surfaces, boxes, crates, transport surfaces, tools, machines) and by dipping/soaking of equipment (e.g. dishes, cutlery, equipment, small machinery, machine items, crates, boxes) in veterinary health care institutions (veterinary clinics, veterinary testing laboratories and associated equipment) and areas associated with companion animals (animals housing e.g. kennels, hutches and cages, as well as associated equipment).

The biocidal product in PT 4 is used indoor for disinfection of hard surfaces, equipment and inner surfaces (CIP) in the food and feed industry (PT 4). The applicant describes the uses more specific as disinfection of hard surfaces by spraying (e.g. work and storage surfaces, boxes, crates, transport surfaces, tools, machines), dipping/soaking of equipment (e.g. dishes, cutlery, equipment, small machinery, machine items, crates, boxes) and disinfection of inner surfaces without circulation as well as surfaces in human drinking water systems (e.g. pipes, tanks, fillers, mixer, other machines which come into contact with food) in food production facilities, beverage production facilities, warehouses, and refrigerated warehouses. One more use is the disinfection of surfaces in veterinary water systems in veterinary practices, animal shelters, animal feeding areas and animal husbandry (animal houses, market pens, slaughterhouses, etc.).

Table 81: Intended uses in PT 3

Assessed PT	PT 3
Assessed scenarios	Use 1: Disinfectant of hard surfaces – professional user – spraying – indoor Use 2: Disinfectant of equipment by soaking – professional user – dipping – indoor
ESD(s) used	Use 1: Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector); RIVM report 601450008, Van der Poel, 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, EN 2011 Use 2: Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV 45 Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011 Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A6
Approach	Use 1: Average consumption-based approach Use 2: Average consumption-based approach
Distribution in the environment	Calculated based on Guidance BPR IV - Part B+C (ECHA, 2017) for both SoCs: Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	No
Confidential Annexes	Yes
Life cycle steps assessed	All Intended Uses: Production: No Formulation No Use: Yes Service life: No
Remarks	

Table 82: Intended uses in PT 4

Assessed PT	PT 4
Assessed scenarios	Use 3: Disinfectant of hard surfaces – professional user – spraying – indoor Use 4: Disinfectant of equipment by soaking – professional user – dipping – indoor Use 5: Disinfectant of inner surfaces without circulation – professional user – indoor Use 6: Disinfectant of surfaces in human drinking water systems – professional user – indoor Use 7: Disinfectant of surfaces in veterinary water systems – professional user – indoor
ESD(s) used	Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas, JRC 2011 Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A6, Minutes of WG-V-2019_ENV
Approach	Use 3: Average consumption-based approach Use 4: Average consumption-based approach Use 5: Average consumption-based approach Use 6: Average consumption-based approach Use 7: Average consumption-based approach
Distribution in the environment	Calculated based on Guidance BPR IV - Part B+C (ECHA, 2017) for both SoCs: Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	FOCUS PEARL refinement was performed for use 3 for Benzoic acid and for use 7 (via slurry/manure) for Benzoic acid
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation No Use: Yes Service life: No
Remarks	-

3.8.4.2 Fate and distribution in exposed environmental compartments

Parameters which describe the fate and distribution of Benzoic acid in the environment are summarised in Table 83 and based on the LoEP of AR 2013, eCA DE. The partitioning coefficients for the aquatic and terrestrial compartment, which are relevant for the environmental emission estimation and exposure assessment are based on these input values.

Table 83: Input parameters (only set values) for calculating the fate and distribution in the environment of Benzoic acid

Input	Value	Unit	Remarks
Molecular weight	122.12	g/mol	
Melting point	122.4	°C	
Boiling point	249.2	°C	
Vapour pressure (at 20°C)	0.04 – 0.07	Pa	for further calculations VP = 0.055 Pa (at 20°C) was used
Water solubility (at 20°C)	pH 5.2: 5 pH 9: 15	g/L	
Log Octanol/water partition coefficient	1.87	Log 10	at 20°C, unionised molecule
Log Organic carbon/water partition coefficient	1.4	Log 10	Benzoic acid mobility was positively correlated with soil pH; Koc = 25.119 L/kg was used in further calculations
Henry's Law Constant (calculated)	0.0016 – 0.0029	Pa × m^3/mol	for further calculations HENRY = 8.402E-04 Pa × m^3/mol (at 12°C) was used
Biodegradability	readily biodegradable		10-day window fulfilled
Rate constant for STP	1	h^{-1}	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4
DT_{50} for biodegradation in surface water	15	d	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 5
DT_{50} for hydrolysis in surface water	no hydrolysis		
DT_{50} for photolysis in surface water	not applicable		
DT_{50} for degradation in soil	0.57	d (at 12ºC)	k_{bio_soil} = 1.22 d^{-1}

Parameters which describe the fate and distribution of Propan-1-ol and Propan-2-ol in the environment are summarised in Table 84 and based on the LoEP of Propan-1-ol (AR 2017, eCA DE) and the LoEP of Propan-2-ol (AR 2014, eCA DE). The partitioning coefficients for the aquatic and terrestrial compartment, which are relevant for the environmental emission estimation and exposure assessment are based on these input values.

Table 84: Input parameters (only set values) for calculating the fate and distribution in the environment of Propan-1-ol and Propan-2-ol

Input	Propan-1-ol	Propan-2-ol	Unit	Remarks
Molecular weight	60.09	60.09	g/mol	
Melting point	-127	-89.5	°C	
Boiling point (at 1013 Pa)	97.2	82.5	°C	

Input	Propan-1-ol	Propan-2-ol	Unit	Remarks
Vapour pressure (at 12°C)	1099	2302	Pa	
Water solubility (at 12°C)	1.0E+03	1.0E+03	g/L	
Log Octanol/water partition coefficient	0.25	0.05	Log 10	
Organic carbon/water partition coefficient (Koc)	3.96	3.3	L/kg	
Henry's Law Constant (at 12°C)	0.364	0.383	Pa × m^3/mol	Propan-1-ol: Temperature corrected from measured Henry's Law constant of 0.76 Pa × m³/mol at 25°C Propan-2-ol: Temperature corrected from measured Henry's Law constant of 0.80 Pa × m³/mol at 25°C
Biodegradability	readily biodegradable	readily biodegradable		10-day window fulfilled
Rate constant for STP	1	1	h^{-1}	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4
DT_{50} for biodegradation in surface water	15	15	d	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 5
DT_{50} for hydrolysis in surface water	no hydrolysis	no hydrolysis		
DT_{50} for photolysis in surface water	not applicable	not applicable		
DT_{50} for degradation in soil	30	30	d (at 12ºC)	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.5, table 6

The distribution for Benzoic acid, Propan-1-ol and Propan-2-ol in the sewage treatment plant was calculated using SimpleTreat v.4.0.

Table 85: Calculated distribution in the STP for Benzoic acid, Propan-1-ol and Propan-2-ol

Compartment	Percentage [%]		
	Benzoic acid	Propan-1-ol	Propan-2-ol
Air	0.0004	0.2602	0.2736
Water	8.004	7.958	7.956
Sludge	0.2343	0.0370	0.0309
Degraded in STP	91.76	91.74	91.74

As the distribution in sewage sludge for Propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant for several biocidal products containing Propan-2-ol as a.s. This was already equally considered for Propan-2-ol as SoC. Furthermore, as the distribution in sewage sludge for Propan-1-ol is also < 0.1 % the approach of no

relevance to further environmental exposure assessment via sludge application on agricultural land should also be transferable to Propan-1-ol, since Propan-1-ol has very similar phys./chem. properties as Propan-2-ol.

3.8.4.3 Foreseeable routes of entry into the environment on the basis of the use envisaged

The use of the biocidal product “A-QUASAN B” as a disinfectant results in exposure of all environment compartments.

Benzoic acid

For the assessment of Benzoic acid in PT 3 the only release pathway is via STP which results in subsequent indirect exposure of the compartments water, sediment, soil and groundwater. The assumptions for the assessment in PT 3 are also valid for the assessment in PT 4 in cases where the environmental release pathway is via sewer and STP. Moreover, for use 7 the assessments in PT 4 are extended by the release pathway via manure/slurry which results in subsequent exposure of the compartments soil, groundwater, surface water and sediment.

Table 86: Identification of relevant receiving compartments based on the exposure pathway for Benzoic acid

	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air*
Use 1	yes	yes (indirect)	yes (indirect)	not relevant
Use 2	yes	yes (indirect)	yes (indirect)	not relevant
Use 3	yes	yes (indirect)	yes (indirect)	not relevant
Use 4	yes	yes (indirect)	yes (indirect)	not relevant
Use 5	yes	yes (indirect)	yes (indirect)	no
Use 6	yes	yes (indirect)	yes (indirect)	no
Use 7 via STP	yes	yes (indirect)	yes (indirect)	no
via manure/ slurry	no	yes (indirect)	yes (indirect)	no

*not relevant means emissions are possible but for further assessment not relevant, no means no emissions,

SoCs Propan-1-ol and Propan-2-ol

During the active substance approval Propan-1-ol and Propan-2-ol, it was assumed that 90 % of Propan-1-ol (CAR Doc.II, 2017, eCA DE) and Propan-2-ol (CAR Doc.II, 2014, eCA DE) are released to air and 10 % of the substances are released to water. This release distribution was only assumed for the intended use of surface disinfection in the CARs of Propan-1-ol and Propan-2-ol. According to the BPC opinion of Propan-2-ol the distribution between water and air should be re-evaluated in the frame of product authorisation. According to the BPC opinion of Propan-1-ol it must be ensured that the assumption of evaporation of the Propan-1-ol does apply to the intended use of the biocidal product. In cases of Propan-1-ol and Propan-2-ol the evaporation of the SoCs are facilitated by the relatively high vapour pressure. In the AR of Propan-1-ol and Propan-2-ol as well as in several PARs of Propan-2-ol is stated, that nearly the whole amount of the SoC applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to sewer systems cannot be completely excluded for liquid products.

Hence, the RefMS DE re-evaluated the release distribution of both SoCs considering the uses of the biocidal product “A-QUASAN B” with the result that the intended uses 1 and 3 take place as surface disinfection as the uses in the CARs of Propan-1-ol and Propan-2-ol. Whereas the intended uses 2 and 4 take place as a dipping bath, where the diluted disinfection solution is not to be intended to evaporate and the intended uses 5 to 7 take place in closed systems which exclude any evaporation during the application of the b.p..

Therefore, for the environmental risk assessment of the intended uses 1 and 3 of the b.p. “A-QUASAN B” the Propan-1-ol and Propan-2-ol distribution to air (90 %) and waste water (10 %) used during the assessment of the active substance is maintained. For all other intended uses 100 % of Propanols is expected to be emitted to waste water. Additionally, for the intended use 7, an assessment of possible emission via manure needs to be performed.

Table 87: Identification of relevant receiving compartments based on the exposure pathway for SoCs Propan-1-ol and Propan-2-ol

	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air*
Use 1	yes	yes (indirect)	not relevant	yes
Use 2	yes	yes (indirect)	not relevant	not relevant
Use 3	yes	yes (indirect)	not relevant	yes
Use 4	yes	yes (indirect)	not relevant	not relevant
Use 5	yes	yes (indirect)	not relevant	no
Use 6	yes	yes (indirect)	not relevant	no
Use 7 via STP	yes	yes (indirect)	not relevant	no
via manure/ slurry	no	Not relevant#)	Not relevant#)	no#)

#) more details in chapter SoC assessment, *not relevant means emissions are possible but for further assessment not relevant, no means no emissions

3.8.4.4 Local emission estimation for relevant environmental compartments

Use 1: PT 3 [Disinfectant of hard surfaces - Professional user - Spraying - Indoor]

The following use description and emission estimation has been provided by the applicant:

A relevant emission scenario was not found for Use 1 in the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products (EN 2011), but two emission scenarios in the PT 2 ESDs (Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, EN 2011, Table 2 and Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector); RIVM report 601450008 (Van der Poel, 2001), Table 3.6) are fitting to the intended use of Use 1. The following worst-case assumption was made on the area to be disinfected. The biocidal product A-QUASAN B is intended to be used in veterinary health care and in companion animal housing. The largest animal to be treated or housed in these types of facilities would be dogs. Housing in these facilities is temporary, therefore a kennel dimension of 2 x 2 x 2 m (length x width x height) would be reasonable. The kennel would have a floor and four walls (5 areas each 4 m^2) to be disinfected. The total area to disinfect in each kennel would be 20 m^2. The number of kennels in a facility will vary greatly, but a reasonable worst case would be 100 kennels. If all of the kennels were disinfected on one day, then 2000 m^2 would be the area to be disinfected in one day. The ESD for PT 2 (Van der Poel, 2001) assumes that the disinfectant is left on the treated surface to dry without rinsing, but a fraction of the solution may theoretically be removed and transferred

to wastewater during next cleaning. The eCA DE supports to use the default fraction of 0.55 for estimation of a.s. releases to wastewater according to ESD PT2, Table 3.6 (Van der Poel, 2001). Furthermore, this value is supported by default a.s. fractions reaching slurry or wastewater of maximum 0.5 given in the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011. The eCA DE supports also that the generally calculations are based on the emission scenario provided in ESD PT 2, Table 2 (EN, 2011).

According to this emission model in ESD for PT 2 (Van der Poel, 2001) the only emission pathways into the environment is via waste water. But according to chapter 3.8.4.2 the distribution for the SoCs Propan-1-ol and Propan-2-ol to air (90 %) and waste water (10 %) used during the assessment of the active substance is maintained.

Based on the risk mitigation measure 1) proposed in SPC to avoid risks to human and animal health, a modified environmental exposure assessment has to be carried out. The RMM requires a rinsing process of treated surfaces with tap water after the recommended treatment time and before re-use. Due to the low vapour pressure for Benzoic acid (compared to those of the SoCs) it must be assumed that residues of a.s. are present on the treated surfaces and that these are released into the waste water with the rinsing process. As a conservative worst case this fraction is assumed to be equal to 100 % of a.s..

The estimations are presented in the following table:

Table 88: Input and output values for local emissions of Use 1 – according to ESD for PT 2, Table 2 (EN, 2011) adapted with a parameter of ESD for PT 2, Table 3.6 (Van der Poel, 2001) and modified on a RMM based assumption

Input	Symbol	Value	Unit	Remarks
Use 1: PT 3: disinfection of hard surfaces				
Application rate of working solution	Vform	0.4	L/m²	according to SPC
Density of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance or Substances of Concern in the biocidal product	$F_{benzoic\ acid}$ $F_{propan\text{-}1\text{-}ol}$ $F_{propan\text{-}2\text{-}ol}$	0.0909 0.217 0.13		9.09 % w/w (according to SPC) 21.7 % w/w (according to Confidential annex 5.1) 13 % w/w (according to Confidential annex 5.1)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.045	-	maximum application concentration according to SPC: 4.5 % preparation based on label recommendation provided by the applicant: 4.5 L b.p. are diluted in 95.5 L water: 4.5/100=0.045
Surface area to be treated	$AREA_{surface}$	2000	m²	Set value according applicant assumptions
Number of applications per day	Nappl	1	d^{-1}	Set value according applicant assumptions
Fraction of active substance released to waste water	$Fwater_{a.s.}$	0.55	-	Default according to ESD PT 2 (Van der Poel, 2001), Tab. 3.6 (corresponding to parameter Fsan)

RMM based Fraction of active substance released to waste water	$Fwater_{a.s.\_RMM}$	1	-	RMM based assumption
Fraction of Substances of Concern released to waste water	$Fwater_{SoC}$	0.1	-	(according to CAR propan-1-ol (eCA DE, 2017) and CAR propan-2-ol (eCA DE, 2014))
Fraction of Substances of Concern released to air	$Fair_{SoC}$	0.9	-	(according to CAR propan-1-ol (eCA DE, 2017) and CAR propan-2-ol (eCA DE, 2014))
Output				
Concentration of active substance or Substances of Concern in the biocidal product: Benzoic acid Propan-1-ol Propan-2-ol	Cform	 90.81 216.78 129.87	g/L	
Application rate of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	Q_{appl}	 1.63 3.90 2.34	g/m^2	
Local release to waste water of the active substance or Substances of Concern: Benzoic acid Benzoic acid_RMM Propan-1-ol Propan-2-ol	$Elocal_{water}$	 1.80 3.27 0.78 0.47	kg/d	
Local release to air of the Substances of Concern: Propan-1-ol Propan-2-ol	$Elocal_{air}$	 7.02 4.21	kg/d	
Calculations				
$Cform = RHO_{b.p.} \bullet Fsubstance \bullet 1000$				
$Q_{appl} = Vform \bullet Cform \bullet Fdil$				
$Elocal_{water} = Q_{appl} \bullet AREA_{surface} \bullet Nappl \bullet Fwater / 1000$				
$Elocal_{air} = Q_{appl} \bullet AREA_{surface} \bullet Nappl \bullet Fair / 1000$				

Use 2: PT 3 [Disinfectant of equipment by soaking - Professional user - Dipping - Indoor]

There are two relevant scenarios which describes the disinfection by a dipping bath. One is the TAB-Entry ENV 45 Disinfection of medical equipment (in PT 2) (TAB v2.1, 2019) and another is the TAB-Entry ENV 55 Capacity of dipping bath in PT 3 (TAB v2.1, 2019). The eCA DE considered that the TAB ENV 45 better fits to the intended use of Use 2 because the biocidal product “A-QUASAN B” is intended to be used for disinfection of equipment in veterinary health care and in companion animal housing. In the view of eCA DE this equipment fits better to the equipment described in PT 2 than to equipment of stables described in PT 3.

According to this emission model, the only emission pathways of a.s. and SoCs into the environment is via waste water. The estimations are presented in the following table:

Table 89: Input and output values for local emissions of Use 2 – according to TAB v.2.1, ENV 45 (2019)

Input	Symbol	Value	Unit	Remarks
Use 2: PT 3: disinfection of equipment by soaking				
Densitiy of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance or Substances of Concern in the biocidal product	$F_{benzoic\ acid}$ $F_{propan\text{-}1\text{-}ol}$ $F_{propan\text{-}2\text{-}ol}$	0.0909 0.217 0.13		9.09 % w/w (according to SPC) 21.7 % w/w (according to Confidential annex 5.1) 13 % w/w (according to Confidential annex 5.1)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.045	-	maximum application concentration according to SPC: 4.5 % preparation, based on label recommendation provided by the applicant: 4.5 L b.p. are diluted in 95.5 L water: 4.5/100=0.045
Volume of solution in dipping bath	Qdipping_bath	10	L	corresponds to 0.01 m^3; Default TAB v.2.1, ENV45 (2019)
Maximum number of dipping bath per day	Ndipping_bath	30	d^{-1}	Default TAB v.2.1, ENV45 (2019)
Fraction of active substance and Substances of Concern released to wastewater	F_{water}	1	-	Default TAB v.2.1, ENV45 (2019)
Output				
Concentration of active substance or Substances of Concern in the biocidal product: Benzoic acid Propan-1-ol Propan-2-ol	Cform	 90.81 216.78 129.87	g/L	
Application rate of the active substance or Substances of Concern: Benzoic acid Propan-1-ol	Q_{appl}	 4.09 9.76	g/L	

Propan-2-ol		5.84		
Local release to waste water of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	$Elocal_{water}$	 1.226 2.927 1.753	kg/d	
Calculations				
Cform = $RHO_{b.p.}$ ● Fsubstance ● 1000				
Q_{appl} = Cform ● Fdil				
$Elocal_{water}$ = Q_{appl} ● Qdipping_bath ● Ndipping_bath ● Fwater / 1000				

Use 3: PT 4 [Disinfectant of hard surfaces- Professional user - Spraying - Indoor]

The environmental emission estimation is based on Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, chapter 2.2 “Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries”, Table 10 (JCR, 2011). For the surface area to be disinfected the default value for slaughterhouses is chosen as a worst case.
According to this emission model the only emission pathway into the environment is via waste water. But according to chapter 3.8.4.2 the distribution for the SoCs Propan-1-ol and Propan-2-ol to air (90 %) and waste water (10 %) used during the assessment of the active substance is maintained. The estimations are presented in the following table:

Table 90: Input and output values for local emissions of Use 3 – according to ESD for PT 4, Table 10 (2011)

Input	Symbol	Value	Unit	Remarks
Use 3: PT 4: disinfection of hard surfaces				
Application rate	Vform	0.4	L/m²	according to SPC
Density of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance or Substances of Concern in the biocidal product	$F_{benzoic\ acid}$ $F_{propan\text{-}1\text{-}ol}$ $F_{propan\text{-}2\text{-}ol}$	0.0909 0.217 0.13		9.09 % w/w (according to SPC) 21.7 % w/w (according to Confidential annex 5.1) 13 % w/w (according to Confidential annex 5.1)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.06	-	maximum application concentration according to SPC: 6 % preparation; description based on label recommendation provided by the applicant:

				6 L b.p. are diluted in 94 L water: 6/100=0.06
Surface area to be treated	$AREA_{surface}$	10000	m^2	Default according ESD PT 4, Tab. 10
Number of applications per day	Nappl	1	d^{-1}	Default according ESD PT 4, Tab. 10
Fraction of active substance or Substances of Concern disintegrated during or after application (before release to the sewage system	Fdis	0	-	Default according ESD PT 4, Tab. 10
Fraction of active substance or Substances of Concern eliminated due to on-site pre-treatment of waste water	Felim	0	-	Default according ESD PT 4, Tab. 10
Fraction of active substance released to waste water	$Fwater_{a.s.}$	1	-	Default according ESD PT 4, Tab. 10
Fraction of Substances of Concern released to waste water	$Fwater_{SoC}$	0.1	-	(according to CAR propan-1-ol (eCA DE, 2017) and CAR propan-2-ol (eCA DE, 2014))
Fraction of Substances of Concern released to air	$Fair_{SoC}$	0.9	-	(according to CAR propan-1-ol (eCA DE, 2017) and CAR propan-2-ol (eCA DE, 2014))
Output				
Concentration of active substance or Substances of Concern in the biocidal product: Benzoic acid Propan-1-ol Propan-2-ol	Cform	 90.81 216.78 129.87	g/L	
Application rate of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	$Qa.i._{appl}$	 2.18 5.20 3.12	g/m^2	
Local release to waste water of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	$Elocal_{water}$	 21.80 5.20 3.12	kg/d	

Local release to air of the Substances of Concern: Propan-1-ol Propan-2-ol	$Elocal_{air}$	 46.82 28.05	kg/d	
Calculations				
Cform = $RHO_{b.p.}$ ● Fsubstance ● 1000				
$Qa.i._{appl}$ = Vform ● Cform ● Fdil				
$Elocal_{water}$ = $Qa.i._{appl}$ ● $AREA_{surface}$ ● Nappl ● (1-Fdis) ● (1-Felim) ● Fwater / 1000				
$Elocal_{air}$ = $Qa.i._{appl}$ ● $AREA_{surface}$ ● Nappl ● (1-Fdis) ● (1-Felim) ● Fair / 1000				

Use 4: PT 4 [Disinfectant of equipment by soaking - Professional user - Dipping - Indoor]

A scenario for PT 4 covering the use of a biocidal product in disinfection baths for instruments used in food industry was agreed at the WG ENV V 2019. The equipment is disinfected in dipping baths with a capacity of 100 litres, the b.p. is diluted to 6 %. After the disinfection process, the solution is disposed of to drain once per day at 5 sites that are connected to the same sewage treatment plant. According to this emission model, the only emission pathway of a.s. and SoCs into the environment is via waste water. The estimations are presented in the following table:

Table 91: Input and output values for local emissions of Use 4 – according to agreed dipping scenario at the WG ENV V 2019 for PT 4

Input	Symbol	Value	Unit	Remarks
Use 4: PT 4: disinfection of equipment by soaking				
Density of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance or Substances of Concern in the biocidal product	$F_{benzoic\ acid}$ $F_{propan\text{-}1\text{-}ol}$ $F_{propan\text{-}2\text{-}ol}$	0.0909 0.217 0.13		9.09 % w/w (according to SPC) 21.7 % w/w (according to Confidential annex 5.1) 13 % w/w (according to Confidential annex 5.1)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.06	-	maximum application concentration according to SPC: 6 % preparation description based on label recommendation provided by the applicant: 6 L b.p. are diluted in 94 L water: 6/100=0.06
Volume of solution in a dipping bath	Vbath	100	L	Default according agreed scenario at the WG ENV V 2019 for PT 4
Number of applications per day	Nappl	5	d^{-1}	Default according agreed scenario at the WG ENV V 2019 for PT 4

Fraction of active substance or Substances of Concern disintegrated during or after application (before release to the sewage system)	Fdis	0	-	Default according ESD PT 4, Tab. 10
Fraction of active substance or Substances of Concern eliminated due to on-site pre-treatment of waste water	Felim	0	-	Default according ESD PT 4, Tab. 10
Fraction of active substance of active substance or Substances of Concern released to waste water	Fwater	1	-	Default according ESD PT 4, Tab. 10
Output				
Concentration of active substance or Substances of Concern in the biocidal product: Benzoic acid Propan-1-ol Propan-2-ol	Cform	 90.81 216.78 129.87	g/L	
Amount of the active substance or Substances of Concern to be used in a dipping bath: Benzoic acid Propan-1-ol Propan-2-ol	Qai_{prescr}	 544.86 1300.68 779.22	g	
Local release to waste water of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	$Elocal_{water}$	 2.72 6.50 3.90	kg/d	
Calculations				
$Cform = RHO_{b.p.}$ ● Fsubstance ● 1000				
Qai_{prescr} = Vbath ● Cform ● Fdil				
$Elocal_{water} = Qai_{prescr}$ ● Nappl ● (1-Fdis) ● (1-Felim) ● Fwater / 1000				

Use 5: PT 4 [Disinfectant of inner surfaces without circulation - Professional user - Indoor]

Emission scenarios for the disinfection of liquid processing are provided in the ESD PT 4 in chapter 2.1.4.1. Closed systems are filed up with the product solution to disinfect the inner surfaces. After the recommended exposure time, the system is emptied and rinsed with tap water. The volume of disinfectant used is 50 L. As this scenario is similar to the scenario for Use 6, only Use 6 (higher volume of 253 L) is calculated as a worst case.

Use 6: PT 4 [Disinfectant of surfaces in human drinking water systems - Professional user - Indoor]

Use 6 describes the disinfection of surfaces in human drinking water systems and is described in the ESD PT 4 in chapter 2.1.4.1. Closed systems are filled with the product solution to disinfect the inner surfaces. After the recommended exposure time, the system is emptied and rinsed with tap water. The volume of disinfectant used is 253 L (applicant information). The a.s. is released to the sewage treatment plant.

Table 92: Input and output values for local emissions of Use 6 – according to ESD for PT 4, Table 4 (2011)

Input	Symbol	Value	Unit	Remarks
Use 6: PT 4: disinfection of inner surfaces without circulation				
Density of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance or Substances of Concern in the biocidal product	$F_{benzoic\ acid}$ $F_{propan\text{-}1\text{-}ol}$ $F_{propan\text{-}2\text{-}ol}$	0.0909 0.217 0.13		9.09 % w/w (according to SPC) 21.7 % w/w (according to Confidential annex 5.1) 13 % w/w (according to Confidential annex 5.1)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.06	-	maximum application concentration according to SPC: 6 % preparation description based on label recommendation provided by the applicant: 6 L b.p. are diluted in 94 L water: 6/100=0.06
Volume of disinfectant used for cleaning	$Vform_{total}$	253	L	applicant information, modified compared to Table 4, ESD PT 4 as the applicant provided a total volume, not subdivided in volumes for process lines, mixing tanks and storage tanks
Fraction of of active substance or Substances of Concern released to waste water	Fwater	1	-	Default according ESD PT 4, Tab. 4

Input	Symbol	Value	Unit	Remarks
Fraction of active substance or Substances of Concern disintegrated during or after application (before release to the sewage system)	Fdis	0	-	Default according ESD PT 4, Tab. 4
Number of applications per day	Nappl	1	d^{-1}	applicant information
Number of days for the emission	Temission	365	d	Default according ESD PT 4, Tab. 4
Output				
Concentration of active substance or Substances of Concern in the biocidal product: Benzoic acid Propan-1-ol Propan-2-ol	Cform	 5.449 13.007 7.792	g/L	
Amount of the active substance or Substances of Concern to be used: Benzoic acid Propan-1-ol Propan-2-ol	Qai	 1378 3291 1971	g	
Local release to waste water of the active substance or Substances of Concern: Benzoic acid Propan-1-ol Propan-2-ol	$Elocal_{water}$	 1.378 3.291 1.971	kg/d	
Calculations				
Cform = $RHO_{b.p.}$ ● Fsubstance ● 1000				
Qai = Cform ● $Vform_{total}$				
$Elocal_{water}$ = Qai ● Fwater ● (1-Fdis) ● Nappl / (1000 ● (365/Temission))				

Use 7: PT 4 [Disinfectant of surfaces in veterinary water systems - Professional user - Indoor]

a. Emission pathway via STP

The intended use is described as drinking water pipe disinfection in veterinary drinking water systems (e.g. in animal housings) by filling up the pipe system with product solution. After the exposure time, the water system is emptied and rinsed with tap water. The recommended application is maximum once per week. The water is emitted to waste water without disintegration before release to the sewer system. RefMS decided to use a modified scenario based on ESD for PT4 (JCR, 2011).

In order to consider the possible entries of b.p. residues into the sewage treatment plant, the calculation scenario already specified for use 6 can be used as the same values for input parameters have to be applied. In conclusion, the local releases to waste water $Elocal_{water}$ of the active substance or SoCs are equal to the above-mentioned values (ref. to Table 92).

b. Emission pathway via slurry/manure

Following the b.p. application in drinking water pipe systems in veterinary pipe systems (e.g. in animal housings) fractions of the b.p, can be transferred to the slurry/manure storage system. In this case, the main receiving compartment is agricultural soil (arable land or grassland) following manure or slurry application on agricultural land. According to available comparable emission/exposure scenarios (ref. to ESD PT3, 2011) further releases of a.s. and SoCs to aquatic compartment (surface water, sediment) and to groundwater have to be considered due to drainage and run-off processes from agricultural soils or leaching processes, respectively. Emission scenarios of PT3 and PT 18 are used for this purpose. In Table 93 the calculations for housings for veal calves are presented as the worst case. A summary for all types of housing is presented in Table 100.

Emission estimation for the SoCs Propan-1-ol and Propan-2-ol are not performed as described in chapter 3.8.4.6.

Table 93: Input and output values for local emissions of Use 7 – according to ESDs for PT 3 (2011) and PT4 (2011)

Input	Symbol	Value	Unit	Remarks
Use 7: PT 4: disinfection of surfaces in veterinary water systems				
Densitiy of biocidal product	$RHO_{b.p.}$	0.999	kg/L	according to chapter 3.2
Fraction of active substance in the biocidal product	$F_{benzoic\ acid}$	0.0909		9.09 % w/w (according to SPC)
Dilution factor (for preparation of the working solution from the formulated biocidal product)	Fdil	0.06	-	maximum application concentration according to SPC: 6 % preparation description based on label recommendation provided by the applicant: 6 L b.p. are diluted in 94 L water: 6/100=0.06

Volume of used disinfectant	$Vform_{total}$	253	L	applicant information
Fraction of active substance disintegrated during or after application (before release to the sewage system	Fdis	0	-	Default according to ESD PT 4, Table 11
Type of housing/manure storage (for application of the notification)	cat-subcat	veal calves	-	worst case, Picklist value according to ESD PT 3, Appendix 1, Table 7 (PEC values for all types of housing see Table 100)
Fraction of active ingredient released	$F_{slurry/manure}$	1	-	set to 1 by default due to worst case assumption
Number of disinfection events = frequency of application per week	N_{app_device}	1	-	applicant information
Number of manure applications for grassland	$Nlapp_{grass}$	4	-	Default according to ESD PT3, Table 1a
Manure application time interval for grassland	Tgr-int	53	d	Default according to ESD PT3, Appendix, Table 12
Number of manure applications for arable land	$Nlapp_{arab}$	1	-	Default according to ESD PT3, Table 1a
Manure application time interval for grassland	Tar-int	212	d	Default according to ESD PT3, Appendix, Table 12
Number of animals	N_{animal}	80	-	Picklist value according to ESD PT3, Table 8
Amount of nitrogen per animal	Q_{nitrog}	0.02382	kg/d	Picklist value according to ESD PT3, Table 11
Nitrogen immission standard for one year on grassland and arable land	Q_N	170	kg/(h* year)	Default according to ESD PT3, Table 13
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05	m	Default according to ESD PT3, Table 1a, Guidance Vol IV Part B+C (2017), Table 10
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20	m	Default according to ESD PT3, Table 1a, Guidance Vol IV Part B+C (2017), Table 10
Density of wet bulk soil	$RHOsoil_{wet}$	1700	kg/m^3	Default according to ESD PT3, Table 1a, Guidance Vol IV Part B+C (2017), Table 3
Intermediate calculations	**Symbol**	**Value**	**Unit**	**Remarks**
Number of biocide applications during storage period for application on grassland	$Napp\_manure_{gr}$	7.6		ESD PT 3, Table 1c
Number of biocide applications during storage period for application on arable land	$Napp\_manure_{ar}$	30.3		ESD PT 3, Table 1c

Amount of active ingredient to be used for disinfection per week Benzoic acid	Qai_{prescr}	1.378	kg	ESD PT 3, Table 1c
Amount of active ingredient in relevant stream after one application Benzoic acid	Qai_{slurry_manure}	1.378	kg	ESD PT 3, Table 1c
Amount of active ingredient in manure or slurry after the relevant number of biocide application for the manure application to grassland Benzoic acid	Qai_{grass}	10.476	kg	ESD PT 3, Table 1c
Amount of active ingredient in manure or slurry after the relevant number of biocide application for the manure application to arable land Benzoic acid	Qai_{arab}	41.768	kg	ESD PT 3, Table 1c
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	$Qnitrog_{grass}$	100.997	kg	ESD PT 3, Table 1c
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	$Qnitrog_{arab}$	403.987	kg	ESD PT 3, Table 1c
Output	**Symbol**	**Value**	**Unit**	**Remarks**
Concentration of the biocide (active ingredient) in soil (mg/kg) in the case of an immission standard for nitrogen and land application on grassland Benzoic acid	PIECgrs-N	20.75	mg/kg	ESD PT 3, Table 1d
Concentration of the biocide (active ingredient) in soil (mg/kg) in the case of an immission	PIECars-N		mg/kg	ESD PT 3, Table 1d

standard for nitrogen and land application on arable land Benzoic acid		5.17		
Calculations				
Cform = $RHO_{b.p.}$ ● Fsubstance ● 1000				
Napp_bioc= Nday ● Napp_device				
$Tbioc_{int}$ = 1d ● d / Napp_device				
Qai_{prescr} = Cform ● ($Vform_{inst}$ + $Vform_{tank}$) ● Fdil ● $Tbioc_{int}$				
Qai_{slurry_manure} = F_{slurry_manure} ● Qai_{prescr}				
Qai_{grass} = Qai_{slurry_manure} ● $Napp\_manure_{gr}$				
Qai_{arab} = Qai_{slurry_manure} ● $Napp\_manure_{ar}$				
$Qnitrog_{grass}$ = N_{animal} ● Q_{nitrog} ● Tgr-int				
$Qnitrog_{arab}$ = N_{animal} ● Q_{nitrog} ● Tar-int				
PIECgrs-N = (100 ● Qai_{grass} ● Q_N) / ($Qnitrog_{grass}$ ● $Nlapp_{grass}$ ● $DEPTH_{grassland}$ ● $RHOsoil_{wet}$)				
PIECars-N = (100 ● Qai_{arab} ● Q_N) / ($Qnitrog_{arab}$ ● $Nlapp_{arab}$ ● $DEPTH_{arable\text{-}land}$ ● $RHOsoil_{wet}$)				

3.8.4.5 Calculated PEC values for the emission pathway via STP

As continuous release of waste water is assumed to the municipal STP, the effluent concentration is representative for the exposure of microorganisms in STP. Thus, PEC_{STP} (= $Clocal_{eff}$) according to equation 41, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017). The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment: $PEC_{local\_surfacewater}$ has been calculated according to equation 51, chapter 2.3.8.3, Guidance on the BPR, Vol. IV, Part B+C (2017) and as the PNEC values for sediment were calculated by the equilibrium partitioning method, the risk assessment for surface water and sediment will be equal. Thus, $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following tables.
The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater: PEC_{local_soil} has been calculated according to equation 69, chapter 2.3.7.5, Guidance on the BPR, Vol. IV, Part B+C (2017) and $PEC_{local\_groundwater}$ has been calculated according to equation 71, chapter 2.3.7.6, Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation.

The local PEC values for a.s. Benzoic acid of biocidal product “A-QUASAN B” from releases via STP are presented in the following table and are used for the environmental risk assessment:

Table 94: Summary table on calculated PEC values for a.s. Benzoic acid

	PEC_{STP}	$PEC_{surface\ water}$	PEC_{soil}	PEC_{GW}	PEC_{air}
	[mg/L]	[mg/L]	[mg/kg_{ww}]	[µg/L]	[mg/m^3]
Use 1	0.072	0.007	2.15E-04	0.064	---
Use 1 – RMM considered	0.131	0.013	3.90E-04	**0.116**	---
Use 2	0.049	0.005	1.46E-04	0.043	---
Use 3	0.872	0.087	0.003	**0.772**	---
Use 4	0.109	0.011	3.24E-04	0.096	---
Use 5/6/7	0.055	0.006	1.64E-04	0.049	---

The calculated results of $PEC_{groundwater}$ for a.s. Benzoic acid exceed the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 2006/118/EC and 98/83/EC) for Use 1 – RMM considered and Use 3. Therefore, the groundwater assessment is refined with the FOCUS PEARL 4.4.4 model for Use 3, since this refinement covers also Use 1 – RMM considered.

A refinement step, which leads to a more realistic estimation, is the use of a standard assessment tool to examine the potential mobility of Benzoic acid in soil and the leaching behaviour to groundwater. A scenario-based transport and fate simulation tool is provided by EU FOCUS models (e.g. PEARL model). Therefore, the higher tier $PEC_{groundwater}$ calculation was conducted with PEARL (v. 4.4.4). Calculations have been performed for all FOCUS scenarios by consideration of the following input parameters (TAB ENV 36):

- Nine representative locations within the EU
- Crop type: grass (alfalfa) as the grassland scenario
  maize as representative for agricultural scenarios,
- Uniform soil incorporation: grassland: incorporation depth of 0.10 m,
  agricultural land: incorporation depth of 0.20 m,
- Application dates and rates are shown in Table 95. The values are calculated by:

$$Application_{rate} = c_{sludge} * App_{sewage}$$

with c_{sludge} = 64.655 mg/kg
$App_{sewage\_agricultural}$ = 5000 kg/ha
App_{sewage_grass} = 1000 kg/ha

Table 95: Scenario parameter for PEARL

Input parameter for the model PEARL – scenario parameters			
Agricultural soil type	**Crop type**	**Application dates**	**Application rate [kg/ha]**
Grassland	grass/alfalfa	1st March	0.06466
Agricultural land	maize	20 d before crop emergence	0.32327

Table 96: Substance parameter for Benzoic acid

Input parameter for the model PEARL – substance parameters		
Parameters	**Unit**	**Benzoic acid**
Molar mass	$g \cdot mol^{-1}$	122.12
Saturated vapour pressure [at 20°C]	Pa	0.055
Solubility in water [at 20°C]	$mg \cdot L^{-1}$	5000
Koc	$L \cdot kg^{-1}$	157.04 (acid) 1.00 (base)
Kom	$L \cdot kg^{-1}$	91.09 (acid) 0.58 (base)
Half-life in soil [at 20°C]	d	0.57
Freundlich exponent	-	1
Plant uptake factor	-	0

Table 97: Summary of results

Summary results for agricultural land and grassland		
Location	**Benzoic acid** [µg/L]	
	Agricultural land	Grassland
CHATEAUDUN	0.000000	0.000000
HAMBURG	0.000000	0.000004
JOKIOINEN	-	0.000001
KREMSMUENSTER	0.000001	0.000000
OKEHAMPTON	0.000001	0.000021
PIACENZA	0.000000	0.000021
PORTO	0.000000	0.000000
SEVILLA	0.000000	0.000000
THIVA	0.000000	0.000000

The results of the $PEC_{groundwater}$ refinement with the simulation model FOCUS PEARL are summarised in Table 97. The average concentration of Benzoic acid closest to the 80th percentile at 1 m soil depth is below the trigger value of 0.1 µg/L (Directive 2006/118/EC; Annex 1) for all grassland and agricultural land scenarios.

Substances of Concern

As concluded in chapter 3.8.4.2 for the environmental risk assessment of the intended uses 1 and 3 of the b.p. “A-QUASAN B” the Propan-1-ol and Propan-2-ol distribution to air (90 %) and waste water (10 %) used during the active substance approval is maintained. For all other intended uses 100 % of Propanols is expected to be emitted to waste water.

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols used in small-scale applications, there is no need for a risk assessment of the subsequent environmental compartments following the release path via air (see TAB v.2.1, ENV-A5, 2019).

The uses 2 and 4 (disinfection of equipment by soaking - dipping in PT 3 and PT 4) and the uses 5, 6 and 7 (disinfection in closed systems: inner surfaces and surfaces in water systems) have no release pathway via air (see chapter 3.8.4.3). Whereas for the uses 1 and 3 (disinfection of hard surfaces - spraying in PT 3 and PT 4) main emissions occur via air but according to the modelled areas for application (see chapter 3.8.4.4) these scenarios do not comply to the definition of a small-scale application. However, it was concluded at 35th BPC-Meeting in the frame of an UA with Propan-1-ol as SoC that the TAB entry ENV-A5 (v2.1, 2019) also becomes applicable to large-scale applications. This TAB entry will be revised by the ECHA SECR. The eCA DE supports this decision and applies this also for this national authorisation of b.p. “A-QUASAN B”.

Besides this new conclusion, RefMS DE also analyses the provided applicant information of the likely tonnage to be placed on the market for the biocidal product “A-QUASAN B” (see chapter 5.3) which indicated that the presented emission calculations are worst case and overestimate seriously the real sold tonnage.

Hence, RefMS DE calculates the emissions based on worst case assumptions (see chapter 3.8.4.4) but considers only emissions along the pathway via waste water for both Substances of Concern.

Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the SoCs Propan-1-ol and Propan-2-ol due to application of biocidal product “A-QUASAN B” (see chapter 3.8.4.2 and Table 85).

As the distribution in sewage sludge for Propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant for several biocidal products containing Propan-2-ol as a.s. This was already equally considered for Propan-2-ol as SoC. Furthermore, as the distribution in sewage sludge for Propan-1-ol is also < 0.1 % the approach of no relevance to further environmental exposure assessment via sludge application on agricultural land should also be transferable to Propan-1-ol, since Propan-1-ol has very similar phys./chem. properties as

Propan-2-ol. Therefore, no PEC_{soil} and PEC_{GW} values for Propan-1-ol and Propan-2-ol following the sludge application were calculated for all uses.

Table 98: Summary table on calculated PEC values for SoC Propan-1-ol

	PEC_{STP}	**$PEC_{surface\ water}$**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	**[mg/L]**	**[mg/kg_{ww}]**	**[µg/L]**	**[mg/m^3]**
Use 1	0.031	0.003	---	---	0.002
Use 2	0.116	0.012	---	---	---
Use 3	0.207	0.021	---	---	0.013
Use 4	0.259	0.026	---	---	---
Use 5/6/7	0.131	0.013	---	---	---

Table 99: Summary table on calculated PEC values for SoC Propan-2-ol

	PEC_{STP}	**$PEC_{surface\ water}$**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	**[mg/L]**	**[mg/kg_{ww}]**	**[µg/L]**	**[mg/m^3]**
Use 1	0.012	0.002	---	---	0.001
Use 2	0.070	0.007	---	---	---
Use 3	0.124	0.012	---	---	0.008
Use 4	0.155	0.016	---	---	---
Use 5/6/7	0.078	0.008	---	---	---

3.8.4.6 Calculated PEC values for the emission pathway via slurry/manure application on agricultural land

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 27 and 29 of OECD ESD PT18 No. 14 (2006) to which ESD PT 3 (2011) refers and adapted to TAB ENV entry ENV 11 (v. 2.1, 2019);
- As the PNEC values for sediment were calculated by the equilibrium partitioning method, the risk assessment for surface water and sediment will be equal. Thus, $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following tables.

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{soil} according to equation 24 b and 25 b of the Recommendation of the AHEE, Addendum to OECD ESD No. 14 on which ESD PT 3 (2011) refers (BPC WG ENV V, 2015) considering recent decisions concerning the parameters $Tgr\text{-}int_{no\_manure}$ (365 d instead 206 d) and k_{leach} (according to eq. 55, Guidance on the BPR, Vol. IV, Part B+C (2017)) as well as the overall removal rate from top soil k (according to eq. 56, same Guidance).;

- $PEC_{groundwater}$ according to equation 26 and 28 of OECD ESD PT18 No. 14 (2006) on which ESD PT 3 (2011) refers and adapted to equation 37 of the Recommendation of the AHEE, Addendum to OECD ESD No. 14.

Phosphorous immission standards were not considered in the current assessment since they are unique in the Netherlands and therefore not applicable EU wide. At the technical meeting I/08 it was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1} \cdot yr^{-1}$ for all soils (arable land and grassland).

The local PEC values for biocidal product “A-QUASAN B” for the release pathway via slurry in use 7 are presented in the following table and are used for the environmental risk assessment:

Table 100: Summary table on calculated PEC for releases via slurry for use 7 for Benzoic acid

System: Nitrogen limited immission	Substance: Benzoic acid	$PEC_{surface\ water}$ [$mg.L^{-1}$]		PEC_{soil} [$mg.kg^{-1}$]		PEC_{GW} [$\mu g.L^{-1}$]	
animal housing		**arable land**	**grassland**	**arable land**	**grassland**	**arable land**	**grassland**
dairy cows		0.052	0.052	0.291	0.292	518	519.7
beef cattle		0.049	0.049	0.273	0.274	487.3	488.9
veal calves		0.921	0.924	5.169	5.187	9212	9242
sows in individual pens		0.187	0.188	1.05	1.054	1871	1878
sows in groups		0.187	0.188	1.05	1.054	1871	1878
fattening pigs		0.144	0.145	0.809	0.812	1442	1447
laying hens in battery cages without treatment		0.046	0.046	0.259	0.26	461.8	463.4
laying hens in battery cages with aeriation		0.046	0.046	0.259	0.26	461.8	463.4
laying hens in battery cages with forced drying		0.046	0.046	0.259	0.26	461.8	463.4
laying hens in compact battery cages		0.041	0.042	0.232	0.233	413.8	415.2
laying hens in free range with litter floor		0.103	0.103	0.576	0.578	1027	1030
broilers in free range with litter floor		0.056	0.056	0.316	0.317	562.6	564.5
laying hens in free range with grating floor		0.051	0.051	0.288	0.289	513.3	515
parent broilers in free range with grating floor		0.084	0.084	0.472	0.474	841.5	844.3
parent broilers in rearing with grating floor		0.142	0.143	0.799	0.802	1424	1428
turkeys in free range with grating floor		0.036	0.037	0.204	0.205	364.2	365.4
ducks in free range with grating floor		0.064	0.064	0.36	0.361	640.7	642.8
gees in free range with litter floor		0.036	0.037	0.204	0.205	364.2	365.4

The calculated results of $PEC_{groundwater}$ for a.s. Benzoic acid exceed the maximum permissible concentration in groundwater of 0.1 µg/L (generic trigger value for a.s. in biocides and their relevant metabolites, degradation and reaction products according to Council Directives 2006/118/EC and

98/83/EC). Therefore, the groundwater assessment for Benzoic acid is refined with the FOCUS PEARL 4.4.4 model for the worst case animal housing (veal calves).

A refinement step, which leads to a more realistic estimation, is the use of a standard assessment tool to examine the potential mobility of Benzoic acid in soil and the leaching behaviour to groundwater. A scenario-based transport and fate simulation tool is provided by EU FOCUS models (e.g. PEARL model). Therefore, the higher tier $PEC_{groundwater}$ calculation was conducted with PEARL (v. 4.4.4). Substance parameters for Benzoic acid can be found in Table 96. Calculations have been performed for all FOCUS scenarios by consideration of the following input parameters:

- Nine representative locations within the EU
- Crop type: grass (alfalfa) as the grassland scenario
  maize as representative for arable scenarios,
- Uniform soil incorporation: grassland: incorporation depth of 0.05 m,
  arable land: incorporation depth of 0.20 m,
- Application dates and rates are shown in Table 101. The values are calculated by:

$$Application_{rate} = PIEC \times RHO_{soil\text{-}wet} \times depth_{incorporation\_grs/ar}$$

with $RHO_{soil\text{-}wet}$ = 1700 kg/m³
$depth_{incorporation\_grs/ar}$ = 0.05 m and 0.20 m for grassland and arable land, respectively
and $PIEC_{soil}$ = 20.75 mg/kg for grassland and 5.17 mg/kg for arable land.

Table 101: Scenario parameters

Input parameter for the model PEARL – scenario parameters (manure application)			
Agricultural soil type	**Crop type**	**Application dates**	**Application rate [kg/ha]**
Grassland	grass/alfalfa	1st March, 23rd April, 15th June and 7th August	17.64 for each application
Arable land	maize	20 d before crop emergence	17.58

Table 102: Summary of results

Summary results for arable land and grassland		
Location	**Benzoic acid [**µg/L]	
	Arable land	Grassland

CHATEAUDUN	0.000000	0.000018
HAMBURG	0.000035	0.000961
JOKIOINEN	-	0.001104
KREMSMUENSTER	0.000068	0.001825
OKEHAMPTON	0.000000	0.004284
PIACENZA	0.000003	0.016748
PORTO	0.000000	0.000000
SEVILLA	0.000000	0.000000
THIVA	0.000000	0.000000

The results of the $PEC_{groundwater}$ refinement with the simulation model FOCUS PEARL for the worst case animal housing (veal calves) are summarised in Table 102. The average concentration of Benzoic acid closest to the 80th percentile at 1 m soil depth is below the trigger value of 0.1 µg/L (Directive 2006/118/EC; Annex 1) for all grassland and arable land scenarios.

In case of the SoCs Propan-1-ol and Propan-2-ol, a qualitative risk assessment is conducted:

The product “A-Quasan-B” is intended to be used as disinfectant for the use in veterinary health care and companion animal housing (PT3) and for use as disinfectant of hard surfaces in food and feed areas which service humans and animals (PT4).
The product contains the active ingredient Benzoic acid (9.09 % w/w a.s in b.p.) and the environmental SoCs Propan-1-ol and Propan-2-ol. According to the information on b.p. composition the content of Propan-1-ol in b.p. formulation is 21.7 % w/w and the content of Propan-2-ol is 13 % w/w. The maximum content of b.p. in the ready to use solution is 6 % (v/v).
The co-formulants Propan-1-ol and Propan-2-ol contained in the product A-QUASAN B, as active substances in other product types, fulfil a criterion for identification as substances of concern and have therefore to be assessed.
In the ARs for Propan-1-ol (2017) and Propan-2-ol (2015) for PTs 1, 2 and 4 is stated that the main emission pathway during surface applications is via air as Propan-1-ol and Propan-2-ol evaporate (within a short time) due to their vapour pressure. As a reasonable worst-case it is assumed in the ARs that 90 % of Propan-1-ol and Propan-2-ol are emitted to air and 10 % to waste water. This distribution is also used for surface applications in PT3. Therefore, the distribution of 90 % emission to air and 10 % emission to waste water is applied for the disinfection of hard surfaces in use 1 (PT3) and use 3 (PT4).

The uses 2 (PT3) and 4 (PT4) are dipping applications, all emissions are expected to be released to the environment via STP.
Similarly, in case of uses 5 and 6 (PT4) the only release pathway to the environment is to be assumed via STP, because the disinfection of inner surfaces in food processing facilities and in human drinking water systems is foreseen and the release pathway via air is neglected.

For use 7 (PT4) "Disinfectant of surfaces in veterinary water systems" the pipe system will be filled with the product solution and left to disinfect for the recommended exposure time. Afterwards the pipes are to be emptied of the solution and rinsed with tap water. The residual product solution can be released to the environment via STP or via manure/slurry application on agricultural land which results in subsequent exposure of the compartments soil, groundwater, surface water and sediment. For use 7 (PT4) the latter exposure pathway due to application of manure/slurry to agricultural land is evaluated qualitatively for the SoCs Propan-1-ol and Propan-2-ol for the following reasons. Thereby the arguments are presented in the order in which the Propanols are distributed in the various environmental compartments after application in the drinking water pipes:

- **Evaporation of Propanols:** The evaporation is facilitated by the relatively high vapour pressure. In the AR of Propan-2-ol as well as in several PARs it is stated, that nearly the whole amount of the SoC applied is released to indoor air, which is emitted to the local outside air without deposition indoors due to surface disinfection. However, releases to manure/slurry as well as sewer systems are likely for liquid products used for disinfection of inner surfaces in closed systems. Nevertheless, it is plausible that evaporation can still take place after the solution has left the pipe system and enters the manure storage tank and subsequently after manure/slurry application on agricultural areas. Additionally, manure/slurry will be stored, decanted and mixed; this stimulates additional evaporation processes. Furthermore, Propan-1-ol and Propan-2-ol is probably removed from soil surfaces by evaporation in a very short time due wind when soil is exposed with slurry/manure. Therefore, it is unlikely for Propan-1-ol or Propan-2-ol to reach the soil in depth and the groundwater.
- **Assumption of no degradation by default in manure**: Regarding the emission pathway assessed, the remaining amounts of Propan-2-ol and Propan-1-ol will be released to manure/slurry. Since no details about degradation behaviour in manure/slurry is available the exposure assessment assumes no degradation by default. However, this assumption is not realistic for a readily biodegradable substance. There are several references from the literature that investigate the anaerobic degradation of Propanols. The study of Bustard et al. (2000) deals with the aerobic degradation of Propan-1-ol or Propan-2-ol in inoculated minimal salt media. According to them Propan-1-ol tends to be degraded faster than Propan-2-ol. This faster biodegradation of Propan-1-ol compared to Propan-2-ol was also found under anaerobic conditions by Hongwei et al. (2004) using quantitative structure biodegradability relationship (QSBR). In general, Propan-2-ol first oxidizes to Acetone and molecular Hydrogen and then Acetone is fermented to Methane and Carbon dioxide. Although the study by Terzis (1994) does not provide specific information on how quickly Propan-2-ol degrades in sewage sludge under anaerobic conditions, it shows that anaerobic biodegradation is effective for the treatment of wastewater containing Propan-2-ol and Acetone. Furthermore, the study of Tonouchi (2004) investigates the anaerobic degradation of Propan-2-ol in anoxic rice soil and a methanogenic

bacterium using Propan-2-ol. The added Propan-2-ol was degraded under methane production in 20 days with temporary accumulation of acetone. The investigations of Demirer and Speece (1998) and additionally Chou et al. (1978), Chou et al. (1979), and Widdel (1986) show that Propan-1-ol was biotransformed to propionic acid under anaerobic conditions with an efficiency of more than 99 % at an influent concentration of 3000 mg COD/L in a single-stage UASB reactor (upflow anaerobic sludge blanket digestion) and did not show any significant inhibitory and/or toxic aspect. Chou et al. (1978) and Chou et al. (1979) were able to show that 56 % Propan-2-ol and 41 % Propan-1-ol were mineralised after 90 days of sludge acclimatisation at a rate of 200 and 110 mg/L/day, respectively. Furthermore, it is reported by Chou et al. (1978) that Propan-1-ol was degraded by acetate cultures within 4 days after cross acclimatisation (a microbial population acclimatised to a particular substrate is often exposed simultaneously to other substrates with a very similar structure). Widdel (1986) also reports that Propan-2-ol is oxidized to acetone. It can therefore be assumed that the degradation of Propanol's takes place significantly faster than the default assumption of no degradation.

- **Worst case standard values for degradation in soil:** In the AR on Propan-1-ol (2017) and in the AR on Propan-2-ol (2015) a DT50 of 30 days (12°C) in soil was assumed, which is the default for compounds that are readily biodegradable, because no data on degradation in soils was available. Further studies on biodegradability in soil, water/sediment or sewage treatment plant were not deemed to be necessary. However, several literature references exist which it may be expected that support the hypothesis that Propan-2-ol is rapidly degraded in soil and therefore the DT50 is expected to be more in the range of hours or a few days, rather than the default value of 30 days. The Handbook of Environmental Degradation Rates (Howard 1991) lists the following half-lives for Propan-2-ol in soil of 24 to 168 hours, resulting from scientific judgement based upon estimated unacclimated aerobic aqueous biodegradation half-life. Furthermore, Wagner (1974) investigated the aerobic degradation of several organic substances in domestic waste water, including Methanol and Propan-2-ol, by means of the respirometric dilution method. The results indicate data on the biomineralisation of Methanol in soil may be used to approximate the degradation in soil of Propan-2-ol. Scheunert et al. (1987) demonstrated that Methanol was readily biodegradable by the microorganisms present in soil, with 46.3 % - 53.4 % degradation after 5 days, based on CO_2 evolution. These data indicate that the half-life of Propan-2-ol in soil, whose degradation kinetics have been shown to be similar to those of Methanol, is most likely significantly shorter than the assumed default value of 30 days. These assumptions should also be transferable to Propan-1-ol, since Propan-1-ol has very similar phys./chem. properties as Propan-2-ol.

Taking these aspects into account, it can be concluded that under relevant field conditions no unacceptable risk for the soil compartment and the groundwater compartment with regard to the SoC Propan-1-ol or Propan-2-ol is expected.

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3.8.4.7 Atmosphere

Due to the intended uses of the b.p. and as already indicated in chapter 3.8.3 emissions to air for the a.s. Benzoic acid are not considered as relevant. Relevant emissions to air could be stated according to chapter 3.8.4.2 for the SoCs Propan-1-ol and Propan-2-ol for the uses 1 and 3 since the b.p. is there applied as surface disinfectant. For these uses PEC_{air} values are presented in chapter 3.8.4.5.

3.8.4.8 Non-compartment specific effects

- **<u>Primary poisoning</u>**

Primary poisoning is not relevant for this product, as its formulation type does not include baits.

- **Secondary poisoning**

As the active substance as well as both SoCs exhibit low bioaccumulation potential as described in chapter 3.8.3.4, assessment of secondary poisoning for the product is not necessary.

3.8.4.9 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

3.8.5 Risk characterisation

The environmental risk characterisation for biocidal active substances in the context of Annex VI of the Biocidal Products Regulation (Regulation (EU) No 528/2012) involves the comparison of PEC and PNEC values for each relevant environmental compartment. For this purpose, risk characterisation ratios (PEC/PNEC) are derived for the use of the product „A-QUASAN B“. If the PEC/PNEC ratio is equal or below 1, this is interpreted as an acceptable risk for the environment.

The PNEC values for Benzoic acid have been taken from the Assessment Report for the active substance, the values are summarised in chapter 3.8.2.5.

The PEC values for the assessment of PT 3 refer to the release pathway via STP which results in subsequent indirect exposure of the compartments water, sediment, soil and groundwater. The assumptions for the assessment in PT 3 are also valid for the assessment in PT 4 in cases where the environmental release pathway is via sewer and STP. However, for use 7 the assessments in PT 4 are extended by the release pathway via manure/slurry, which results in subsequent exposure of the compartments soil, groundwater, surface water and sediment.

3.8.5.1 Aquatic compartment

- **STP**

Table 103 Summary table on calculated PEC/PNEC for STP

Summary table on calculated PEC/PNEC values						
PT	**Use**	**Scenario**	**Benzoic acid**	**Propan-1-ol**	**Propan-2-ol**	**∑**
3	1	Hard surfaces – spraying	0.007	0.003	0.002	0.012
	1 – RMM considered	Hard surfaces – spraying	0.013	0.003	0.002	0.018

Summary table on calculated PEC/PNEC values						
PT	**Use**	**Scenario**	**Benzoic acid**	**Propan-1-ol**	**Propan-2-ol**	∑
	2	Equipment by soaking –dipping	0.005	0.012	0.007	0.024
4	3	Hard surfaces – spraying	0.087	0.021	0.012	0.120
	4	Equipment by soaking –dipping	0.011	0.026	0.016	0.052
	5	Inner surfaces without circulation	0.006	0.013	0.008	0.027
	6	Surfaces in human drinking water systems				
	7	Surfaces in veterinary water systems				

- **Surface water and sediment from releases via STP**

Table 104 Summary table on calculated PEC/PNEC for surface water

Summary table on calculated PEC/PNEC values						
PT	**Use**	**Scenario**	**Benzoic acid**	**Propan-1-ol**	**Propan-2-ol**	∑
3	1	Hard surfaces – spraying	0.003	0.001	7.44E-04	0.005
	1 – RMM considered	Hard surfaces – spraying	0.005	0.001	7.44E-04	0.007
	2	Equipment by soaking –dipping	0.002	0.005	0.003	0.009
4	3	Hard surfaces – spraying	0.035	0.008	0.005	0.048
	4	Equipment by soaking –dipping	0.004	0.010	0.006	0.021
	5	Inner surfaces without circulation	0.002	0.005	0.031	0.039
	6	Surfaces in human drinking water systems				
	7	Surfaces in veterinary water systems				

- **Surface water and sediment from releases via manure/slurry in Use 7**

Table 105 Summary table on calculated PEC/PNEC values for surface water from releases via manure/slurry in Use 7

System: Nitrogen limited immission	Substance: Benzoic acid	PEC surface water		PNEC surface water	PEC/PNEC surface water	
animal housing		arable land	grassland		arable land	grassland
		[mg.L^{-1}]		[mg.L^{-1}]	[mg.L^{-1}]	
dairy cows		0.052	0.052	2.5	0.021	0.021
beef cattle		0.049	0.049		0.020	0.020
veal calves		0.921	0.924		0.368	0.370
sows in individual pens		0.187	0.188		0.075	0.075
sows in groups		0.187	0.188		0.075	0.075
fattening pigs		0.144	0.145		0.058	0.058
laying hens in battery cages without treatment		0.046	0.046		0.018	0.018
laying hens in battery cages with aeriation		0.046	0.046		0.018	0.018
laying hens in bat. cages with forced drying		0.046	0.046		0.018	0.018
laying hens in compact battery cages		0.041	0.042		0.016	0.017
laying hens in free range with litter floor		0.103	0.103		0.041	0.041
broilers in free range with litter floor		0.056	0.056		0,022	0.022
laying hens in free range with grating floor		0.051	0.051		0.020	0.020
parent broilers in free range with grating floor		0.084	0.084		0.034	0.034
parent broilers in rearing with grating floor		0.142	0.143		0.057	0.057
turkeys in free range with grating floor		0.036	0.037		0.014	0.015
ducks in free range with grating floor		0.064	0.064		0.026	0.026
gees in free range with litter floor		0.036	0.037		0.014	0.015

Conclusion:

The requirements for acceptable risk according to the BPR guidance Vol IV part B + C (2017) are met for the product „A-QUASAN B“ for the environmental compartment STP as well as for the environmental compartment surface water (from releases via STP and in use 7 via the release via slurry and manure). According to the CAR for Benzoic acid PT3 and PT4 (2013) the risk of Benzoic acid to the sediment is the same as that described for surface water, because $PNEC_{sediment}$ was derived from the $PNEC_{water}$ using the equilibrium partitioning method.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

- **Soil (emissions via STP)**

Table 106 Summary table on calculated PEC/PNEC values for soil

Summary table on calculated PEC/PNEC values[13] for the active substance benzoic acid			
PT	**Use**	**Scenario (for professional use and indoor)**	**PEC/PNEC$_{soil}$**
3	1	Hard surfaces –spraying	1.43E-04
	1 – RMM considered	Hard surfaces –spraying	2.60E-04
	2	Equipment by soaking –dipping	9.73E-05
4	3	Hard surfaces – prof. user – spraying	1.73E-03
	4	Equipment by soaking –dipping	2.16E-04
	5	Inner surfaces without circulation	1.10E-04
	6	Surfaces in **human** drinking water systems	1.10E-04
	7 **via STP**	Surfaces in **veterinary** water systems	1.10E-04

- **Soil (emissions via manure/slurry in use 7)**

Table 107 Summary table on calculated PEC/PNEC values for soil due to manure/slurry application in use 7

System Nitrogen limited immission	**Substance** Benzoic acid	**PEC$_{soil}$ [mg.kg^{-1}]**		**PNEC$_{soil}$ [mg.kg^{-1}]**	**PEC/PNEC$_{soil}$**	
animal housing		**arable land**	**grassland**		**arable land**	**grassland**
dairy cows		0.291	0.292	1.5	0.194	0.195
beef cattle		0.273	0.274		0.182	0.183
veal calves		5.169	5.187		**3.446**	**3.458**
sows in individual pens		1.05	1.054		0.700	0.703
sows in groups		1.05	1.054		0.700	0.703
fattening pigs		0.809	0.812		0.539	0.541
laying hens in battery cages without treatment		0.259	0.260		0.173	0.173
laying hens in battery cages with aeriation		0.259	0.260		0.173	0.173
laying hens in bat. cages with forced drying		0.259	0.26		0.173	0.173
laying hens in compact battery cages		0.232	0.233		0.155	0.155

laying hens in free range with litter floor	0.576	0.578		0.384	0.385
broilers in free range with litter floor	0.316	0.317		0.211	0.211
laying hens in free range with grating floor	0.288	0.289		0.192	0.193
parent broilers in free range with grating floor	0.472	0.474		0.315	0.316
parent broilers inrearing with grating floor	0.799	0.802		0.533	0.535
turkeys in free range with grating floor	0.204	0.205		0.136	0.137
ducks in free range with grating floor	0.36	0.361		0.240	0.241
gees in free range with litter floor	0.204	0.205		0.136	0.137

Conclusion:

The requirements for acceptable risk according to the BPR guidance Vol IV part B + C (2017) are met for the product „A-QUASAN B“ for the environmental compartment soil from releases via STP (Table 105).

Propan-1-ol and Propan-2-ol: As the distribution in sewage sludge for the SoCs Propan-1-ol and Propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant. Therefore, a sum of PEC/PNEC ratios for Propan-1-ol and Propan-2-ol and the active substance Benzoic acid compounds is not considered. For detailed discussion please refer to chapter 3.8.3 and 3.8.4.5. For use 7 (PT4) the exposure pathway due to application of manure/slurry to agricultural land is evaluated qualitatively for the SoCs Propan-1-ol and Propan-2-ol for the reasons stated in chapter 3.8.4. It can be concluded that under relevant field conditions no unacceptable risk for the soil compartment and the groundwater compartment with regard to the SoC Propan-1-ol or Propan-2-ol is expected.

Benzoic acid: Based on standard calculations applying the ESD for PT 3 (JCR, 2011) in which no degradation of the active substances during manure/slurry storage is considered (chapter 2.1.4.1), application of the product once per week would be acceptable in all of the animal categories except for „veal calves” due to unacceptable PEC/PNEC values for soil.

Overall, we do not consider the default worse case values appropriate for the active substance Benzoic acid and take the following arguments into consideration in order to show that a weekly application of “A-QUASAN B” is acceptable in all of the animal categories. It has to be acknowledged that there is no direct application of the product “A-QUASAN B” to the environmental compartment soil, but used product is disposed of in the local manure/slurry storage tank and later applied to agricultural land (for further details please refer to chapter 3.8.4.4. Local emission estimation for relevant environmental compartments). Therefore, as the active substance is readily biodegradable within the 10-day window (AR, 2013), possibly degradation of the active substance can take place in the steps before the application to soil (e.g., during the disinfection, storage of the manure/slurry, application of the manure/slurry to land). For details see the following discussion:

- The product is used for the purpose of the protection of human and animal health by cleaning and disinfection to control pathogens in drinking water pipes. The assumption of the full residual presence by default in the pipe system after the disinfection (as default for CIP applications, ESD PT4, JCR 2011) is unfounded for Benzoic acid.
- The mode of action of Benzoic acid is non-selective and is based on the following mechanisms (for further details please refer to AR (2013) in PT3 and PT4): At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the benzoic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. Therefore, it can be assumed, that due to penetration into microorganisms the concentration of Benzoic acid will decline during the disinfection process of drinking water pipes for drinking water of animals.
- Manure is typically stored for a certain time period before being spread on fields. The application is not allowed at all times during the year, and is considered to take place one to several times a year depending on the type of land (ESD PT3, JCR, 2011). No degradation of the active substance during manure/slurry storage is considered in the standard calculations based on the ESD PT3 by default (chapter 2.1.4.1). However, the time spans between residual b.p. releases to manure/slurry and manure/slurry application to agricultural land most probably promote declining concentrations of Benzoic acid in manure/slurry. According to the AR for Benzoic acid (AR, 2013) complete anaerobic biodegradation can be assumed for Benzoic acid. An anaerobic biodegradation test was submitted by the applicant as a product type specific (PT 3) data requirement caused by releases of Benzoic acid into manure storage facilities. The result shows that more than 75% of theoretical gas production is achieved within 60 days of incubation, which means that complete anaerobic biodegradation can be assumed for Benzoic acid.
- Benzoic acid is also used extensively as additive in food and feeding stuff for preservation or as antioxidants (Zusatzstoff- Zulassungsverordnung – ZzulV, Annex V). Moreover, Benzoic acid is a natural substance in plants (fruits, nuts, spices and vegetable). In consequence, it is also naturally occurring in soil where it can be readily biodegraded. From the literature it is known that Benzoic acid is rapidly biodegraded under aerobic and anaerobic conditions in soil: In Verschueren (2009) biodegradation half live of Benzoic acid in non-adapted aerobic subsoil (loam and sand) is reported to be 0.30 days under test conditions (20°C), biodegradation half live converted to an average EU outdoor temperature of 12°C is 0.57 days. This study is used as key study to calculate the PEC in soil and groundwater. Furthermore, Verschueren (2009) refers to a publication of Alexander and Lustigman (1966) in which Benzoic acid was shown to be completely degraded within one day by a soil microflora. For further details concerning biodegradation please refer to chapter -3.8.3.1 Biodegradation- and the information presented in the AR (2013).

Consequently, we assume that a weekly application of "A-QUASAN B" is acceptable in all of the animal categories for the active substance Benzoic acid and unacceptable risk to soil following use 7 as a disinfectant is not expected.

References

- Verschueren, K. (2009). Handbook of Environmental Data on Organic Chemicals. 5th ed., Wiley & Sons, Vol 1, 382-386, Vol 4, 4157. Not GLP, published.
- Alexander, M., Lustigman B.K. (1966). Effect of chemical structure on microbial degradation of substituted benzenes. J. Agr. Food Chem., 14, 410-413.

- **Groundwater**

For the active substance Benzoic acid $PEC_{groundwater}$ values are calculated below the quality standard of 0.1 µg/L for plant protection products and biocidal products according to Directive 98/83/EG and Council Directives 2006/118/EC after refinement with FOCUS PEARL 4.4.4 model. For further details please refer to chapter 3.8.4.5.

3.8.5.3 Atmosphere

Due to the intended uses of the b.p. and on basis of the available substance information for a.s. and for both SoCs the environmental risk for the atmosphere can be assumed as low.

3.8.5.4 Non-compartment specific

Primary poisoning and secondary poisoning

As indicated in chapter 3.8.4.8, primary and secondary poisoning is not relevant for this product.
A concern for a bioaccumulation potential of a chemical exists when a substance has a log Kow > 3, is highly adsorptive or belongs to a structural class of substances that is known to bioaccumulate and no mitigations regarding its degradation properties exist. None of these points apply to Benzoic acid.

3.8.5.5 PBT assessment

The active substance Benzoic acid, as well as the SoC Propan-1-ol and Propan-2 -ol are neither PBT – no vP /vB- candidate. For further details please refer to respective CARs and AR stated in chapter 3.8.2.

3.8.5.6 Endocrine disrupting properties

Benzoic acid is not identified as an ED substance in wildlife. (CAR 2013). The full composition of the product as well as the results of the ED-assessment of the co-formulants are summarised in the

Confidential Part of this document. Based on available data, none of the co-formulants present in the product “A-QUASAN B”, is identified as an Endocrine disruptor.

3.8.5.7 Summary of risk characterisation

Table 108 : Summary table on calculated PEC/PNEC values for the active substance and SoC

Summary table on calculated PEC/PNEC values for the active substance and SoC			
	PEC/ $PNEC_{STP}$	**PEC/PNEC water & sediment**	**PEC/ $PNEC_{soil}$**
PT3 - Use1	0.012	0.005	1.43E-04
PT3 - Use 1 – RMM considered	0.018	0.007	2.60E-04
PT3 - Use 2	0.024	0.009	9.73E-05
PT4 - Use 3	0.120	0.048	1.73E-03
PT4 - Use 4	0.052	0.021	2.16E-04
PT4 - Use 5	0.027	0.039	1.10E-04
PT4 - Use 6			
PT4 - Use 7 via STP			
PT4 - Use 7 via Manure/slurry (grassland)	-/-		
dairy cows		0.021	0.195
beef cattle		0.020	0.183
veal calves		0.370	**3.458**
sows in individual pens		0.075	0.703
sows in groups		0.075	0.703
fattening pigs		0.058	0.541
laying hens in battery cages without treatment		0.018	0.173
laying hens in battery cages with aeriation		0.018	0.173
laying hens in battery cages with forced drying		0.018	0.173
laying hens in compact battery cages		0.017	0.155
laying hens in free range with litter floor		0.041	0.385
broilers in free range with litter floor		0.022	0.211
laying hens in free range with grating floor		0.020	0.193
parent broilers in free range with grating floor		0.034	0.316
parent broilers in rearing with grating floor		0.057	0.535
turkeys in free range with grating floor		0.015	0.137
ducks in free range with grating floor		0.026	0.241
gees in free range with litter floor		0.015	0.137

No unacceptable risks for the environment are to be expected by the use of the biocidal product “A-QUASAN B”. We assume that a weekly application of “A-QUASAN B” is acceptable in all of the animal categories for the active substance Benzoic acid and unacceptable risk to soil following as a disinfectant is not expected.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.4), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Table 109

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Report no.	Author(s)	Year	Owner company
	3.1.1. Physical state (at 20 °C and 101,3 kPa)	Description of the physical state, colour and odour of MENNO Florades		Kellner, G.	2007	MENNO CHEMIE-VERTRIEB GMBH
	3.1.1. Physical state (at 20 °C and 101,3 kPa)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.1.2. Colour (at 20 °C and 101,3 kPa)	Description of the physical state, colour and odour of MENNO Florades		Kellner, G.	2007	MENNO CHEMIE-VERTRIEB GMBH
	3.1.2. Colour (at 20 °C and 101,3 kPa)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.1.3. Odour (at 20 °C and 101,3 kPa)	Description of the physical state, colour and odour of MENNO Florades		Kellner, G.	2007	MENNO CHEMIE-VERTRIEB GMBH

	3.1.3. Odour (at 20 °C and 101,3 kPa)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	Determination of the Acidity or Alkalinity of MENNO Florades	43961349	Fieseler, A.	2008	MENNO CHEMIE-VERTRIEB GMBH
	3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.3. Relative density (liquids) and bulk, tap density (solids)	Determination of the Relative Density of MENNO Florades	43962182	Fieseler, A.	2008	MENNO CHEMIE-VERTRIEB GMBH
	3.3. Relative density (liquids) and bulk, tap density (solids)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.4.1.1. Accelerated storage test	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH

	3.4.1.2. Long term storage test at ambient temperature	Shelf Life Following Storage at Ambient Temperature over 65 resp. 68 Months with MENNO Florades	CC05D04	Kellner, G.	2005	MENNO CHEMIE-VERTRIEB GMBH
	3.4.1.3. Low temperature stability test (liquids)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.4.2.2. Temperature and humidity	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.4.2.3. Reactivity towards container material	Shelf Life Following Storage at Ambient Termperature over 65 resp. 68 Months with MENNO Florades	CC05D04	Kellner, G.	2005	MENNO CHEMIE-VERTRIEB GMBH
	3.5.7. Persistent foaming	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.5.7. Persistent foaming	Determination of physico-chemical Properties for A-QUASAN	Mo6532	Manka, S.	2019	MENNO CHEMIE-VERTRIEB GMBH
	3.7. Degree of dissolution and dilution stability	Determination of physico-chemical Properties for A-QUASAN	Mo6532	Manka, S.	2019	MENNO CHEMIE-VERTRIEB GMBH
	3.7. Degree of dissolution and dilution stability	Determination of physico-chemical Properties for A-QUASAN	Mo6532	Manka, S.	2019	MENNO CHEMIE-VERTRIEB GMBH

	3.8. Surface tension	Determination of the Surface Tension of MENNO Florades in Aqueous Solution	IF-100/22588-00	Schulz, H.	2000	MENNO CHEMIE-VERTRIEB GMBH
	3.8. Surface tension	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	3.9. Viscosity	Determination of the Viscosity of MENNO Florades	43963196	Fieseler, A.	2008	MENNO CHEMIE-VERTRIEB GMBH
	3.9. Viscosity	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	4.6. Flammable liquids	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH
	4.17.1. Auto-ignition temperatures of products (liquids and gases)	Determination of the Auto-Ignition Temperature (Liquids and Gases) of MENNO Florades according to EC Council Directive 92/69/EEC, Part A.15	200.4048.AFG	Angly, H.	2000	MENNO CHEMIE-VERTRIEB GMBH
	4.17.1. Auto-ignition temperatures of products (liquids and gases)	MENNO FLORADES Physical Chemical Properties & Storage Stability 8 weeks at 40°C, 7 days at 0°C	SSL03114	Bockholt, K.	2015	MENNO CHEMIE-VERTRIEB GMBH

	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of an Analytical Method for the Determination of Benzoic Acid in Formulation	43964101	Meinerling, M., Mollandin, G.	2008	MENNO CHEMIE-VERTRIEB GMBH
	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	The analysis of formic acid in feed		n.a.	n.a.	
	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	CRL Evaluation Report on the Analytical Methods submitted in connection with the Application for the Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003		Jaroslava, P., Molteni, R., Robouch, P., Simone, G.	2010	
	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Method 1671, Revision A: Volatile Organic Compounds Specific to the Pharmaceutical Manufacturing Industry by GC/FID		n.a.	1998	
	5.2.2. Air	Benzoic acid: Residue analytical method for the determination in air	140127DH/CRA15572	Buttler, O.	2014	MENNO CHEMIE-VERTRIEB GMBH

	5.2.2. Air	FORMIC ACID - NIOSH Manual of Analytical Methods (NMAM), Fourth Edition, 8/15/94		n.a.	1994	
	5.2.2. Air	Ethylene glycol - Method no. PV2024	T-PV2024-01-9902-CH	Potter, W.	1999	
	5.2.2. Air	GLYCOLS - NOSH Manual of Analytical Methods (NMAM), Fourth Edition		n.a.	1996	
	5.2.2. Air	Glycols - Method for the determination of diethylene glycol, ethylene glycol and propylene glycol in workplace air using gas chromatography		Giesen, Y., Friedrich, C, Breuer, D., Fauss, J., Hebisch, R., Brock, T. H., Hartwig, A., MAK Commission	2018	
	5.2.3. Water (including drinking water) and sediment	Benzoic acid (test item: Benzoic-1-13C acid) - Residue analytical method for the determination in groundwater	140602DH/CRA16162	Buttler, O.	2014	MENNO CHEMIE-VERTRIEB GMBH
	5.2.4. Animal and human body fluids and tissues	Benzoic acid - Residue Analytical Method for the Determination in Liver and Blood	150126DO/CRA15572	Buttler, O.	2017	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1656: 2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1656: 2009 (AC:2010) 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1656: 2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1656: 2009 (AC:2010) 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1656: 2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1656: 2009 (AC:2010) 20°C + membrane filtration	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1657:2005/AC:2007 modified* Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1) A-QUASAN	D70-2014 EN 1657: 2005 / AC:2007 fungicidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1657:2005/AC:2007 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1657: 2005 / AC:2007 yeasticidal 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1657:2005/AC:2007 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1657: 2005 / AC:2007 yeasticidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1657:2005/AC:2007 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1, obligatory and additional conditions) A-QUASAN	D70-2014 EN 1657: 2005 / AC:2007 yeasticidal 20°C + membrane filtration	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 14349:2012 Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action (phase 2 step 2)	D70-2014 EN 14349: 2012 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 14349:2012 Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action (phase 2 step 2)	D70-2014 EN 14349: 2012 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 16438:2014 Quantitative surface test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action (phase 2 step 2)	D70-2014 EN 16438:2014 yeasticidal 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 16438:2014 Quantitative surface test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action (phase 2 step 2)	D70-2014 EN 16438:2014 yeasticidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1276:2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (phase 2 step 1) A-QUASAN	D70-2014 EN 1276:2009 (AC:2010) 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1276:2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (phase 2 step 1) A-QUASAN	D70-2014 EN 1276:2009 (AC:2010) 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1276:2009 (AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (phase 2 step 1) A-QUASAN	D70-2014 EN 1276:2009 (AC:2010) 20°C + membrane filtration	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1650:2008+A1:2013 Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1) A-QUASAN	D70-2014 EN 1650:2008+A1:2013 fungicidal 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1650:2008+A1:2013 Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1) A-QUASAN	D70-2014 EN 1650:2008+A1:2013 fungicidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1650:2008+A1:2013 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1) A-QUASAN	D70-2014 EN 1650:2008+A1:2013 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1650:2008+A1:2013 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1) A-QUASAN	D70-2014 EN 1650:2008+A1:2013 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 1650:2008+A1:2013 Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1) A-QUASAN	D70-2014 EN 1650:2008+A1:2013 fungicidal 20°C + membrane filtration	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	EN 13697:2001 mod.* Quantitative non-porous surface test for the evaluation of bactericidal, yeasticidal and/or fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase2 step2)A-QUASAN	D70-2014 EN 13697:2001 modified 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 2) A-QUASAN	D70-2014 EN 13697:2001 modified bactericidal 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 2) A-QUASAN	D70-2014 EN 13697:2001 bactericidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 2) A-QUASAN	D70-2014 EN 13697:2001 modified fungicidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 2) A-QUASAN	D70-2014 EN 13697:2001 modified yeasticidal 10°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 2) A-QUASAN	D70-2014 EN 13697:2001 yeasticidal 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Ausflockung_Kontrolluntersuchungen_28.04.2020		Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Gegenüberstellung der Prüfergebnisse von A-QUASAN - A-QUASAN ohne Benzoesäure - Ameisensäure		Hunsinger, B.	2016	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test Report EN13697:2001 modified*Quantitative non-porpus surface test for the evaluation of bactericidal,yeasticidal and/or fungicidal activity of chemical disinfectants and antispetics used in food, industrial,domestic and institutional areas A-QUASAN	D70a-2014 EN13697:2001 modified 20°C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 14349:2012 Quantitative surface test for the evaluation of bactericidal activity of chemical disinfetants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action A-QUASAN	D70a-2014 EN14349:2012 10 °C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 16438:2014 Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action A-QUASAN	D70a-2014 EN16438:2014 yeasticidal 10 °C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Prüfbericht EN 13697:2015 Quantitativer Oberflächenversuch nicht-poröser Oberflächen zur Bestimmung der bakteriziden und/oder fungiziden Wirkung von chemischen Desinfektionsmitteln und Antiseptika	D99-2016 EN13697:2015	Hunsinger, B.	2016	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Prüfbericht EN 14349:2012 Quantitativer Oberflächenversuch zur Bestimmung der bakteriziden Wirkung von chemischen Desinfektionsmitteln und Antispetika für den Vetrinärbereich auf nicht-porösen Oberflächen ohne mechanische Wirkung	D99-2016 EN14349:2012 10 °C	Hunsinger, B.	2016	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Prüfbericht EN 16438:2014 Quantitativer Oberflächenversuch zur Bestimmung der fungiziden oder levuroziden Wirkung chemischer Desinfektionsmittel und Antiseptika für den Veterinärbereich auf nicht-porösen Oberflächen ohne mechanische Wirkung	D99-2016 EN16438:2014 10°	Hunsinger, B.	2016	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13697:2001 modified* Quantitative non-porous surface test for the evaluation of bactericidal, yeasticidal and/or fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas	D74-2014 EN13697:2001 modified 20 °C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 14349 Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action	D74-2014 EN 14349:2012 10°C	Hunsinger, B.	2016	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 16438:2014 Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action	D74-2014 EN16438:2014 yeasticidal 10 °C	Hunsinger, B.	2015	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Comparison results of CONTROL B determined according EN 1656 versus EN 13727 QUANTITATIVE SUSPENSION TEST for the evaluation of BACTERICIDAL ACTIVITY of chemical disinfectants and antiseptics (phase 2 step 1)	D201-2020 Control B according EN1656 versus EN137272	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH

	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Test report EN 13727:2012+A2:2015 Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2 step 1)	D201-2020 EN 13727:2012+A2:2015 20°C / 0,3 g/l BSA	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT EN 1657:2016 QUANTITATIVE SUSPENSION TEST for the evaluation of FUNGICIDAL or YEASTICIDAL ACTIVITY of chemical disinfectants and antiseptics used in the veterinary area (phase 2 step 1)	D201-2020 EN 1657:2016 10°C / 3 g/l BSA / 60 min yeasticidal	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH
	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	TEST REPORT EN 1650:2019 QUANTITATIVE SUSPENSION TEST for the evaluation of FUNGICIDAL or YEASTICIDAL ACTIVITY of chemical disinfectants and antiseptics and antiseptics used in food, industrial, domestic and institutional areas (phase 2 step 1)	D201-2020 EN 1650:2019 20°C / 0,3g/l BSA / 60 min fungicidal	Hunsinger, B.	2020	MENNO CHEMIE-VERTRIEB GMBH

	8.1. Skin corrosion or skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity- Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)	Acute dermal irritation/corrosion test of “MENNO FLORADES“ in rabbits	10-03-0862/00-94	Anonymous[14]	1994	MENNO CHEMIE-VERTRIEB GMBH
	8.2. Eye irritation (1) The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008) (1) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.	Acute eye irritation/corrosion test of “MENNO FLORADES“ in rabbits	10-03-0861/00-94	Anonymus[14]	1994	MENNO CHEMIE-VERTRIEB GMBH

[14] Study with vertebrates. Please, refer to IUCLID file for the name of the author(s).

	8.3. Skin sensitisationThe assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided	Maximisation sensitisation test according to Magnusson & Kligman of "VP-FL/5" (commercial name MENNO Florades) in the Guinea pig	10-5-0202-02	Anonymous[14]	2003	MENNO CHEMIE-VERTRIEB GMBH
	8.5.1. By oral route	Acute oral toxicity test of “MENNO FLORADES“ in rats	10-04-0859/00-94	Anonymous[14]	1994	MENNO CHEMIE-VERTRIEB GMBH
	8.5.3. By dermal route	Acute dermal toxicity test of “MENNO FLORADES“ in rats	10-04-0860/00-94	Anonymous[14]	1994	MENNO CHEMIE-VERTRIEB GMBH
	8.8. Food and feedingstuffs studies	Safety and efficacy of benzoic acid as a technological feed additive for weaned piglets and pigs for fattening		EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) et al.	2019	

	8.8. Food and feedingstuffs studies	Scientific Opinion on the safety and efficacy of formic acid when used as a technological additive for all animal species		EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)	2014	
	8.8. Food and feedingstuffs studies	Scientific Opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as feed hygiene agents for all animal species		EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)	2015	

4.2 List of studies for the active substance(s)

4.2.1 Benzoic acid

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[15]) of the active substance Benzoic acid for use in veterinary hygiene (product-type 3) and food and feed area (product-type 4). Please, refer to the corresponding Assessment Report for a reference list.

15 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Output tables from exposure assessment tools

Output tables from <u>human health</u> exposure assessment tools

4.3.1 Safety for professional users

OutputTablesHHExpoAssessmentTools.

5 Confidential annex (Access level: “Restricted” to applicant and authority)

6 Confidential annex – MS only (Access level: “Restricted - Authority”)