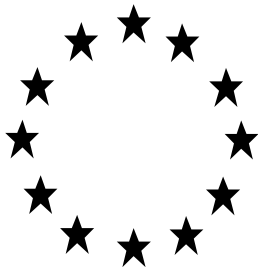
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Antisept A
Product type(s):	1,2,4
Active ingredient(s):	Propan-2-ol
Case No. in R4BP	BC-VC025442-50
Asset No. in R4BP	DE-0016013-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/02.00003 710-05-02-00003-00-00-00-0000
Date	03.02.2021

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product Antisept A with the active substance Propan-2-ol (64.00% w/w) is used in human hygiene (product-type 01), as a disinfectant not intended for direct application to humans and animals (product-type 02) and used in the food and feed area (product-type 04) for

- hand disinfection by professional and non-professional users.
- small surface disinfection by professional users.
- small surface disinfection in the food and feed area by professional users.

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.

According to Regulation (EC) No 1272/2008[2] the product is classified as Flam. Liq. 2, Eye Irrit. 2 and STOT SE 3. 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:

- The conclusions and recommendations of the German Assessment Report for the approval of the active substance Propan-2-ol including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.

Approval of the active substance

The active substance Propan-2-ol is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

[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.

- Product-type 01 and 02: 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.
- Product-type 04: 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.

  For biocidal products, authorisations are subject to the following conditions:

  1) 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[3] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded;
  2) Biocidal products containing propan-2-ol 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 propan-2-ol into food or it has been established pursuant to that Regulation that such limits are not necessary.

Composition and formulation

The ready-to-use solution Antisept A contains the active substance Propan-2-ol.

No substance of concern has been identified.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 3.8.8.6).

Please refer to chapter 2.2 (Composition and formulation) and **Fehler! Verweisquelle konnte nicht gefunden werden.** (Full composition of the product) for detailed 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).

[3] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

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

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.

A human health risk assessment has been carried out for non-professional and professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional and professional users, bystanders and residents. Regarding non-professional and 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.

Please note that the risk assessment for human health has been carried out with a slightly higher concentration of Propan-2-ol (64.73% w/w) due to differences in conversion methods from “% v/v” to “% w/w” during the determination of the product identity. Using the harmonised conversion method from BPC 29, the correct concentration of Propan-2-ol in the assessed product Antisept A is 64.0% w/w. However, this has no influence on the conclusive statements in chapters 3.6.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.

A risk assessment for the environment has been carried out for non-professional and 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.

Endocrine disrupting properties

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance. Additionally, there is no indication for endocrine disrupting properties of the co-formulants of the biocidal product.

In summary, there is no indication for endocrine disrupting properties of the biocidal product.

Comparative Assessment

Since the active substance propan-2ol has not been identified as a candidate for substitution a comparative assessment was not necessary.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Antisept A

2.1.2 Manufacturer(s) of the product

Name of manufacturer	CG Chemikalien GmbH & Co. KG
Address of manufacturer	Ulmer Strasse 1, DE-30880 Laatzen, Germany
Location of manufacturing sites	Ulmer Strasse 1, DE-30880 Laatzen, Germany

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

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601, 3196 KK Rotterdam, The Netherlands
Location of manufacturing sites	Vondelingenweg 601, 3196 KK Rotterdam, The Netherlands

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 (%)
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	64% w/w[5]

- Information on the full composition is provided in the confidential[6] 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 ☒ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-0014121-0000)

2.2.3 Information on the substance(s) of concern

No substance of concern was identified.

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5 This is equal to a value of 70,0 %v/v. This is based on following calculation on the density of the product and the propanol density (d_4^{20} = 0.7850): X % (m/m) = 700 ml * (density (pure propanol)) / 1000 ml * (density (product)). Please be aware of the fact that volume contradiction has to be taken into account.

6 Access level: "Restricted" to applicant and authority

2.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.5 Type of formulation

Liquid (ready to use)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[7]

Besides the active substance propan-2-ol, other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance propan-2-ol (CAS-No 67-63-0) is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Based on the data submitted from the applicant for a 3rd party dossier labelling with EUH066 (Repeated exposure may cause skin dryness or cracking) is required. Local skin effects and reactions have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

7 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.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Eye Irrit. 2	H319	
STOT SE 3	H336	
Flam. Liq. 2	H225	
Labelling	**Code**	**Pictogram / Wording**
	GHS07	
	GHS02	
Signal word	-	Danger
Hazard statements	H319	Causes serious eye irritation
	H336	May cause drowsiness or dizziness
	H225	Highly flammable liquid and vapour.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
Supplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P235	Keep cool.
	P261	Avoid breathing dust/fume/gas/vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	(P280)	(Wear eye protection/face protection.)
	P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position 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.
	P312	Call a POISON CENTER or doctor/ physician if you feel unwell.
	P337 + P313	If eye irritation persists: Get medical advice/attention
	P370 + P378	In case of fire: Use alcohol-resistant foam to extinguish.
	P403 + P233	Store in a well ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to…
Note	-	-

In fact H319 would trigger P280 (Wear eye protection/face protection.). However, for non-professional use correct application of personal protective equipment cannot be assumed. Based on a qualitative risk assessment an additional advice (labelling) with “Avoid contact with eyes” and the other precautionary statements P305 + P351 + P338 and P337 + P313 are considered sufficient to protect the non-professional user from the corresponding risk. H319 also trigger P264 (Wash … thoroughly after handling.). This precautionary is also not required since the biocidal product is also intended for use on hands and other body parts. If it is washed away efficacy might not be sufficient. In addition, propan-2-ol is very volatile and will evaporate from contaminated skin rapidly. Thus, washing of hands or other body parts is not necessary.
H336 would trigger P304 + P340 (IF INHALED: Remove person to fresh air and keep comfortable for breathing.). According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation of the biocidal product this precautionary statement is not required for the non-professional user.
According to Article 35 Regulation (EC) No 1272/2008 the packaging – which is supplied to the general public and contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II - shall bear a **tactile warning of danger**.
For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM) as well as categories of users to which the use is restricted, please refer to chapter 2.4 and 2.5.

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[8]

2.4.1 Use 1 appropriate for authorisation – hand disinfection (professional user)

Product Type(s)	1
Where relevant, an exact description of the use	Ready to use disinfectant for the hygienic and surgical handrub disinfection.

8 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.

Target organism(s) (including development stage)	bacteria; yeasts; enveloped viruses (only for hygienic hand disinfection)
Field(s) of use	Indoor
Application method(s)	**Hygienic/surgical hand disinfection:** The ready to use solution is poured into the palms of one hand out of an automatic dispenser. The application should be performed according to EN 1500 (hygienic handrub) and EN 12791 (surgical handrub). Hands have to be kept sufficiently wet and have to be rubbed firmly and carefully for the required contact time. While performing surgical handrub hands have to be kept above ellbows. Only use on visibly clean skin. **Hygienic hand disinfection:** Contact time for bacteria, yeasts and enveloped viruses: at least 0.5 minutes **Surgical hand disinfection** (without long term effect according to EN 12791): Contact time for bacteria, yeasts: at least 1.5 minutes
Application rate(s) and frequency	hygienic hand disinfection : 4 mL, 25 hand rubs/day surgical hand disinfection: 20 mL, 4 rubs/day
Category(ies) of users	Professional user
Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

2.4.1.1 Use-specific instructions for use

1. Keep skin sufficiently wet over the whole contact time.
2. Only use on visibly clean skin.

2.4.1.2 Use-specific risk mitigation measures

1. For refilling, a funnel must be applied.
2. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:

   For refilling procedure, the use of eye protection during handling of the product is recommended.

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 and precautionary statements in chapter 2.3

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

See chapter 2.5

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

2.4.2 Use 2 appropriate for authorisation – hand disinfection (non-professional user)

Product Type(s)	1
Where relevant, an exact description of the use	Ready to use disinfectant for the hygienic handrub disinfection.
Target organism(s) (including development stage)	bacteria; yeasts; enveloped viruses
Field(s) of use	Indoor Non-professional users will apply alcohol-based hand rubs only occasionally for hygienic reasons when entering/leaving hospitals or for hygiene reasons at home.
Application method(s)	Hygienic hand disinfection Hands have to be rubbed firmly and carefully for at least 30 seconds. It has to be ensured that the hands are kept wet during treatment. Only use on visibly clean skin. Contact time for bacteria, yeasts and enveloped viruses: at least 0.5 minutes

Application rate(s) and frequency	hygienic hand disinfection 4 mL, 3 events/day
Category(ies) of users	General public (non-professional user)
Pack sizes and packaging material	Bottle (1 L, HDPE)

2.4.2.1 Use-specific instructions for use

1. Use 4 mL per each application for max. 3 times per day.
2. Keep skin sufficiently wet over the whole contact time.
3. Only use on visibly clean skin.

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

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 and precautionary statements in chapter 2.3

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

See chapter 2.5

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

2.4.3 Use 3 appropriate for authorisation – small surface disinfection (health care sector, institutional area, pharmaceutical and cosmetic industry)

Product Type(s)	2
Where relevant, an exact description of the use	Ready to use solution for disinfection of small surfaces in health care sector, institutional area, pharmaceutical and cosmetic industry.
Target organism(s) (including development stage)	bacteria (incl. mycobacteria); yeasts
Field(s) of use	Indoor Application in health care sector, institutional area, pharmaceutical and cosmetic industry for disinfection of hard non-porous surfaces.
Application method(s)	The biocidal product is applied to the surface by either spraying or pouring (pre-clean roughly where necessary). Make sure to wet surfaces completely. After the required contact time the whole surface is wiped with cloth or tissue (post-rinse where necessary). **In health care, institutional area, pharmaceutical industry (without cosmetic industry):** Required contact time for bacteria (incl. mycobacteria) and yeast: at least 5 min at 20°C **In cosmetic industry:** Required contact time for bacteria and yeast on dirty surfaces: at least 15 min at 20°C. Required contact time for bacteria (incl. mycobacteria) and yeast on carefully cleaned surfaces: at least 5 min at 20 °C.
Application rate(s) and frequency	small surface disinfection (0.5 m^2 area): 25 mL, 4 events/day
Category(ies) of users	Professional user
Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

2.4.3.1 Use-specific instructions for use

1. Do not apply more than 25 ml per 0.5 m².
2. Make sure to wet surfaces completely.
3. Pre-clean surfaces or post-rinse off, if necessary.
4. Used wipes must be disposed in a closed container.

2.4.3.2 Use-specific risk mitigation measures

1. The product must only be applied for disinfection of small surfaces.
2. For medical practices and small rooms, provide adequate ventilation (industrial ventilation or keeping windows and doors open). The stay in the treated area should be minimised.
3. For refilling, a funnel must be applied.
4. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   For refilling procedure, the use of eye protection during handling of the product is recommended.

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 and precautionary statements in chapter 2.3

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

See chapter 2.5

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

2.4.4 Use 4 appropriate for authorisation – small surface disinfection (food and feed area)

Product Type(s)	4
Where relevant, an exact description of the use	Ready to use solution for disinfection of small surfaces in food and feed area.
Target organism(s) (including development stage)	Bacteria (incl. mycobacteria); yeasts; viruses

Field(s) of use	Indoor Application for disinfection of hard non-porous surfaces in food/feed preparation and handling (kitchen, restaurants grocery shops, butcher etc.) and in food/feed production facilities (alcoholic beverages (e.g. breweries) as well as processed food/feed (meat, vegetables, fruits etc.).
Application method(s)	The biocidal product is applied to the surface/device by either spraying or pouring (pre-clean roughly where necessary). Make sure to wet surfaces and devices completely. After the required contact time the whole surface is wiped with cloth or tissue (post-rinse where necessary). **In food and feed area (including meat industry), dirty surfaces:** - Required contact time for bacteria (incl. mycobacteria) and yeast: 5 min at 20°C **In Brewery, dirty surfaces:** - Required contact time for bacteria and yeast: 15 min at 20°C **In food and feed area (including brewery, milk industry, meat industry) with carefully cleaned surfaces:** - Required contact time for bacteria (incl. mycobacteria) and yeast 5 min at 20°C - Required contact time for viruses: 2 min at 20°C
Application rate(s) and frequency	small surface disinfections (canteens/kitchen, 1 m^2 area): 50 mL/m^2, 4 events/day small surface disinfection in food/feed processing facilities: 4 events/day, 50ml/m^2
Category(ies) of users	Professional user
Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

2.4.4.1 Use-specific instructions for use

1. Do not apply more than 50 ml per m^2.
2. Make sure to wet surfaces completely.
3. Pre-clean surfaces or rinse off, if necessary.
4. Used wipes must be disposed in a closed container.

2.4.4.2 Use-specific risk mitigation measures

1. The product must only be applied for disinfection of small surfaces.
2. For refilling, a funnel must be applied.
3. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   For disinfection of food processing machinery and refilling procedure, the use of eye protection during handling of the product is recommended.

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 and precautionary statements in chapter 2.3

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

See chapter 2.5

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

2.5 General directions for use

2.5.1 Instructions for use

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2.5.2 Risk mitigation measures

1. Keep out of reach of children and pets.
2. Avoid contact with eyes.

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

1. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
2. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
3. Call a POISON CENTER or doctor/physician if you feel unwell.
4. If eye irritation persists, get medical advice/attention.

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

Shelf-life: 24 month

2.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.6 Packaging

Table 3

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	HDPE	professional, non-professional	Yes
Canister	5 L and 10 L	HDPE	HDPE	professional	Yes

Drum	60 L and 200 L	Coated steel	Plastic, coated brass	professional	Yes
IBC	1000 L	HDPE	HDPE	professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – hand disinfection (professional user)

Product Type(s)	1
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria (aerobic/anaerobic, Gram-positive and Gram-negative); fungi/yeasts; enveloped viruses
Field(s) of use	indoor
Application method(s)	hygienic/surgical hand disinfection The ready for use solution is poured into the palms of one hand out of an automatic dispenser. Hands have to be rubbed firmly and carefully for at least 30 seconds (hygienic handrub), respectively 90 seconds (surgical handrub). The application should be performed according to EN 1500. It has to be ensured that the skin is kept wet during treatment. If necessary, more solution is to be taken from the dispenser. While performing surgical handrub hands have to be kept above elbows.
Application rate(s) and frequency	hygienic hand disinfection : 4 mL, 25 hand rubs/day surgical hand disinfection: 20 mL, 4 rubs/day
Category(ies) of users	Professional user
Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

3.1.2 Intended use 2 – hand disinfection (non-professional user)

Product Type(s)	1

Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	bacteria, aerobic/anaerobic, Gram-positive and Gram-negative; fungi/yeasts; enveloped viruses
Field(s) of use	Indoor Non-professional users will apply alcohol-based hand rubs only occasionally for hygienic reasons when entering/leaving hospitals or for hygiene reasons at home.
Application method(s)	hygienic hand disinfection
Application rate(s) and frequency	4 mL, 3 events/day
Category(ies) of users	non-professional user
Pack sizes and packaging material	bottle (1 L, HDPE)

3.1.3 Intended use 3 –surface disinfection

Product Type(s)	2
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	bacteria, aerobic/anaerobic, Gram-positive and Gram-negative; fungi/yeasts; enveloped viruses
Field(s) of use	Indoor Alcohol-based disinfectants are used for cleaning of floors, working areas/desks, shelves, machinery devices or any other hard surfaces in health care sector, institutional areas and pharmaceutical/cosmetic industry.
Application method(s)	The biocidal product is applied to the surface by either spraying or pouring and the whole surface is afterwards wiped with cloth or tissue.
Application rate(s) and frequency	small surface disinfection (0.5 m^2 area): 25 mL, 4 events/day
Category(ies) of users	Professional user

Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

3.1.4 Intended use 4 – surface disinfection (food and feed area)

Product Type(s)	4
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	bacteria, aerobic/anaerobic, Gram-positive and Gram-negative; fungi/yeasts; enveloped viruses
Field(s) of use	Indoor Alcohol-based disinfectants are used for cleaning of floors, working areas/desks, shelves, machinery devices or any other hard surfaces in food/feed area.
Application method(s)	The biocidal product is applied to the surface by either spraying or pouring and the whole surface is afterwards wiped with cloth or tissue.
Application rate(s) and frequency	small surface disinfections (canteens/kitchen, 1 m2 area): 50 mL, 4 events/day surface disinfection in food/feed processing facilities: 4 events/day, 50mL/m²
Category(ies) of users	Professional user
Pack sizes and packaging material	bottle (1 L, HDPE), canister (5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

3.2 Physical, chemical and technical properties

Table 4: 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 OPPTS 830-6302	Antisept A Batch no. 624408001 (70% v/v isopropanol)	liquid	III_3.4_01 Study No. 15121802G978
Colour at 20 °C and 101.3 kPa	Visual OPPTS 830-6303	Antisept A Batch no. 624408001 (70% v/v isopropanol)	Clear colourless	III_3.4_01 Study No. 15121802G978
Odour at 20 °C and 101.3 kPa	Olfactory OPPTS 830-6304	Antisept A Batch no. 624408001 (70% v/v isopropanol)	slightly of alcohol	III_3.4_01 Study No. 15121802G978
Acidity / alkalinity	CIPAC MT 75.3	Antisept A Batch no. 624408001 (70% v/v isopropanol)	pH-value (1%v/v): 6.22 pH-value (undiluted): 7.43	III_3.2_01 Study No. 15121802G907

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative density / bulk density	EU A.3, OECD 109 Pycnometer method	Antisept A Batch no. 624408001 (70% v/v isopropanol)	D^{20}_4: 0.8587	III_3.3_01 Study No. 15121802G912
Storage stability test – **accelerated storage**	CIPAC MT 46	Antisept A Batch no. 624408001 (70% v/v isopropanol)	No changes in the appearance of the product after storage for 8weeks at 40°C. The Isopropanol content increased (+0.64%) from 69.23% (start value) to 69.67% (after 8 weeks at 40°C).	III_3.4_01 Study No. 15121802G978
Storage stability test – **long term storage at ambient temperature**		Antisept A Batch no. 624408001 (70% v/v isopropanol)	Results after 24 months storage: No changes in the appearance (clear colourless liquid with slightly alcoholic odour) of	III_3.4_02 Study No. 15121802G001

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the product after storage for 24 months at 20°C. The Isopropanol content decreased (-0.5%) from 70.73% (start value) to 70.37% (after 24 months at 20°C).	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Antisept A Batch no. 624408001 (70% v/v isopropanol)	No changes in the appearance of the product after storage for 1 week at 0°C. No phase transition was observed.	III_3.4_03 Study No. 15121802G977
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			In line with Annex IV of Regulation (EU) No 528/2012 further testing on effects of light is considered to be not necessary. Based on the	Waiving[9]

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

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			available UV spectra it can be concluded that Propan-2-ol does not absorb in the relevant spectal range of natural sunlight. Therefore no relevant effects of light on the active substance are expected.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			In line with Annex IV of Regulation (EU) No 528/2012 further testing on effects of humidity and temperature were considered not necessary. The biocidal is an aqueous solution and no changes of the product were observed in the storage test at 0 °C and 40 °C.	Waiving[9]
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			As the product is a liquid substance no testing with regard to wettability has to be conducted.	Waiving[9]
Suspensibility, spontaneity and dispersion stability			As the product is a liquid substance no testing with regard to Suspensibility, spontaneity and dispersion stability has to be conducted.	Waiving[9]
Wet sieve analysis and dry sieve test			No sieve testing can be technically performed, as Propan-2-ol is a liquid which is miscible in water.	Waiving[9]
Emulsifiability, re-emulsifiability and emulsion stability			No testing on emulsifiability can be technically performed, as Propan-2-ol is a liquid which is miscible in water.	Waiving[9]
Disintegration time			Testing for this endpoint is not relevant for the formulation type of the biocidal product	Waiving[9]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Particle size distribution, content of dust/fines, attrition, friability			Testing on particle size distribution is technically not feasible as Propan-2-ol is a liquid.	Waiving[9]
Persistent foaming			Testing for this endpoint is not relevant for the formulation type of the biocidal product	Waiving[9]
Flowability/Pourability/Dust ability			study technically not feasible: The product is neither in granular form, nor a suspension, nor a dust.	Waiving[9]
Burning rate — smoke generators			As usage in smoke generators is not foreseen for the biocidal product, testing on burning rate, burning completeness and composition of smoke was not conducted.	Waiving[9]
Burning completeness — smoke generators				Waiving[9]
Composition of smoke — smoke generators				Waiving[9]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols			Spraying is not foreseen for the biocidal product	Waiving[9]
Physical compatibility			Combination with other products is not foreseen.	
Chemical compatibility			Combination with other products is not foreseen.	
Degree of dissolution and dilution stability			Testing for this endpoint is technically not feasible for the formulation type of the biocidal product.	
Surface tension	EU A.5; OECD 115 Plate method	Antisept A Batch no. 624408001 (70% v/v isopropanol)	71.74 mN/m at 20°C, Concentration 1g/L	III_3.8_01 Study No. 15121802G960
Viscosity	OECD 114 falling ball viscosimeter	Antisept A Batch no. 624408001 (70% v/v isopropanol)	3.413 mPa/s (at 20 °C), 1.72 mPa/s (at 40 °C)	III_3.9_01 Study No. 15121802G984

Table 5

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. The biocidal product is a clear colourless liquid with slightly alcoholic odour. The pH of the neat product is 7.43 and the density: D^{20}_4: 0.8587. The

submitted accelerated, long-term and low storage test show no degradation of the actives substance and no changes of the appearance. Thus, a shelf life of 24 months can be granted.

3.3 Physical hazards and respective characteristics

Table 6: 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			Waiver: The study does not need to be conducted because there are no chemical groups present in propan-2-ol and water which are associated with explosive or self-reactive properties with reference to the screening procedures in Appendix 6 of the UN-MTC, see Tables A6.1 and A6.3	IUCLID[10]
Flammable gases	study scientifically unjustified			Waiver	IUCLID[10]
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID[10]
Oxidising gases	study scientifically unjustified			Waiver	IUCLID[10]

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

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Waiver	IUCLID[10]
Flammable liquids	Calculation method acc. To 2.6.4.3. of Annex I, Part 2 of CLP Regulation		Flash point: < 23 °C (calculated) Boiling point: 80.6 °C of azeotropic mixture	Flammable liquid, Category 2 based on GHS/CLP criteria	Gmehling and Rasmussen (1982)
Flammable solids	study scientifically unjustified				IUCLID[10]
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 with reference to the screening procedures in Appendix 6 of the UN-MTC, see Tables A6.1 and A6.3.	IUCLID[10]
Pyrophoric liquids	study scientifically not necessary			Waiver: The product is considered to be not pyrophoric based on experience in manufacture and handling	IUCLID[10]
Pyrophoric solids	study scientifically unjustified			Waiver	IUCLID[10]
Self-heating substances and mixtures	study scientifically unjustified			Waiver	IUCLID[10]
Substances and mixtures which in contact with	study scientifically not necessary			Waiver: Based on the chemical structure of propan-2-ol and the fact that the product is an	IUCLID[10]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
water emit flammable gases				aqueous solution testing is considered as not necessary.	
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the product is flammable.	IUCLID[10]
Oxidising solids	study scientifically unjustified			Waiver	IUCLID[10]
Organic peroxides	study scientifically not necessary			Waiver: Testing is considered to be not necessary, as propan-2-ol is not an organic peroxide.	IUCLID[10]
Corrosive to metals	study scientifically not necessary			Waiver: The existing information in the available BAM Liste 2015 clearly show stability of several metals exposed to Propan-2-ol. This information is considered as valid while the biocidal product has a neutral pH value (pH 6.5-8.5) and no bromide or chloride anions are present.	IUCLID[10]
Auto-ignition temperature (liquids and gases)	study scientifically not necessary		Auto-ignition temperature: 399 °C (for pure propan-2-ol)	According a report of the German PTB aqueous solutions of combustible liquids are exceptional, since water as incombustible substance shows an inerting effect in the mixture (Hirsch, W., Brandes, E., Zündtemperaturen binärer Gemische bei erhöhten Ausgangsdrücken, PTB Braunschweig, 2005). Assuming the lowest available auto-ignition temperature of propan-2-ol (399 °C) as worst case is considered to be sufficiently protective for the usage of the product.	Hirsch, W., Brandes, E. (2005)

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver	IUCLID[10]
Dust explosion hazard	study scientifically unjustified			Waiver	IUCLID[10]

Table 7

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Assuming the lowest available auto-ignition temperature of propan-2-ol (399 °C) as worst case is considered to be sufficiently protective for the usage of 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 and is not considered as being corrosive to metals. Based on the available information on the substance properties a flashpoint below 20 °C can be calculated for a mixture of 70 % (v/v) propan-2 -ol and 30 % (v/v) water. The boiling point of the mixture is higher than 35 °C. Therefore, the biocidal product is classified as Flammable liquid, Category 2 based on GHS/CLP criteria.

3.4 Methods for detection and identification

Table 8

Analytical methods for the analysis of the product Antisept A 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		
Isopropanol	GC/FID	sixfold determination of the blank value in calibration solvent chloroform No signals in the range of isopropyl alcohol were observed	500 – 2500 mg/L; R^2: 0.99987	2 / 10	98.0 – 99.8	98.7	0.6	499 mg/L	III_5.1_01
				Measured triplicate 700, 1500 and 2000 mg/L	100.1 – 100.4 98.5 – 99.4 98.9 – 100.7	100.3 99.0 99.2			

Table 9

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 for PT1, PT2, PT4; LoEP (07/2014)
Drinking water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)
Surface water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)
Air	propan-2-ol	3.2 mg/m³	$AEL_{medium\text{-}term}$:10.7 mg/kg bw/d (general population) AR for PT1, PT2, PT4; LoEP (07/2014)
Animal and human body fluids and tissues	no relevant residues		not classified as toxic or very toxic
Food of plant origin	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)
Food of animal origin	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)

Table 10

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		
propan-2-ol	GC-FID, DB-5MS column	confirmation by GC-MS possible	Calibration in solvent: 0.34 – 3.4 µg/mL R^2=0.9983 matrix-matched calibration: 0.50 – 12.56 mg/mL R^2=0.9998	Air 21 °C, 80 % rel humidity (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6 Dry air (18 L	99.2-101 102-103.6 102.7-104.9 102.1-104.8 103.2-104.3 102.6-104.6	100.2 102.9 103.6 103.2 103.7 103.8	0.8 0.8 1.0 1.1 0.3 0.7	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit of 0.05 * OSHA target concentration of 983 mg/m³)	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997

				sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6	 101.1-103.4 102.3-104.5 102.5-104.4 104-106.1 103.3-105.3 103.1-107.3	 102.5 103.3 103.4 104.8 104.5 105.4	 1.0 0.9 0.7 0.8 0.7 1.7		
propan-2-ol	GC-MS using DB-5 column, m/z 59 as quantifier and m/z 45 as qualifier	confirmation not included, since for second fragment ion no validation data presented	0.025 – 7.4 mg/mL R^2=0.995 – 1.000	Air (considering maximum sample volume of 23.8 L of OSHA-method 9.4 mg/m³ / 5 93.8 mg/m³ / 5	 97.3-103 106-115	 99.2 111	 2.6 3.1	LOQ of the method is dependent on sampling volume: The lowest concentration of 0.025 mg/mL corresponds to	DocIIIA, 4.1; 11/2015 Alcohol Task Force, 2015

				250 mg/m³ / 4 750 mg/m³ / 5	105-110 104-110	107 107	2.1 2.3	3.1 mg/m³ 2-propanol in air at the maximum sampling volume of 23.8 L in the OSHA method (9.4 mg/m³ - it refers to the validated QC-standard of 0.075 mg/mL and the supposed maximum sample volume of 23.8 L of OSHA-method)	

Table 11

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: No data waiving 2. 5.2.1. Soil: Data waving is accepted 3. 5.2.2. Air: For analytical methods for air, the applicant refers to the CAR for the active substance propan-2-ol. 4. 5.2.3. Water (including drinking water) and sediment: Data waiving is accepted 5. 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: Data waiving is accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 12

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s), residues and substances of concern was/were acceptable. The methods provided regarding the residues were acceptable. Method(s) regarding residues and substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The biocidal product “Antisept A” contains the active substance propan-2-ol and is used for hand disinfection (hygienic and surgical) in PT 1 as well as surface disinfection in PT 2 and PT 4.
Concerning the use in PT 1, the product is intended to be used on visible clean hands in health care as well as non-health care areas.
Concerning the use in PT 2, the product is intended to be used for the disinfection of clean and dirty hard non-porous surfaces (e.g disinfection of floors, working areas/desks, shelves or any other hard surfaces) in the health care sector, institutional areas, pharmaceutical and cosmetic industry.
Concerning the use in PT 4, the product is intended to be used for the disinfection of clean and dirty hard non-porous surfaces (e.g. disinfection of floors, working areas/desks, shelves, machinery devices or any other hard surfaces) in food/feed preparation and handling (kitchen, restaurants grocery shops, butcher etc.) and in food/feed production facilities (alcoholic beverages (e.g. breweries), processed food/feed (meat, vegetables, fruits etc.).

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

The biocidal product “Antisept A” is intended to have bactericidal, mycobactericidal as well as yeasticidal activity. Furthermore, the applicant claims efficacy against enveloped viruses.

3.5.3 Effects on target organisms, including unacceptable suffering

Application of the product “Antisept A” leads to the irreversible inactivation of bacterial cells, yeast cells and enveloped as well as some non-enveloped viruses.

3.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of action. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm’s proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes’ coagulation leads to a loss of cellular activity resulting in the cell’s death.

Propan-2-ol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant). The time required for sufficient inactivation is strongly depending on the formulation, concentrations of propan-2-ol contained in the applied biocidal product, the type of target organisms and on the specific use conditions.

3.5.5 Efficacy data

As the product is intended to be applied for disinfection, it 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. Experimental data is summarised in Table 13.

The intended use concentration of the active substance propan-2-ol is 64.00% (w/w). Concerning surface disinfection, the ready-to-use solution is intended to be sprayed or poured onto a surface (disinfection without mechanical action) and the surface is wiped with a cloth after the required contact time.

Table 13

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**
Yeasticidal activity	Hand disinfection, Surface disinfection	Antisept A	*Candida albicans*	EN 13624:2013	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80 % Interfering substances: 0.3 g/l BSA (clean conditions) Contact time: 30 sec	Yeasticidal efficacy was shown after 30 sec at 80% product concentra-tion.	*III_6.7_02*
Bactericidal activity	Hand disinfection,	Antisept A	*Staphylococcus aureus, Enterococcus hirae,*	EN 13727:2015	Quantitative suspension test	Bactericidal efficacy was shown after 30 sec at	*III_6.7_03*

	Surface disinfection		*Escherichia coli* and *Pseudomonas aeruginosa*		Test temperature: 20°C Test concentration: 10 %, 50 % and 80 % Interfering substances: 0.3 g/l BSA (clean conditions) Contact time: 30 sec	50% product concentration.	
Bactericidal activity	Hand disinfection (hygienic)	Antisept A	*Escherichia coli*	EN 1500: 2013	Phase 2, step 2 test Test concentration: 100% Contact time: 30 sec	Product complies with requirements of the standard if 4 ml are applied with a contact time of 30 sec.	*III_6.7_04*
Bactericidal activity	Surface disinfection	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa*	EN 13727:2015	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80 % Interfering substances: 3 g/l BSA and 3 ml/L sheep erythrocytes (dirty conditions) Contact time: 60 sec	Bactericidal efficacy was shown after 60 sec for 50 % product concentration.	*III_6.7_05*
Yeasticidal activity	Surface disinfection	Antisept A	*Candida albicans*	EN 13624:2013	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80 %	Yeasticidal efficacy was shown after 60 sec for 80% product concentration.	*III_6.7_06*

					Interfering substances: 3 g/l BSA and 3 ml/L sheep erythrocytes (dirty conditions) Contact time: 60 sec		
Bactericidal and yeasticidal activity	Surface disinfection	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa* *Candida albicans*	EN 13697:2015	Quantitative non-porous surface test Test temperature: 20°C Test concentration: 10 %, 50 % and 100 % Interfering substances: 3 g/l BSA and 3 ml/L sheep erythrocytes (dirty conditions) Contact time: 5 min	Bactericidal and yeasticidal efficacy were shown after 5 min for 50 % product concentration.	*III_6.7_07*
Bactericidal activity	Surface disinfection	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginosa*	EN 13697:2015	Quantitative non-porous surface test Test temperature: 20°C Test concentration: 10 %, 50 % and 100 % Interfering substances: 3 g/l BSA (dirty conditions) Contact time: 5 min	Bactericidal efficacy was shown after 5 min for 50 % product concentration.	*III_6.7_08*
Bactericidal activity	Surface disinfection	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginosa*	EN 1276: 2009	Quantitative suspension test Test temperature: 20°C	Bactericidal efficacy was shown after 5 min for 50% product concentration.	*III_6.7_09*

					Test concentration: 10 %, 50 % and 80 % Interfering substances: 3 g/l BSA (dirty conditions) Contact time: 5 min		
Yeasticidal activity	Surface disinfection	Antisept A	*Candida albicans*	EN 1650: 2013	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80 % Interfering substances: 3 g/l BSA (dirty conditions) Contact time: 15 min	Yeasticidal efficacy was shown after 15 min for 50% product concentration .	*III_6.7_10*
Efficacy against enveloped viruses	Hand disinfection	Antisept A	*Modified vaccinia virus Ankara*	EN 14476:2013 +A1 2015	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 %, 80 % and 97% Interfering substances: 0.3 g/l BSA (clean conditions) Contact time: 30 sec, 60 sec, 30 min	Efficacy against the test organism was shown after 30 sec for 80% product concentration .	*III_6.7_11*
Efficacy against microbial flora of skin	Hand disinfection (surgical)	Seewaskept (63.1 g/100 g propan-2-ol and water)	*Microbial flora of skin*	DIN EN 12791	Phase 2, step 2 test Contact time: 1.5 min (Reference product: 3 min)	Product complies with requirements of the standard if the skin is kept sufficiently	*III_6.7_12*

					Reference product: 60 % (v/v) propan-1-ol	wet for a contact time of at least 1.5 min.	
Virucidal activity	Surface disinfection	Antisept A	*Adenovirus type 5 strain adenoid 75 (ATCC VR-5)*	DIN EN 14476:2013 +A1 2015	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 %, 80 % and 97% Interfering substances: 0.3 g/l BSA (clean conditions) Contact time: 30 sec, 1 min, 2 min and 30 min	Efficacy against the test organism was shown after 2 min for 80 % product concentration .	*III_6.7_13*
Virucidal activity	Surface disinfection	Antisept A	*Murine Norovirus (Berlin 06/06/DE Isolate S99*)	DIN EN 14476:2013 +A1 2015	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 80 % and 97% Interfering substances: 3 g/l BSA and 3 ml/L sheep erythrocytes (dirty conditions) Contact time: 30 sec, 1 min, 2 min and 30 min	Efficacy against the test organism was shown after 1 min for 97 % product concentration .	*III_6.7_14*
Bactericidal activity	Surface disinfection (cosmetic industry)	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa*	DIN EN 1276: 2009	Quantitative suspension test Test temperature: 20°C Test concentration:	The validation of the control without product (control of test conditions) showed no surviving cfu for all test	*III_6.7_15*

					10 %, 50 % and 80% Interfering substances: 5 g/L SDS (dirty conditions) Contact time: 5 min	organisms except *P. aeruginosa.* This suggests that SDS itself can carry out a bactericidal effect. Efficacy against *P. aeruginosa* was shown after 5 min for 50 % product concentration .	
Yeasticidal efficacy	Surface disinfection (cosmetic industry)	Antisept A	*Candida albicans* *Aspergillus brasiliensis* *Saccharomyces cerevisiae (ATCC 9763)* *Saccharomyces cerevisiae (DSM 70487)*	DIN EN 1650: 2013	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80% Interfering substances: 5 g/L SDS (dirty conditions) Contact time: 15 min	The validation of the control without product (control of test conditions) showed no surviving cfu for all test organisms. This suggests that SDS itself can carry out a fungicidal effect.	*III_6.7_16*
Yeasticidal efficacy	Surface disinfection (breweries)	Antisept A	*Candida albicans* *Aspergillus brasiliensis* *Saccharomyces cerevisiae (ATCC 9763)* *Saccharomyces cerevisiae (DSM 70487)*	DIN EN 1650: 2013	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80% Interfering substances: 10 g/L yeast extract (dirty conditions) Contact time: 15 min	Yeasticidal efficacy was shown after 15 min for 50% product concentration .	*III_6.7_17*
Bactericidal activity	Surface disinfection (breweries)	Antisept A	*Staphylococcus aureus, Enterococcu*	DIN EN 1276: 2009	Quantitative suspension test	Bactericidal efficacy was shown after 5	*III_6.7_18*

			s hirae, Escherichia coli, Pseudomonas aeruginosa		Test temperature: 20°C Test concentration: 10 %, 50 % and 80% Interfering substances: 10 g/L yeast extract (dirty conditions) Contact time: 5 min	min for 50 % product concentration.	
Bactericidal / yeasticidal activity	Surface disinfection (breweries)	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa* *Candida albicans Aspergillus brasiliensis*	DIN EN 13697: 2015	Quantitative non-porous surface test Test temperature: 20°C Test concentration: 10 %, 50 % and 100 % Interfering substances: 10 g/L yeast extract (dirty conditions) Contact time: 15 min	Bactericidal efficacy was shown after 15 min for 100 % product concentration. Yeasticidal efficacy was shown after 15 min for 50% product concentration.	*III_6.7_19*
Yeasticidal activity	Surface disinfection (breweries)	Antisept A	*Saccharomyces cerevisiae (ATCC 9763) Saccharomyces cerevisiae (DSM 70487)*	DIN EN 13697: 2015	Quantitative non-porous surface test Test temperature: 20°C Test concentration: 10 %, 50 % and 100 % Interfering substances: 10 g/L yeast extract (dirty conditions) Contact time: 15 min	Yeasticidal efficacy was shown after 15 min for 50% product concentration.	*III_6.7_20*

Bactericidal / yeasticidal activity	Surface disinfection (cosmetic industries)	Antisept A	*Staphylococcus aureus, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa* *Candida albicans Aspergillus brasiliensis*	DIN EN 13697: 2015	Quantitative non-porous surface test Test temperature: 20°C Test concentration: 10 %, 50 % and 100 % Interfering substances: 5 g/L SDS (dirty conditions) Contact time: 15 min	The validation of the control without product (control of test conditions) was valid for all test organisms except for *S. aureus* and *E. hirae* (gram-positive bacteria). This suggests that SDS itself can carry out a bactericidal effect. Efficacy against gram negative bacteria was shown after 15 min for 100 % product concentration and yeasticidal efficacy was shown after 15 min for 50 % product concentration.	*III_6.7_21*
Mycobactericidal activity	Hand disinfection, Surface disinfection	Antisept A	*Mycobacterium terrae* *Mycobacterium avium*	DIN EN 14348:2005	Quantitative suspension test Test temperature: 20°C Test concentration: 10 %, 50 % and 80% Interfering substances: 3 g/L BSA and 3 ml/L sheep erythrocytes (dirty conditions) Contact time: 5 min	Mycobactericidal efficacy was shown after 5 min for 50 % product concentration.	*III_6.7_23*

To prove the bactericidal/ mycobactericidal and yeasticidal efficacy as well as the efficacy against some viruses, the applicant submitted 14 phase 2, step 1 tests (EN13727, EN 13624, EN 1276, EN 1650, EN 14348, EN 14476) and seven phase 2, step 2 tests (EN 1500, EN 12791, EN 13697). The results are summarized in Table 14 below.

Table 14

Method	Test organisms	Interfering substances					
		-	0.3 g/L BSA	3 g/L BSA	3 g/L BSA + 3 ml/L sheep erythrocytes	10 g/L yeast extract	5 g/L SDS
EN 1276	*Standard organisms*			5 min, 50 %		5 min, 50 %	5 min, 50 %[2]
EN 13727	*Standard organisms*		30 sec, 50 %		60 sec, 50 %[1]		
EN 1650	*C. albicans*			15 min, 50 %		15 min, 50 %	Not valid
EN 1650	*S. cerevisiae (two standard organisms)*					15 min, 50 %	Not valid
EN 13624	*Standard organism*		30 sec, 80 %		60 sec, 80 %		
EN 14348	*Standard organisms*				5 min, 50 %		
EN 14476	*MVA*		30 sec, 80 %				
EN 14476	*Adenovirus*		2 min, 80 %				
EN 14476	*MNV*				1 min, 97 %		
EN 1500	*E. coli*	4 ml, 30 sec					
EN 12791	-	keep hands sufficiently wet for at least 90 sec					
EN 13697	*Standard organisms*			5 min, 50 %	5 min, 50 %	15 min, 100 %	15 min, 100 %[3]
EN 13697	*C. albicans*				5 min, 50 %	15 min, 50 %	15 min, 50 %

EN 13697	*S. cerevisiae (two different standard organisms)*					15 min, 50 %	

[1] without *E. coli* (sufficient for surface disinfection according to EN 13727)
[2] only valid for *P. aeruginosa*
[3] only valid for gram-negative bacteria

Phase 2, step 1 and phase 2, step 2 tests with 5 g/L SDS as interfering substance (high soiling for cosmetic industry) were only valid for some of the tested organisms, since validation A (sample without product addition) yielded no or only a few colony forming units at the end of the test. This suggests that SDS has a certain bactericidal efficacy itself. However, since the phase 2, step 2 tests with high soiling for cosmetic industry were are valid for gram-negative bacteria as well as yeast within 15 min at 100 % product concentration but not for gram-positive bacteria. However, in the phase 2, step 1 and phase 2 step 2 tests with medical high soiling (3 g/L BSA and 3 ml/L sheep erythrocytes) no difference in the required contact time (60 s in phase 2 step 1 test, 5 min in phase 2 step 2 test) or concentration (50 %) between gram-negative and gram-positive bacteria could be discerned. Due to the comparable results for gram-negative and gram-positive bacteria in the phase 2, step 1 and phase 2 step 2 tests with medical soiling the evaluating German CA is of the opinion that the results for the gram-negative bacteria in the phase 2, step 2 tests with high soiling for cosmetic industry can be transferred to the gram-positive bacteria. Therefore, the determined efficacious conditions (15 min, 100 %) for the phase 2, step 2 tests with high soiling for cosmetic industry are considered to be acceptable for the cosmetic industry.

According to EU guidance[11], a limited virucidal claim is not possible for surface disinfection in PT 2 and PT 4. Since no efficacy against Poliovirus has been shown in the course of product authorisation, no virucidal claim is possible for surface disinfection in PT 2. Since according to EU guidance full virucidal activity in PT 4 does not require efficacy against Poliovirus, and efficacy against *Adenovirus* and *MNV* has been demonstrated, a full virucidal claim in PT 4 is acceptable, but only on carefully cleaned surfaces.

3.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of the active substance propan-2-ol, the development of resistance is not expected and not reported. A natural resistance of sporulated bacteria is known where 2-propanol is ineffective at any concentration. Likewise, 2-propanol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-

[11] Guidance on the Biocidal Products Regulation. Volume II Efficacy – Assessment and Evaluation Part (B+C), Version 3.0 from April 2018.

enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.
No management strategies have been developed since no occurrence of resistance has been observed.

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 product “Antisept A”.

3.5.8 Evaluation of the label claims

The following biocidal label claims are considered to be suitable for product labels of the product “Antisept A” (non-biocidal label claims have not been evaluated):

Hand disinfection (hygienic), clean conditions (PT 1):

- Bactericidal, yeasticidal efficacy as well as efficacy against enveloped viruses (required use conditions: keep hands sufficiently wet (use 4 ml), required contact time: at least 30 sec)

Hand disinfection (surgical), clean conditions, without long-term effect according to EN 12791 (PT1):

- Bactericidal and yeasticidal efficacy (required use conditions: keep hands and forearms sufficiently wet for at least 1.5 min)

Disinfection of clean and dirty hard non-porous surfaces by spraying / pouring (PT 2):

- Bactericidal (incl. mycobacteria), yeasticidal efficacy
- In health care, institutional areas, pharmaceutical industry (without cosmetic industry): Required contact time for bacteria (incl. mycobacteria) and yeast: at least 5 min at 20°C
- In cosmetic industry:
- Required contact time for bacteria and yeast on dirty surfaces: at least 15 min at 20°C.
- Required contact time for bacteria (incl. mycobacteria) and yeast on carefully cleaned surfaces: at least 5 min at 20 °C.

Disinfection of clean and/or dirty hard non-porous surfaces by spraying / pouring (PT 4):

- Bactericidal (incl. mycobacteria), yeasticidal and virucidal efficacy
- In food/feed area (including meat industry), dirty surfaces:

Required contact time for bacteria (incl. mycobacteria) and yeast: 5 min at 20°C

- In Brewery, dirty surfaces:
  Required contact time for bacteria and yeast: 15 min at 20°C
- In food/feed area (including brewery, milk industry, meat industry) with carefully cleaned surfaces: Required contact time for Bacteria (incl. mycobacteria) and yeast 5 min at 20°C
  Required contact time for viruses: 2 min at 20°C

The following use-instructions have to be included to ensure efficacy:

PT 1:
- Keep skin sufficiently wet over the whole contact time.
- Only use on visibly clean skin.

PT 2/ 4:
- Make sure to wet surfaces completely.
- Pre-clean surfaces or rinse off, if necessary.

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 used with other biocidal products.

3.5.10 Data waiving and conclusion

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	6.7. Efficacy data to support these claims Read-across to support efficacy of Antisept A to Seewasept
Justification	The product Seewasept is used to prove efficacy of Antisept A for surgical hand disinfection. Since Seewasept (63.1 % w/w) contains a slightly lower a.s. concentration than Antisept A (64.00 % w/w) without any additional co-formulants, the read-across is considered acceptable.

Table 16

Conclusion on the efficacy
From the submitted studies, it can be concluded that the product “Antisept A” shows sufficient bactericidal (incl. mycobacteria) and yeasticidal efficacy as well as efficacy against enveloped viruses

as substantiated according to European Standards (EN). Resistance is not reported or known at the time being.
Hence, with regard to efficacy, the requirements for the authorisation of the product “Antisept A” have been met for the following conditions:

Hand disinfection (hygienic), clean conditions:

- Bactericidal, yeasticidal efficacy as well as efficacy against enveloped viruses (required use conditions: keep hands sufficiently wet (use 4 ml), required contact time: at least 30 sec)

Hand disinfection (surgical) , clean conditions, without long-term effect according to EN 12791:

- Bactericidal and yeasticidal efficacy (required use conditions: keep hands and forearms sufficiently wet for at least 1.5 min)
- A long term effect in accordance to EN 12791 cannot be claimed, since no stronger effect than the reference product 3 hours after application of the test product for 1.5 min has been demonstrated

Disinfection of clean and dirty hard non-porous surfaces by spraying / pouring (PT 2):

- Bactericidal (incl. mycobacteria but excluding bacterial spores), yeasticidal efficacy
- In health care, institutional areas, pharmaceutical industry (without cosmetic industry):
  Required contact time for bacteria (incl. mycobacteria) and yeast: at least 5 min at 20°C
- In cosmetic industry:
  Required contact time for bacteria and yeast on dirty surfaces: at least 15 min at 20°C.
  Required contact time for bacteria (incl. mycobacteria) and yeast on carefully cleaned surfaces: at least 5 min at 20 °C.

Disinfection of clean and/or dirty hard non-porous surfaces by spraying / pouring (PT 4):

- Bactericidal (incl. mycobacteria but excluding bacterial spores), yeasticidal and virucidal efficacy
- In food/feed area (including meat industry), dirty surfaces:
  Required contact time for bacteria (incl. mycobacteria) and yeast: 5 min at 20°C
- In Brewery, dirty surfaces:
  Required contact time for bacteria and yeast: 15 min at 20°C
- In food/feed area (including brewery, milk industry, meat industry) with carefully cleaned surfaces:
  Required contact time for Bacteria (incl. mycobacteria) and yeast 5 min at 20°C
  Required contact time for viruses: 2 min at 20°C

Efficacy has not been proven with soiling for milk industry.

The following use-instructions have to be included to ensure efficacy:

PT 1:

- Keep skin sufficiently wet over the whole contact time.
- Only use on visibly clean skin.

PT 2/ 4:

- Make sure to wet surfaces completely.
- Pre-clean surfaces or rinse off, if necessary.

3.6 Risk assessment for human health

Please note that the risk assessment for human health has been carried out with a slightly higher concentration of propan-2-ol (64.73% w/w instead of 64.00 % w/w) due to differences in conversion methods from "% v/v" to "% w/w" during the determination of the product identity. However, this has no influence on the conclusive statements in this chapter.

3.6.1 Assessment of effects of the active substance on human health

Table 17

Propan-2-ol	Value	Study	Safety factor
AEL acute/medium/long-term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	6.4
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	3.8

Table 18

Propan-2-ol	Value	Reference
Inhalative absorption	100 %	Assessment Report (RMS DE (2014))
Oral absorption	Nearly complete following oral, inhalation and intravenous exposure.	Slauter et al., 1994
Dermal absorption	Absorption rate (transdermal flux) in rat study: 0.85 mg/cm^2/h for aqueous solution containing 70 % propan-2-ol (by weight) Since the biocidal product (Antisept A) consists only of the active substance and water toxicological properties can be derived from data provided for the active substance.	Boatman et al., 1998

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 19

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, "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, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 20

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin. Repeated exposure may cause skin dryness or cracking.
Justification for the value/conclusion	According to Regulation (EC) No 1272/2008 Annex VI propan-2-ol is not skin irritating in rabbits. Studies on skin irritation in human subjects reveal no skin irritating properties. According to the CLP criteria, the biocidal product does not need to be classified with respect to local effects on the skin. However, according to the third party dossier for propan-2-ol local skin effects and reactions have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. Therefore, an appropriate labelling is indicated.
Classification of the product according to CLP	Classification for skin corrosion or irritation is not required. Supplemental hazard statement: EUH066 (Repeated exposure may cause skin dryness or cracking)

3.6.2.2 Eye irritation

Table 21

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, "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, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 22

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to the eyes.
Justification for the value/conclusion	Classification of the active substance according to Regulation (EC) No 1272/2008 and its concentration in the biocidal product Propan-2-ol (64.00 %, w/w): Eye Irrit. 2, H319; Generic concentration limit: 10 % (w/w)
Classification of the product according to CLP	Eye Irrit. 2, H319 (Causes serious eye irritation.)

3.6.2.3 Respiratory tract irritation

Table 23

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, "other endpoints"
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. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.

Table 24

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation the biocidal product is not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin-sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health , “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, and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 26

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation the biocidal product is not skin-sensitising.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitization (ADS)

Table 27

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 or its components are not available.

Table 28

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal products or their components with the corresponding concentration are not available.
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 29

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, “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, and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 30

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acute toxicity via the oral route.
Justification for the selected value	The oral LD_{50} of all components are > 2000 mg/kg bw. Hence, the oral LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
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 31

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, "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, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 32

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acute toxicity via the inhalation route.
Justification for the selected value	The inhalations LC_{50} of all components are above the limits for classification. Hence, the inhalation LC_{50} of the biocidal product will also above these limits.
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 33

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, "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, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no indication of synergistic effects between any of the components since the biocidal product is a simple dilution of the active substance in water. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 34

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute toxicity via the dermal route.
Justification for the selected value	The dermal LD_{50} of all components are > 2000 mg/kg bw. Hence, the dermal LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 35

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	The applicant has access to a 3rd party dossier. This dossier contains the same studies and information on dermal absorption submitted and evaluated for the CAR. Additional information in the third party dossier was considered not relevant for the derivation of a dermal absorption value. The dermal absorption value derived in the CAR is based on the publication of Boatman et al. (1998). This study was also submitted for the 3rd party dossier. Hence, conclusions from the CAR are also valid for this dossier. From the publication of Boatman et al. a dermal flux rate 0.85 mg/cm²/h was derived for a 70 % aqueous dilution on rat skin. The composition of the test formulation and biocidal product are very similar. It is not expected that the slightly lower concentration in the biocidal product 64.00 % vs. 70 % has a significant effect.

Table 36

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s)	All scenarios with dermal contact Concentration a.s.: 64.00 % (w/w)
Value	Flux rate: 0.85 mg/cm²/h
Justification for the selected value(s)	Boatman, 1998; see table above

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

Not relevant.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

According to Regulation (EC) No 1272/2008 Annex VI, Table 3.1 the active substance is classified with STOT SE 3 (H336, May cause drowsiness or dizziness). Based on the high active substance

concentration in the biocidal product (> 60 %) and the recommended generic concentration limit of 20 % for substances classified as STOT SE 3, this classification is also required for the biocidal product.

3.6.2.11 Summary of effects assessment

Table 37

Endpoint	Brief description
Skin corrosion and irritation	Based on the intrinsic properties of the single components. Not corrosive or irritating to the skin. Repeated exposure may cause skin dryness or cracking. Labelling with EU066 is required.
Eye irritation	Based on the intrinsic properties of the single components. Irritating to the eyes (Eye Irrit. 2, H319).
Respiratory tract irritation	Based on the intrinsic properties of the single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of the single components. Not skin-sensitising.
Respiratory sensitization (ADS)	Based on the known intrinsic properties of the single components. Not sensitising to the respiratory tract.
Acute toxicity by oral route	Based on the known intrinsic properties of the single components. No acute toxicity via the oral route.
Acute toxicity by inhalation	Based on the known intrinsic properties of the single components. No acute toxicity via the inhalation route.
Acute toxicity by dermal route	Based on the known intrinsic properties of the single components. No acute toxicity via the dermal route.
Information on dermal absorption	Based on dermal absorption data from Boatman et al. (1998). Flux rate: 0.85 mg/cm2/h.
Available toxicological data relating to non-active substance(s)	Substances of concern were not identified.
Available toxicological data relating to a mixture	Not required.
Other relevant information	Based on the intrinsic properties of the active substance also the biocidal product is classified with STOT SE 3, H336 (May cause drowsiness or dizziness).

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 38

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	Not applicable	Yes	Yes	Not applicable	Yes	Yes	Not applicable
Dermal	Not applicable	Yes	Yes	Not applicable	Not expected	No	Not applicable
Oral	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	No	No

List of scenarios

Table 39

Summary table: scenarios (professionals)				
Scenario number	**Scenario** (e.g. mixing/ loading)	**Use no. (Product type)**	**Primary or secondary exposure Description of scenario** **Name of the use (see chapter 3.1)**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Hand disinfection - hygienic	1 (PT 01)	Primary exposure of a professional user resulting from hand disinfection (hand rubbing) with an alcohol based disinfectant in form of a ready-to-use product in naturally ventilated rooms, e.g. a patient room in a hospital. Secondary exposure of a professional bystander who is present in the room where the hand disinfection is carried out can be expected. Hand disinfection	Professional
2.1	Small surface disinfection – in between disinfection - hospital room	3 (PT 02)	Primary exposure of a professional user resulting from application (pouring & wiping / spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in	Professional

			naturally ventilated rooms, e.g. a patient room in a hospital. Secondary exposure of a professional bystander who is present in the room where the surface disinfection is carried out can be expected. Surface disinfection	
2.2	Small surface disinfection - in between disinfection - medical practice	3 (PT 02)	Primary exposure of a professional user resulting from application (pouring & wiping, spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in naturally ventilated rooms e.g. a room in a medical practice (covers health care sector, institutional areas, pharmaceutical and cosmetic industry). Secondary exposure of a professional bystander who is present in the room where the surface disinfection is carried out can be expected. Surface disinfection	Professional
2.3	Small surface disinfection in laboratory	3 (PT 02)	Primary exposure of a professional user resulting from application (pouring & wiping / spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in technically ventilated rooms, e.g. a work bench in a laboratory. Secondary exposure of a professional bystander who is present in the laboratory where the surface disinfection is carried out can be expected Surface disinfection	Professional
3	Refilling		Decanting/Refilling of disinfectant from canisters (5 L, 10 L), drums (60 L, 200 L), or IBC (1000 L) into handy sized packages (manually or with hand pumps, connecting lines). Secondary exposure of a professional bystander is not expected.	Professional
4.1	Small surface disinfection in kitchens and canteens	4 (PT 04)	Primary exposure of a professional user resulting from application (pouring & wiping / spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in food contact areas, e.g. a work bench in a kitchen.	Professional

			Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out can be expected. Surface disinfection (food and feed area)	
4.2	Disinfection of food processing machinery	4 (PT 04)	Primary exposure of a professional user resulting from application (pouring & wiping / spraying & wiping) of an alcohol based, disinfectant in form of a ready-to-use product on food processing machinery and its parts in a technically ventilated production hall, e.g. a bakery (20 °C), including lower temperatures e.g. in a meat processing factory (10 °C). Secondary exposure of a professional bystander who is present in the production hall where the surface disinfection is carried out can be expected. Surface disinfection (food and feed area)	Professional

Table 40

Summary table: scenarios (non-professionals)			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1a.	application	PT1; Intensive care or other applications in hospitals and similar areas, adult, one application	non-professional users
1b.	application	PT1; Intensive care or other applications in hospitals and similar area, adult, 3 applications	non-professional users
2a.	application	PT1; Dialysis or any other applications in the private area, adult, one application	non-professional users
2b.	application	PT1; Dialysis or any other applications in the private area,	non-professional

		adult, 3 applications	users
2c.	application	PT1; Dialysis, or any other applications in the private area, child, one application	non-professional users
2d.	application	PT1; Dialysis, or any other applications in the private area, child, 3 applications	non-professional users
3a.	post-application	PT1; Secondary exposure from hand disinfection, adult	general public, bystanders
3b.	post-application	PT1; Secondary exposure from hand disinfection, child	general public, bystanders
3c.	post-application	PT1; Secondary exposure from hand disinfection, toddler	general public, bystanders
4a.	post-application	PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, adult	general public, bystanders
4b.	post-application	PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, child	general public, bystanders
4c.	post-application	PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, toddler	general public, bystanders
5a.	post-application	PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, adult	general public, bystanders
5b.	post-application	PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, child	general public, bystanders
5c.	post-application	PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, toddler	general public, bystanders

3.6.3.1.1 Industrial exposure

For the biocidal product “Antisept A”, no industrial applications are requested by the applicant.

3.6.3.1.2 Professional exposure

The biocidal product (b.p.) ‘Antisept A’ is a ready-to-use (RTU) disinfectant containing “propan-2-ol” (CAS-No.: 67-63-0, 64.73 % (w/w)) as the active substance (a.s.).

Within PT01 it is used for hygienic / surgical hand disinfection by hand rubbing. Within PT 02 it is used for disinfection of small surfaces, e.g. in the health care sector, institutional areas, pharmaceutical and cosmetic industry. Within PT 04 it is used for disinfection of small surfaces in food contact areas in canteens and kitchens and of food processing machinery.

‘Antisept A’ is marketed in the following different package sizes:

- bottle (1 L, HDPE),
- canister (5 L and 10 L, HDPE),
- drums (60 L and 200 L, coated steel),
- IBC (1000 L, HDPE).

Depending on the package size the applicant described the refilling from larger package sizes into small application bottles.

The exposure to the a.s. propan-2-ol is assessed separately for the different applications and is described in individual subsections of the current chapter.
The exposure assessment is usually based on the harmonised 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 with the corresponding parts from HEEG / HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

The inhalation exposure to the volatile active substance propan-2-ol is assessed using the consumer exposure model ConsExpo Web.

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

Due to local effects of the active substance propan-2-ol a qualitative local risk assessment is performed and described in chapter 3.6.4.5: Risk for professional users.

Scenario 1 - Hand disinfection

The exposure assessment of hand disinfection is based on the approach described in the recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure “Hand disinfection in hospitals”.

‘Antisept A’ is a ready-to-use hand disinfectant in 1-L-bottles. For hand disinfection, the liquid is applied onto dry hands which are then rubbed intensively. The disinfectant is left on the skin and evaporates off.

As a realistic worst-case scenario, it is assumed that a health care worker in a hospital performs 25 hand rubs per shift. As it is unrealistic that all 25 hand rubs are carried out in one room during an 8-h shift of a heath care worker, a more realistic exposure scenario is calculated. It is assumed that one nurse is responsible for 8 patients. During her work in a patient room, 3 hand disinfections are performed. After visiting of 4 patient rooms, she reenters the first room and performs again 3 hand disinfections in each room. In summary, 25 applications per shift are carried out.

Dermal exposure

Exposure to the skin occurs as the biocidal product is directly applied to both hands. The dermal exposure is limited to the time the disinfectant remains on the hands and calculated as described in the ad hoc working group recommendation no. 9. For a realistic worst case assumption, the total applied amount is taken into account.

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (7770 Pa (30 °C, skin temperature)). A refined calculation of the inhalation exposure for the professional user to the a.s. is carried out according to recommendation no. 9 using the consumer exposure model ConsExpo Web “Exposure to vapour: Constant rate release” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

‘Antisept A’ is taken from a bottle or dispenser and applied on the hands. The procedure is carried out below eye height so that an exposure of the eyes is not expected. Moreover, the liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure

Secondary dermal exposure of a professional bystander in the same room is not expected, because due to the high vapour pressure of the active substance the product quickly evaporates from the skin. It is possible that inhalation exposure occurs to a professional bystander who is present in the room where

the hand disinfection is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 41

Details of Scenario 1 - Hand disinfection - hygienic	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Number of hand disinfections per day	25
Volume of b.p. per application	4 ml
Exposed skin area (both hands)	820 cm²
ConsExpo Web parameters	
Room volume	80 m³
Ventilation rate	1.5 / h
Emission duration	1 min (60.55 sec*)
Product amount for one hand disinfection (Volume b.p. * density)	3.43 g
Exposure duration per application	10 min**
Mode of release	Constant rate

* calculated evaporation time at 30°C according to HEAdhoc-Recommendation No. 9
** according to HEAdhoc-Recommendation No.9

Calculations

The results of the calculation for potential inhalation and dermal exposure (Tier 1) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure.

Refilling of hand disinfection bottles (PT 01) was requested by the applicant for pharmaceutical or cosmetic industry, only (not for the health care sector due to German expert's opinion (VAH) suggesting development of microbial resistance and reduction of efficacy if refillable bottles are not cleaned, properly). Nevertheless, as worst case assessment it is considered for health care sector, also. Results of the calculation for the combined scenario, which includes refilling of the application bottles prior to the hand disinfection, are given in Table 49: Combined exposure from professional uses.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 (Safety for professional users) of this PAR. For risk characterisation, see chapter 3.6.4.5 (Risk characterisation for human health).

Further information and considerations

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. As the product is intended for the use on bare skin, personal protection measures are not applicable.

Classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. For hand disinfection by professional users, the product is applied onto the hands from a short distance in downwards direction as well as rubbed over them below eye height, so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.

Surgical hand disinfection includes both hands and forearms but due to the specific situation it is carried out less frequently than a hygienic hand disinfection, it is assumed that the exposure scenario for hygienic hand disinfection also covers the situation for surgical hand disinfection (according to HEAdhoc recommendation 1).

Scenario 2 – Small surface disinfection

- 2.1 – in between disinfection – hospital room
- 2.2 – in between disinfection – medical practices
- 2.3 – small surface disinfection in laboratory

The assessments are based on Recommendation no. 15 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc), “Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer”.

Scenario 2.1: In between disinfection in hospitals and 2.2: In between medical practices

The first two scenarios (in hospitals, in medical practices (including health care sector, institutional areas, pharmaceutical and cosmetic industry)) cover disinfection of small surfaces with an alcohol based disinfectant in naturally ventilated rooms, e.g.

- in a patient room of a hospital (80 m^3) performed by specialised cleaning personal or
- in a medical practice (20 m^3) performed by nurses and health care workers which represents a realistic worst case scenario.

They are introduced, because in the assessment report (CAR) for propan-2-ol, the scenarios for propan-2-ol consider disinfection in technically ventilated rooms as laboratory scenario, only. Alcohol based RTU products are usually applied for in between disinfection of small surfaces e.g. after contamination by a potentially infectious patient secretion.

The complete exposure assessments of both types of users are available in the Annex 4.3.1: Safety for professional users, Based on the results, scenario 2.2 (medical practices) is the worst case. Therefore, scenario 2.2 is described in more detail in the following section and is brought to risk characterisation.

For disinfection of small surfaces, the application liquid is either poured or sprayed from a hand-held bottle onto the surface or onto a wipe. Finally, the surface is wiped off. To get the alcoholic disinfectant effectively onto the surface by spraying, it is carried out directly from a very short distance. Therefore, the process relevant for inhalation exposure is evaporation of the solution from the treated surface.

The disinfectant product is used in health care industry, institutions, health care facilities, dentists, hospital rooms and isolation rooms.

Based on recommendation 15, a nurse or health care worker is expected to enter 4 naturally ventilated rooms per working day performing one surface disinfection in each room during the stay of 20 minutes in the room. Then, he/she is assumed to repeat the process revisiting each room in turn (2 visits per room per day). In total, the staff person carries out 8 surface disinfections in 4 different rooms per day. The treated surfaces for a single use in PT 02 comprise an area of 0.5 m².

Prior to application, refilling of application bottles may be performed which is assessed in scenario 3.

Dermal Exposure

During the application phase dermal exposure can be expected when the biocidal products is distributed by wiping with a wipe (e.g. a single use paper towel) in one hand. It is assumed that the area of one palm is exposed to the biocidal product during the application procedure. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5: Risk for professional users. For informational purpose, dermal exposure is calculated based on the 75th percentile value of the model BEAT ‘small scale wiping’ (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalative Exposure

Exposure to vapour occurs during the application phase due to high vapour pressure of the active substance propan-2-ol (room temperature). A calculation of the inhalation exposure for the professional

user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

For the treatment of small surfaces the application liquid is directly applied to the surface from a short distance, so that exposure to the eyes is not expected. Moreover, the application liquid rapidly evaporates and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure

Secondary dermal exposure of a professional bystander in the same room is not expected because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the room where the disinfection of a small surface is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 42

Details of Scenario 2 - Small surface disinfection in between disinfection • **2.1 hospital room** • **2.2 medical practice**	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Number of surface disinfections per day	10
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	50 ml/m²
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	80 m³ (scenario 2.1 – hospital room) 20 m³ (scenario 2.2 – medical practice)
Ventilation rate	1.5 / h
Treated surface area	0.5 m²
Product amount per application	21.47 g (25 ml)
Frequency of use	4 rooms visited (2 visits per room per day)
Exposure duration	20 min
Mode of release	evaporation

Calculations

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 49: Combined exposure from professional uses. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR: Safety for professional users. For risk characterisation, see chapter 3.6.4: Risk characterisation for human health.

Further information and considerations

Since for scenario 2.1 “Small surface disinfection - in between disinfection - hospital room” no systemic risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

For scenario 2.2 “Small surface disinfection - in between disinfection - medical practice” a risk was identified resulting from the quantitative risk assessment in Tier 1 and thus a Tier 2 refinement was calculated taking improved ventilation (cross ventilation providing an air exchange rate of 5 /h) and the use of protective gloves into account.
Classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. For disinfection of small surfaces by professional users, the product is usually applied from a short distance in downwards direction to the surface, so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.

The used paper towels have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

For refilling of 1 L-application bottles from larger storage containers, please refer to scenario 3, below.

Scenario 2.3: Small surface disinfection in laboratory

Exposure assessment of small surface disinfection in technically ventilated rooms (e.g. laboratories) is based on the approach described in the assessment report (CAR) for propan-2-ol. Alcohol based ready to use (RTU) products are applied for rapid in-between disinfection of small surfaces, e.g. prior to a new task to remove potential contamination e.g. of biomaterial from the previous task. The assessment is based on the Recommendation no. 15 of the BPC Ad hoc Working Group on Human Exposure “Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer”.

‘Antisept A’ is a ready-to-use surface disinfection solution. For the disinfection of small surfaces

- the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally the surface to be disinfected is wiped off. Or
- the application liquid is sprayed onto the surface which is then left to dry.

To get the alcoholic disinfectant effectively onto the surface by spraying, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is the evaporation of the use solution from the treated surface.

The scenario covers rapid disinfection of small surfaces in technically ventilated rooms such as laboratories. It is assumed that a staff person in a laboratory carries out 10 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 0.5 m² is commonly performed in laboratories prior to every new task to remove potential contamination e.g. of biomaterial from a previous task. As a realistic worst case scenario, it is assumed that one person

disinfects its working bench every 45 minutes in a small room and that the person does not leave the room in-between (realistic worst-case assumption).

Dermal exposure

During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with a wipe e.g. a single use paper towel in one hand. It is assumed that the area of one palm is exposed to the biocidal product. Dermal exposure is calculated via dermal flux (for details, please refer to chapter 3.6.4.5).

For informational purpose, dermal exposure is additionally calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

For the treatment of small surfaces e. g. work benches a small amount of the application liquid is directly applied to the surface from a short distance, so that exposure to the eyes is not expected. Moreover, the application liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure

Dermal exposure of a professional bystander in the same room is not expected, because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the laboratory where the disinfection of a small surface is carried out. Secondary inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 43

Details of Scenario 2.3 - Small surface disinfection in laboratory	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Number of surface disinfections per day	10 (in 10 different rooms)
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	50 ml/m²
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	25 m³
Ventilation rate	8 / h
Treated surface area	0.5 m²
Product amount per application	21.47 g (25 ml)
Exposure duration per application	45 min
Mode of release	evaporation

Calculations

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 49: Combined exposure from professional uses. 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: Risk characterisation for professional users.

Further information and considerations

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

The used paper towels have to be discarded in a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

Classification of the b.p requires additional assessment of local risks (see 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. For disinfection of small surfaces by

professional users, the product is usually applied from a short distance in downwards direction to the surface so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.

For refilling of 1 L-application bottles from larger storage containers, please refer to scenario 3, below.

Scenario 3 - Refilling

The refilling scenario covers manual filling of application bottles with the ready-to-use solution from up to 10-L storage canisters as a realistic worst case scenario. It is assumed that a (maintenance) person lifts the canister with both hands. So, refilling requires the use of an adequate funnel. After the refilling process the person closes the bottles with a screw cap and lifts the bottle to put it aside. This results in dermal exposure of 1 palm.

Dermal exposure

Exposure of the palm of one hand is expected during replacement of refilled bottles, due to spilled quantities on the outside. Dermal exposure is calculated via dermal flux (for details, please refer to chapter 3.6.4.5). For informational purpose, dermal exposure is also calculated based on “Mixing and loading model 4” (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG).

Inhalation exposure

Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the a.s. during the manual pouring of the b.p. from a bigger vessel into e.g. a trigger spray bottle.
It is assumed that the procedure in general is carried out in a small room. The modelled scenario includes a 10 min exposure phase for the loading activity and a 470 min non-exposure period. Calculation of inhalation exposure to the a.s. is carried out using the near field model of the Advanced REACH Tool 1.5 (ART) which assesses inhalation exposure to vapour during decanting. It is further assumed that the relatively small size of the opening of the canister and of the bottle reduces contact between the b.p. and adjacent air.

Exposure of the eyes

Accidental splashes to the eyes cannot be excluded during manual decanting. Even if local effects for eye irritation are taken into account via the AEL according to the CAR of propan-2-ol, it is assumed that possible eye irritation on a daily basis should be avoided. Therefore, wearing of eye protection is recommended for this task.

Secondary exposure

For a professional bystander, exposure via inhalation arising from evaporation of spills during refilling of disinfectant is possible and assumed to be in the same order of magnitude or lower as for the operator.

Dermal exposure of a professional bystander to the spills is not expected due to the high vapour pressure of the a.s.

Table 44

Details of Scenario 3 - Refilling	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ConsExpo Web parameters	
Room volume	Small workroom only
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1-1 l/minute
Containment level	Handling that reduces contact between product and adjacent air
Loading type	Splash loading

Calculations

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the hand disinfection are given in Table 49: Combined exposure from professional uses. 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: Risk for professional users.

Further information and considerations

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation Accidental splashes to the eyes cannot be excluded during manual decanting, thus, eye protection is recommended.

It is assumed that refilling from drums or IBCs is carried out by the help of **dosing pumps** or connecting lines leading to less exposure as manual decanting.

Refilling of hand disinfection bottles (PT 01) was requested by the applicant for pharmaceutical or cosmetic industry only (not for the health care sector due to German expert's opinion (VAH), suggesting development of microbial resistance and reduction of efficacy if refillable bottles are not cleaned, properly). Refilling of bottles for use in PT01 may nevertheless occur e.g. in the pharmaceutical industry.

Scenario 4.1 - Small surface disinfection in kitchens and canteens

The exposure assessment of the small surface disinfection in kitchens and canteens is based on the approach described in the assessment report (CAR) for propan-2-ol. Alcohol based ready-to-use (RTU) products are applied for rapid in-between disinfection of small surfaces, e.g. prior to a new task.

'Antisept A' is a ready-to-use surface disinfection solution. For the disinfection of small surfaces

- the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally the surface to be disinfected is wiped off. Or
- the application liquid is sprayed onto the surface which is then left to dry.

To get the alcoholic disinfectant effectively onto the surface by spraying, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

The scenario covers rapid disinfection of small surfaces in kitchens and canteens. It is assumed that a staff person in a kitchen or canteen carries out 4 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 1 m² is commonly performed in kitchens and canteens after the finish of special tasks (e.g. working with eggs or egg-containing substances). As a realistic worst case scenario, it is assumed that one person disinfects its working bench every 120 minutes in a small room and that the person does not leave the room in-between (realistic worst-case assumption).

Dermal exposure

During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with e.g. a single use paper towel in one hand. It is assumed that the area of one palm is exposed to the biocidal product during the application procedure. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.

For informational purpose, dermal exposure is calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure of the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

For the treatment of small surfaces e. g. work benches (chopping board), a small amount of the application liquid is applied to the surface from a short distance in a downward direction, so that exposure to the eyes is not expected. Moreover, the liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure

Secondary dermal exposure of a professional bystander in the same room is not expected, because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the kitchen or canteen where the disinfection of a small surface is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 45

Details of Scenario 4.1 - Small surface disinfection in kitchens and canteens	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Number of surface disinfections per day	4 (in 1 room)
Exposed skin area (one palm)	205 cm²
Application duration	2 min
Application rate	50 ml/m²
Temperature (room)	25° C
ConsExpo Web parameters	
Room volume	25 m³
Ventilation rate	15 / h
Treated surface area	1 m²
Product amount per application	42.94 g (50 ml)
Exposure duration	120 min
Mode of release	Evaporation

Calculations

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 49: Combined exposure from professional uses. 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

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

The used paper towels have to be discarded in a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. For disinfection of small

surfaces by professional users the product is usually applied from a short distance on the surface in downwards direction so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.

This scenario also covers the application of propan-2-ol based disinfectants for disinfection of small surfaces in e.g. supermarkets, which have a larger room volume but a lower air exchange rate.

For refilling of 1 L-application bottles from larger storage containers, please refer to scenario 3, above.

Scenario 4.2 - Disinfection of food processing machinery

The exposure assessment for disinfection in food contact areas and of food processing machinery is based on the approach described in the assessment report (CAR) for propan-2-ol.

'Antisept A' is a ready-to-use surface disinfection solution. For the disinfection of small surfaces

- the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally the surface to be disinfected is wiped off. Or
- the application liquid is sprayed onto the surface which is then left to dry.

To get the alcoholic disinfectant effectively onto the surface by spraying, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

The scenario covers disinfection of food processing machinery. It is assumed that a staff person in a production hall of e.g. a bakery or brewery (20° C) carries out 4 disinfections of food processing machinery per day, e.g. after the finishing of special tasks (e.g. handling with eggs or egg-containing food). According to the CAR for propan-2-ol, the alcoholic disinfection of a cutting machine and a packaging machine - and thus of a total surface of approx. 4.6 m² - is a representative task for disinfection of food processing machinery.
The scenario represents a slightly modified version of the respective scenario in the assessment report (CAR) for propan-2-ol. In the present scenario, the worker is present in the production hall for the complete working day and performs disinfection every 120 min whereas in the CAR he leaves the production hall for a short break after the disinfections. Also, this scenario considers a production hall with a temperature of 20°C instead of 10°C as in contrast to the CAR for propan-2-ol, disinfections are also intended for the use in e.g. bakeries or breweries. The changes to the corresponding scenario of the CAR for propan-2-ol only trigger negligible deviations in exposure.

Dermal exposure

During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping e.g. with a single use paper towel in one hand. Both hands are used for wiping of the food processing machinery and its parts, which may not be easily accessible. It is assumed that the palms of both hands are exposed to the product. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5. For informational purpose dermal exposure was calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure of the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

Disinfection of the food processing machinery may include the treatment of not easily accessible parts of the machinery, which also may be in the height of the operator’s face. Thus, incidental exposure of eyes to the biocidal product is possible to occur. Even if the local effects for eye irritation are taken into account via the AEL according to the CAR of propan-2-ol, it is assumed that possible eye irritation on a daily basis should be avoided and therefore wearing of eye protection for this task is recommended.

Secondary exposure

Secondary dermal exposure of a professional bystander in the same production hall is not expected because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface.

It is possible that inhalation exposure occurs to a professional bystander who is present in the production hall where the surface disinfection is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 46

Details of Scenario 4.2 - Disinfection of food processing machinery	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	64.73 % (w/w)
Density of the b.p.	0.8587 g/cm³
Number of surface disinfections	4 per day
Exposed skin area (two palms)	410 cm²
Application duration	5 min
Application rate	50 ml/m²
Temperature (room)	20° C
ConsExpo Web parameters	
Room volume production hall	1584 m³
Room volume around the machine (near field)*	300 m³
Treated surface area	4.6 m²
Ventilation rate	20 / h
Product amount per application	197.5 g (230 ml)
Exposure duration per application	120 min
Mode of release	Evaporation

Calculations for scenario 4.2

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47: Estimated exposure from professional uses and Table 48: Exposed skin area and application time for dermal exposure. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 49: Combined exposure from professional uses. 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

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

This scenario also covers the disinfection of food processing machinery at lower temperature which is applicable e.g. in a meat processing factory (10 °C). The decrease in temperature triggers a slight decrease in inhalation exposure, only.

The used paper towels have to be discarded in a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from the used towels.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. As for disinfection of food processing machinery the product is applied on surfaces and also in eye height, eye contact can occur and the use of eye protection is necessary.

For refilling of application bottles from larger storage containers, please refer to scenario 3, above.

Summary of professional exposure

The following tables give an overview of the assessed exposure values. In Table 47, the estimated external inhalation exposure and external dermal exposure are listed. In Table 48, the values of the assumed exposed skin area and application time for dermal exposure are summarised. In chapter 3.6.3.5, Table 57, the internal total exposure (total uptake) is available. In Annex 4.3.1: Safety for professional users, the external and internal exposure values are available for the scenarios.

Table 47

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenario	**Use no. (Product type)**	**Tier/PPE**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1: Hand disinfection - hygienic	1 (PT 01)	Tier 1	12.47	55584*
Scenario 2.a: Small surface disinfection in – in between disinfection – hospital room	3 (PT 02)	Tier 1	40.08	952*
		Tier 2 (Protective gloves)	40.08	95.16*
Scenario 2.b: Small surface disinfection – in between disinfection – medical pratice	3 (PT 02)	Tier 1	157	952*
		Tier 2 (Improved ventilation / air exchange rate of 5/h; protective gloves)	103	95.16*
Scenario 2.c: Small surface disinfection in laboratory	3 (PT 02)	Tier 1	86.72	1189*
		Tier 2 (Protective gloves)	86.72	119*
Scenario 3: Refilling	1, 3 and 4 (PT 01, 2, 4)	Tier 1	0.79	4.29*
		Tier 2 (Protective gloves)	0.79	0.43*
Scenario 4.a: Small surface disinfection in kitchens and canteens	4 (PT 04)	Tier 1	37.20	952*
		Tier 2 (Protective gloves)	37.20	95.16*
Scenario 4.b: Disinfection of food processing machinery	4 (PT 04)	Tier 1	11	2379*
		Tier 2 (Protective gloves)	11	238*

*) The dermal risk assessment is based on calculation of dermal flux, which does not include the external dermal exposure. In this case, the PPE protective gloves is not considered.

Table 48

Summary table - Exposed skin area and application time for dermal exposure.						
Scenario	**Product type**	**Application time [min]**	**Application frequency/ day**	**Exposed skin area [cm²]**	**Exposed hand (palm) surfaces**	**Application time/day [min]**
Scenario 1: Hand disinfection - hygienic	PT 01	1.01	25	820	2 hands	25.23
Scenario 2.1: Small surface disinfection -in between disinfection - hospital room	PT 02	1	8	205	1 palm	8
Scenario 2.2: Small surface disinfection – in between disinfection –medical practice	PT 02	1	8	205	1 palm	8
Scenario 2.3: Small surface disinfection in laboratory and biotechnology	PT 02	1	10	205	1 palm	10
Scenario 3: Refilling	PT 01/ PT 02/ PT 04	0.50	1	205	1 palm	0.50
Scenario 4.1: Small surface disinfection in kitchens and canteens	PT 04	2	4	205	1 palm	8
Scenario 4.2: Disinfection of food processing machinery	PT 04	5	4	410	2 palms	20

Combined scenarios

If refilling of small application bottles is carried out by the same staff members as the disinfection itself, exposure from both scenarios has to be combined.

Table 49

Summary table: combined exposure from professional uses For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenario	**Use no. (Product type)**	**Tier/PPE*)**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1.a: Hand disinfection and Scenario 3: Refilling	1 (PT 01)	Tier 1	13.26	55588*
		Tier 2 (Protective gloves for refilling)	13.26	55584*
Scenario 2.a: Small surface disinfection – in between – hospital room and Scenario 3: Refilling	3 (PT 02)	Tier 1	40.87	956*
		Tier 2 (Protective gloves)	40.87	95.59*
Scenario 2.b: Small surface disinfection – in between – medical practice and Scenario 3: Refilling	3 (PT 02)	Tier 1	158	956*
		Tier 2 (Improved ventilation / air exchange rate of 5/h; protective gloves)	104	95,59*
Scenario 2.c: Small surface disinfection in laboratory and Scenario 3: Refilling	3 (PT 02)	Tier 1	87.51	1194*
		Tier 2 (Protective gloves)	87.51	119*
Scenario 4.a: Small surface disinfection in kitchens and canteens and Scenario 3: Refilling	4 (PT 04)	Tier 1 (Eye protection)	37.49	1230
		Tier 2 (Protective gloves)	37.49	123
Scenario 4.b: Disinfection of food processing machinery and Scenario 3: Refilling	4 (PT 04)	Tier 1	11.89	2383
		Tier 2 (Protective gloves)	11.89	238

*) The dermal risk assessment is based on calculation of dermal flux, which does not include the external dermal exposure. In this case, the PPE protective gloves is not considered.

3.6.3.1.3 Non-professional exposure

In accordance to efficacy studies, the applicant assumes that the non-professionals will apply alcohol-based hand rubs (4 mL per event) only occasionally for hygienic reasons when entering/leaving hospitals or for hygiene reasons at home. Therefore, 3 events/day each with an application rate of 4 mL are assumed as reasonable. In the CAR two scenarios are described. In scenario 1 three-fold use of 3 mL product is assumed for a visitor in a hospital. In scenario 2 up to one application of 3 mL in the household (e.g. for home-dialysis patients) was assumed. These scenarios are also representative for this biocidal product and therefore, they were used in the PAR. However, the application amount was increased to 4 mL and the concentration of the active substance was adapted.

The exposure assessments for non-professional users according to the CAR are based on the TNsG models/defaults and Consexpo 4.1. Although the CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal products of the BPF that new agreements on some parameters such as HEEG opinions are applicable. Therefore, the exposure assessments for non-professional users are amended accordingly.

The applications assessed according to the listed scenarios are considered to represent also a realistic worst case for all other potential applications.

Based on a propan-2-ol concentration of 70 % (v/v) German authorities estimated a mass per mass concentration of 64.73 %. However, on the BPC 29 a slightly different transformation method was agreed resulting in a concentration of 64 % (w/w). The exposure and risk assessment was finalised before this agreement. Since this slightly lower concentration does not change the final outcome of the risk assessment, the corresponding section of the PAR was not revised.

- **Scenario [1]**

Table 50

Description of Scenario [1]		
PT1: Primary exposure, intensive care or other applications in hospitals and similar areas: Visitors of patients in intensive health care units have to disinfect their hands before entry. Access is usually limited to adults. It is assumed that up to 3 applications are performed per day. It was expected that the minimum room size for patients is about 25 m^3. This would be equivalent to an area of 10 m^2 and a height of 2.5 m, which is expected to be a minimum for patient rooms in hospitals. The air changing rate in normal intensive care units is about 3 h^{-1} according to German DIN 1946-4 (2207). It is assumed that application is a serial event within the time of 2.5 h. Additional uses of the same biocidal product by other persons are not considered. The scenario was calculated in line with the CAR for the active substance with some amendments regarding default parameters. For dermal exposure as a worst case scenario it is assumed that the total applied volume of the biocidal product (4 mL) covers completely the surface of the hands (820 cm^2). This would result in a total amount of 2223 mg propan-2-ol. Exposure is limited to the time until the active substance is evaporated. Time of evaporation for propan-2-ol was calculated according to the TGD on Risk Assessment, App. I, App. IF (2003) as given below: According to this equation the evaporation time is about 65 s. The absorption/dermal flux rate for propan-2-ol in a 70 % aqueous dilution on rat skin has been estimated as 0.85 mg cm^{-2} h^{-1} (Boatman et al. 1998) and considered applicable for this biocidal product.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g mol^{-1}
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05

	Exposure frequency (CAR, propan-2-ol, 2014)	3 d^{-1}
	Body weight, adult (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Weight fraction compound (applicant)	64.73 % (w/w)
	Inhalation model: Exposure to vapour – instantaneous release	
	Exposure duration (CAR, propan-2-ol, 2014)	2.5 h
	Room volume (CAR, propan-2-ol, 2014)	25 m^3
	Ventilation rate (German DIN 1946-4, 2007)	3 hr^{-1}
	Applied amount (applicant)	3.43 g (4 mL)
	Inhalation rate, adult (short- and long-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.25 m^3/h (0.021 m^3/min)
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	65 sec per application/event (rounded)
	Frequency (CAR, propan-2-ol, 2014)	3 d^{-1}
	Exposed area (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	820 cm^2 (two hands)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 mg cm^{-2} h^{-1}

Calculations for Scenario 1

Inhalation exposure is calculated according to ConsExpo 4.1. For the corresponding Consexpo report refer to the section 4.3.2

Inhalation exposure = 0.62 mg/kg bw (1 application)
= 1.85 mg/kg bw/d (3 applications)

For dermal exposure the evaporation time (see table above) is calculated according to the following equation (the density of the biocidal product is 0.8587 g/cm^3):

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 62 s (rounded 65 s = 0.01806 h)

t: time [s]	
m: mass of propan-2-ol on surface:	2223 mg (= appl. rate x density x conc. a.s)
R: gas constant:	8.314 J K^{-1} mol^{-1}
T: skin/surface temperature:	303.15 K
M: molar mass:	60.1 g mol^{-1}
β: mass transfer coefficient, for calculation see TGD:	8.7 m h^{-1}
p: vapour pressure of the pure substance:	7600 Pa (30 °C)
A: surface area (hands):	820 cm^2
K: conversion factor:	36000

With the parameters in the table above the dermal exposure is calculated:

Dermal exposure = dermal flux rate x evaporation time x hand surface / body weight
= 0.85 mg cm^{-2} h^{-1} x 0.01806 h x 820 cm^2 / 60 kg
= 0.21 mg/kg bw (1 application)
= 0.63 mg/kg bw/d (3 applications)

- **Scenario [2]**

Table 51

Description of Scenario [2]		
PT1; Primary exposure, dialysis and other applications in the private area: Patients performing home dialysis have to disinfect their hands before the operation. However, this scenario is considered applicable for any other hand disinfection in the private area. A dialysis is performed maximum once each day. However, in specific cases hand disinfection will be performed more frequently in private households. Hence, a maximum application rate of 3 d^{-1} is also assessed. Thus, patients are daily and therefore chronically exposed to the biocidal product and the active substance. The room volume is assumed as 25 m^3. This would be equivalent to a (small) room with an area of 10 m^2 and 2.5 m height. The air exchange rate in private houses and the exposure duration are assumed to be 0.6 h^{-1} and 10 h, respectively. The scenario was calculated in line with the active substance CAR with some amendments regarding default parameters. It is expected that persons performing home dialysis are of low activity and exercise level. Therefore, the inhalation rate for long-term exposure according to the HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017 (16 m^3/d = 0.67 m^3/h) was selected. The biocidal product is used by adults and children but not by toddlers.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g mol^{-1}
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 d^{-1} / 3 d^{-1}

	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Body weight, child, 6 – 11 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Weight fraction compound (applicant)	64.73 % (w/w)
	Inhalation model: Exposure to vapour – instantaneous release	
	Exposure duration (CAR, propan-2-ol, 2014)	10 h
	Room volume (CAR, propan-2-ol, 2014)	25 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	0.6 hr^{-1}
	Applied amount (applicant)	3.43 g (4 mL)
	Inhalation rate, adult (long-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.67 m^3/h (16 m^3/d)
	Inhalation rate, child, 6 – 11 y (long-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.5 m^3/h (12 m^3/d)
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	65 sec per application/event (rounded)
	Exposed area, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	820 cm^2 (two hands)
	Exposed area, child, 6 – 11 y (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	427.8 cm^2 (two hands)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 mg cm^{-2} h^{-1}

Calculations for Scenario [2]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to section 4.3.2.

2a/b. Adults

Inhalation exposure = 1.65 mg/kg bw/d (1 application)

= 4.95 mg/kg bw/d (3 applications)

2c/d. Children

Inhalation exposure = 3.10 mg/kg bw/d (1 application)
= 9.29 mg/kg bw/d (3 applications)

For dermal exposure the evaporation time (see table above) is calculated according to the following equation (the density of the biocidal product is 0.8587 g/cm^3):

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 62 s (rounded 65 s = 0.01806 h)

t: time [s]
m: mass of propan-2-ol on surface: 2223 mg (= appl. rate x density x conc. a.s)
R: gas constant: 8.314 J K^{-1} mol^{-1}
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g mol^{-1}
β: mass transfer coefficient, for calculation see TGD: 8.7 m h^{-1}
p: vapour pressure of the pure substance: 7600 Pa (30 °C)
A: surface area (hands): 820 cm^2
K: conversion factor: 36000

With the parameters in the table above the dermal exposure is calculated:

2a. + 2b. Adults
Dermal exposure = dermal flux rate x evaporation time x hand surface / body weight
= 0.85 mg cm^{-2} h^{-1} x 0.01806 h x 820 cm^2 / 60 kg
= 0.21 mg/kg bw/d (1 application)
= 0.63 mg/kg bw/d (3 applications)

2c.+ 2.d. Children
Dermal exposure = 0.85 mg cm^{-2} h^{-1} x 0.01806 h x 427.8 cm^2 / 23.9 kg
= 0.27 mg/kg bw/d (1 application)
= 0.82 mg/kg bw/d (3 applications)

Table 52

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1a] PT1; Intensive care or other applications in hospitals and similar areas, adult, one application	1	0.62	0.21	-	0.83

Scenario [1b] PT1; Intensive care or other applications in hospitals and similar areas, adult, 3 applications	1	1.85	0.63	-	2.48
Scenario [2a] PT1; Dialysis or any other applications in the private area, adult, one application	1	1.65	0.21	-	1.86
Scenario [2b] PT1; Dialysis or any other applications in the private area, adult, 3 applications	1	4.95	0.63	-	5.58
Scenario [2c] PT1; Dialysis, or any other applications in the private area, child, one application	1	3.10	0.27	-	3.37
Scenario [2d] PT1; Dialysis, or any other applications in the private area, child, 3 applications	1	9.29	0.82	-	10.11

- **Combined scenarios**

Combination of primary exposure scenarios for non-professional users is not considered relevant.

Simultaneous exposure on the same day to both scenarios is very unlikely.

3.6.3.1.4 Secondary exposure of the general public

- **Scenario [3]**

Table 53

Description of Scenario [3]
PT1; Secondary exposure from hand disinfection Secondary inhalation exposure may occur to bystanders (general public) in a room where hand disinfection is performed (e.g. in a hospital by medical staff). The maximum aerial concentration of propan-2-ol after professional use for hand disinfection is 12.5 mg/m^3. This value is higher than the maximum concentration after non-professional use (scenario 1: 8.7 mg/m^3; scenario 2: 11.2 mg/m^3). Hence, the value of 12.5 mg/m^3 is used for exposure assessment as a worst case. Defaults according to HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products (2017) are used. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.

	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.2, Table 47)	12.5 mg/m³
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler (HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Exposure duration (CAR, propan-2-ol, 2014)	2.5 h
	Inhalation rate, adult (short-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.25 m³/h
	Inhalation rate, child, 6 – 11 y (short-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.32 m³/h
	Inhalation rate, toddler (short-term, HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [3]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

3a. Adults

Inhalation exposure = 12.5 mg/m³ x 1.25 m³/h x 2.5 h x 100 % / 60 kg

0.65 mg/kg bw/d

3b. Children

Inhalation exposure = 12.5 mg/m³ x 1.32 m³/h x 2.5 h x 100 % / 23.9 kg

1.73 mg/kg bw/d

3c. Toddlers

Inhalation exposure = 12.5 mg/m³ x 1.26 m³/h x 2.5 h x 100 % / 10 kg

3.94 mg/kg bw/d

- **Scenario [4]**

Table 54

Description of Scenario [4]		
PT2; Secondary exposure from small surface disinfection by professional users (healthcare and institutional areas). Secondary inhalation exposure may occur to bystanders (general public) in a room where surface disinfection has been performed. Particularly for institutional areas and healthcare areas such an exposure must be expected. The following assessment refers to exposure from application by medical stuff in hospitals. Based on the long exposure time this scenario is considered sufficiently conservative also for other applications in institutional or healthcare areas. The maximum aerial concentration of propan-2-ol after professional use for such an application is 40.1 mg/m³ (8-h-TWA, 3.6.3.1.2, Table 47). Even if this value has been estimated for a professional user performing disinfection in different rooms (based on data in the file Profi Antisept A.xlsx embedded in section **Fehler! Verweisquelle konnte nicht gefunden werden.**) it can be assumed that the concentration for a patient staying the whole time in the same room will not be higher. This value was applied for exposure assessment. Defaults according to HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products (2017) are used. It is assumed that a person (patient) stays for 24 h in such a room. Hence, inhalation rates for long-term exposure are applied. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable. The time weighted average for professional users refers to 8 h exposure. Taken into consideration a time interval of 24 h (the exposure time of a patient in a hospital room) the value is only about 13.36 mg/m³. This value was used for Tier 2.		
	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.2, Table 47)	40.1 mg/m³
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler (HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Exposure duration (expert judgement)	24 h
	Inhalation rate, adult (long-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	16 m³/d

	Inhalation rate, child, 6 – 11 y (long-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	12 m³/d
	Inhalation rate, toddler (long-term, HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	8 m³/d
	Uptake fraction (inhalation absorption)	100 %
Tier 2	Aerial concentration (expert judgement, see above)	13.36 mg/m³

Calculations for Scenario [4]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

Tier 1

4a. Adults

Inhalation exposure = 40.1 mg/m³ x 16 m³/d x 1 d x 100 % / 60 kg
10.69 mg/kg bw/d

4b. Children

Inhalation exposure = 40.1 mg/m³ x 12 m³/d x 1 d x 100 % / 23.9 kg
20.13 mg/kg bw/d

4c. Toddlers

Inhalation exposure = 40.1 mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg
32.08 mg/kg bw/d

Tier 2

4a. Adults

Inhalation exposure = 13.36 mg/m³ x 16 m³/d x 1 d x 100 % / 60 kg
3.56 mg/kg bw/d

4b. Children

Inhalation exposure = 13.36 mg/m³ x 12 m³/d x 1 d x 100 % / 23.9 kg
6.71 mg/kg bw/d

4c. Toddlers

Inhalation exposure = 13.36 mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg
10.69 mg/kg bw/d

- **Scenario [5]**

Table 55

Description of Scenario [5]		
PT4; Secondary exposure from small surface disinfection in kitchens and canteens Secondary exposure of bystanders (general public) after professional application in kitchens and canteens is probably a rare event. The general public has normally no access to areas where such surfaces are treated. They will only stay in the dining room, which is usually not in the vicinity of the treated surfaces. In addition disinfection will normally be performed at the end of working day, when the canteens or restaurants are already closed and bystanders are not present. However, as a worst case it is assumed that bystanders are exposed to the same aerial concentration than the professional user. An exposure duration of 1 h equivalent to a long lunch break is assumed. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.		
	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.2, Table 47)	37.2 mg/m³
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler (HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Exposure duration (expert judgement)	1 h
	Inhalation rate, adult (short-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.25 m³/h
	Inhalation rate, child, 6 – 11 y (short-term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.32 m³/h
	Inhalation rate, toddler (short-term, HEAdhoc recommendation No.14, Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [5]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

5a. Adults

Inhalation exposure = 37.2 mg/m³ x 1.25 m³/h x 1 h x 100 % / 60 kg

0.78 mg/kg bw/d

5b. Children

Inhalation exposure = 37.2 mg/m³ x 1.32 m³/h x 1 h x 100 % /23.9 kg

2.05 mg/kg bw/d

5c. Toddlers

Inhalation exposure = 37.2 mg/m³ x 1.26 m³/h x 1 h x 100 % / 10 kg

4.69 mg/kg bw/d

Table 56

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3a] PT1; Secondary exposure from hand disinfection, adult	1	0.65	-	-	0.65
Scenario [3b] PT1; Secondary exposure from hand disinfection, child	1	1.73	-	-	1.73
Scenario [3c] PT1; Secondary exposure from hand disinfection, toddler	1	3.94	-	-	3.94
Scenario [4a] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, adult	1	10.69	-	-	10.69
	2	3.56	-	-	3.56
Scenario [4b] PT2: Secondary exposure from disinfection of small surfaces by professional users, child	1	20.13	-	-	20.13
	2	6.71	-	-	6.71
Scenario [4c] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, toddler	1	32.08	-	-	32.08

	2	10.69	-	-	10.69
Scenario [5a] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, adult	1	0.78	-	-	0.78
Scenario [5b] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, child	1	2.05	-	-	2.05
Scenario [5c] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, toddler	1	4.69	-	-	4.69

- **Combined scenarios**

Combination of scenarios for non-professional and secondary exposure of the general public is considered not relevant. These scenarios are very specific and it is very unlikely that they will occur on the same day.

3.6.3.2 Dietary exposure

The intended use descriptions of the propan-2-ol-containing biocidal product for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The products are to be used as hand or surface disinfectants that do not come into direct contact with food, feedstuff or livestock animals. Even so, use as a non-professional hand disinfectant or as surface disinfectant in food/feed processing areas could potentially lead to transfer of residues onto food. However, due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from treated hands or surfaces to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-2-ol as a biocide in PT 1, PT 2 or PT 4 can be excluded.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not applicable.

3.6.3.5 Summary of exposure assessment

Table 57

Scenarios and values to be used in risk assessment (professional)			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE[2)]**	**Estimated total uptake[3)]** **mg/kg bw/d**
1 Hand disinfection – hygienic[1)]	Professionals	Tier 1	6.96
2.1 Small surface disinfection – in between disinfection – hospital room [1)]	Professionals	Tier 1	7.07
2.2 Small surface disinfection - in between disinfection - medical practice	Professionals	Tier 2 (Improved ventilation / air ex-change rate of 5/h)	17.61
2.3 Small surface disinfection in laboratory and biotechnology[1)]	Professionals	Tier 1	14.94
3 Refilling[1)]	Professionals	Tier 1	0.16
4.1 Small surface disinfection in kitchens and canteens[1)]	Professionals	Tier 1	6.59
4.2 Disinfection of food processing machinery[1)]	Professionals	Tier 1	3.77

1) For secondary exposure of the scenarios it is assumed that inhalation exposure is in the same order of magnitude, dermal exposure is not expected
2) The tier for which a safe use is observed is listed in the table above
3) For calculation of total uptake (estimated inhalation uptake and dermal flux), please refer to chapter 3.6.4.5.

Table 58

Scenarios and values to be used in risk assessment (non-professional)			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1a.	Non-professional user; PT1; Intensive care or other applications in hospitals and similar areas, adult, one application	1	0.83 mg/kg bw/d
1b.	Non-professional user; PT1; Intensive care or other applications in hospitals and similar areas, adult, 3 applications	1	2.48 mg/kg bw/d
2a.	Non-professional user; Non-professional user; PT1; Dialysis or any other applications in the private area, adult, one application	1	1.86 mg/kg bw/d
2b.	Non-professional user; PT1; Dialysis or any other applications in the private area, adult, 3 applications	1	5.58 mg/kg bw/d
2c.	Non-professional user; PT1; Dialysis, or any other applications in the private area, child, one application	1	3.37 mg/kg bw/d
2d.	Non-professional user; PT1; Dialysis, or any other applications in the private area, child, 3 applications	1	10.11 mg/kg bw/d
3a.	General public, bystander; PT1; Secondary exposure from hand disinfection, adult	1	0.65 mg/kg bw/d
3b.	General public, bystander; PT1; Secondary exposure from hand disinfection, child	1	1.73 mg/kg bw/d
3c.	General public, bystander; PT1; Secondary exposure from hand disinfection, toddler	1	3.94 mg/kg bw/d
4a.	General public, bystander; PT2: Secondary exposure from disinfection of small surfaces by professional users healthcare and institutional areas, adult	1	10.69 mg/kg bw/d
		2	3.56 mg/kg bw/d

4b.	General public, bystander; PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, child	1	20.13 mg/kg bw/d
		2	6.71 mg/kg bw/d
4c.	General public, bystander; PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, toddler	1	32.08 mg/kg bw/d
		2	10.69 mg/kg bw/d
5a.	General public, bystander; PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, adult	1	0.78 mg/kg bw/d
5b.	General public, bystander; PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, child	1	2.05 mg/kg bw/d
5c.	General public, bystander; PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, toddler	1	4.69 mg/kg bw/d

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 shown in Table 59.

Table 59

Reference values of the active substance propan-2-ol					
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
AEL acute/medium/long-term General population	Human volunteer (Sethre et al., 2000a)		6.4		10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)
AEL acute/medium/long-term Professional workers	Human volunteer (Sethre et al., 2000a)		3.8		17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)
Dermal absorption	Boatman et al., 1998				Absorption rate (transdermal flux) in rat study: 0.85 mg/cm^2/h for aqueous solution containing 70 % propan-2-ol (by weight) Since the biocidal product (dummy) consists only of the active substance and water toxicological properties can be derived from data provided for the active substance.
Inhalative absorption	Assessment-Report (RMS DE (2014))				100 %
Oral absorption	Slauter et al., 1994				Nearly complete following oral, inhalation and intravenous exposure.

3.6.4.2 Maximum residue limits or equivalent

MRLs are not required.

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

General considerations

The biocidal product Antisept A contains propan-2-ol (CAS No.: 67-63-0) as active substance. The occupational risk assessment takes into account systemic and local effects of the active substance propan-2-ol.

Systemic effects

The primary toxic effect of the active substance propan-2-ol is acute CNS depression (central nervous system depression) and results in the classification of the biocidal product Antisept A with H336 (May cause drowsiness or dizziness). The risk characterisation for systemic effects of propan-2-ol is performed with the AEL approach. In this approach total internal body burden (total uptake) is compared 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 Antisept A.

Details of risk characterisation

Reference value

As reference value the $AEL_{long\text{-}term}$ of 52.6 ppm propan-2-ol is used. This external reference value corresponds to a systemic $AEL_{long\text{-}term}$ of 17.9 mg propan-2-ol/kg bw/d.

Calculation of total uptake and exposure-to-AEL ratio (%)

The calculation of dermal uptake significantly depends on the methodology used for calculation of dermal absorption. Due to rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm²/h) instead of data

on percentage of dermal absorption is used for the calculation of the dermal uptake. For inhalation route 100 % is assumed as default absorption for propan-2-ol. The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal product Antisept A 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 %.

Dermal uptake (mg/kg bw/d) = dermal flux of propan-2-ol (mg/cm^2/h) x exposed skin area (cm^2) x application time/day (h) / 60 kg.

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 propan-2-ol resulting from the use of the biocidal product Antisept A is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 60 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal product Antisept A. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 60. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 60, the scenarios “hand disinfection – hygienic”, “small surface disinfection – in between disinfection – hospital room”, “small surface disinfection in laboratory”, “small surface disinfection in kitchens and canteens” as well as “disinfection of food processing machinery and ”refilling”) yield an exposure-to-AEL ratio of less than 100 % already in Tier 1. By contrast, for the scenario ‘small surface disinfection – in between disinfection – medical practices’ 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.

Risk assessment results of all scenarios that are shown in Table 61 are regarded as worst case assumptions for risk assessment of the respective secondary exposure. As mentioned in chapter 3.6.3 dermal exposure of the bystander, i.e. secondary dermal exposure, is not expected for any of the scenarios mentioned in Table 60. Inhalation exposure of the bystander, i.e. secondary inhalation exposure, is assumed to be in the same order of magnitude or lower than exposure of the operator for the scenarios mentioned in Table 60.

Table 60 Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal product Antisept A

Scenario		$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Exposure-to-AEL ratio %	Acceptable (yes/no)
Hand disinfection - hygienic	Tier 1	17.9	2.08	4.89	6.96	38.9	yes
Small surface disinfection - in between disinfection - hospital room	Tier 1	17.9	6.68	0.39	7.07	39.5	yes
Small surface disinfection – in between disinfection – medical practices	Tier 1	17.9	26.17	0.39	26.55	148.3	no
	Tier 2	17.9	17.22	0.39	17.61	98.4	yes
Small surface disinfection in laboratory	Tier 1	17.9	14.45	0.48	14.94	83.4	yes
Small surface disinfection in kitchens and canteens	Tier 1	17.9	6.20	0.39	6.59	36.8	yes
Disinfection of food processing machinery	Tier 1	17.9	10.58	1.94	12.52	69.9	yes
Refilling	Tier 1	17.9	0.13	0.02	0.16	0.9	yes

Tier 1: no PPE (hand disinfection – hygienic, small surface disinfection - in between disinfection – hospital room, small surface disinfection - in between disinfection – medical practice, small surface disinfection in laboratory, small surface disinfection in kitchens and canteens).

Eye protection (refilling, disinfection of food processing machinery).

Tier 2: Increased ventilation rate of 5/hour (small surface disinfection – in between disinfection – medical practise).

[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100 % absorption by inhalation

[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60 kg, application time/day and exposed skin area see Table 51 (chapter 3.6.3).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the intended uses “hand disinfection – hygienic”, “small surface disinfection - in between disinfection - hospital room”, “small surface disinfection – in between disinfection – medical practices”, “small surface disinfection in laboratory”, “small surface disinfection in kitchens and canteens”, “disinfection of food processing machinery” as well as from refilling at the latest after Tier 2 consideration.

The risk characterisation for scenarios is regarded as worst case assumption for the respective secondary exposure scenarios. Therefore, a risk for professional users resulting from secondary exposure is unlikely since the respective rísk characterisation consistently yields exposure-to-AEL ratios of less than 100 % at the latest after Tier 2 consideration.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance propan-2-ol and no substances of concern.

Nevertheless, a risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A risk for professional users referring to the active substance propan-2-ol resulting from the combined uses of the biocidal product Antisept A is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 61 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal product Antisept A. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 61. However, the underlying calculations are based on unrounded exposure values. As shown in Table 61, the combined scenarios “hand disinfection – hygienic + refilling”, “small surface disinfection - in between disinfection - hospital room + refilling”, “small surface disinfection in laboratory + refilling”, “small surface disinfection in kitchens and canteens + refilling” and “disinfection of food processing machinery + refilling” yield an exposure-to-AEL ratio of less than 100 % already in Tier 1. By contrast, for the combined scenario “small surface disinfection – in between disinfection – medical practices + refilling” 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 61 Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenarios for the biocidal product Antisept A

Combined Scenario		$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake[1] mg/kg bw/d	Estimated dermal uptake[2] mg/kg bw/d	Estimated total uptake mg/kg bw/d	Exposure-to-AEL ratio %	Acceptable (yes/no)
Hand disinfection - hygienic + refilling	Tier 1	17.9	2.21	4.91	7.12	39.77	yes
Small surface disinfection – in between disinfection – hospital room + refilling	Tier 1	17.9	6.81	0.41	7.22	40.4	yes
Small surface disinfection – in between disinfection – medical practices + refilling	Tier 1	17.9	26.30	0.41	26.71	149.2	no
	Tier 2	17.9	17.35	0.41	17.77	99.2	yes
Small surface disinfection in laboratory + refilling	Tier 1	17.9	14.58	0.51	15.09	84.3	yes
Small surface disinfection in kitchens and canteens + refilling	Tier 1	17.9	6.33	0.41	6.74	37.7	yes
Disinfection of food processing machinery + refilling	Tier 1	17.9	1.97	1.96	3.93	21.9	yes

Tier 1: no PPE (hand disinfection – hygienic + refilling, small surface disinfection – in between disinfection- hospital room + refilling (eye protection for refilling), small surface disinfection – in between disinfection – medical practices + refilling, small surface disinfection in laboratory + refilling, small surface disinfection in kitchens and canteens + refilling, disinfection of food processing machinery + refilling).

Tier 2: Increased ventilation rate of 5/hour (small surface disinfection – in between disinfection- medical practices + refilling).

[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100% absorption by inhalation

[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60kg, application time/day and exposed skin area see Table 51 (chapter 3.6.3).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the combined scenarios “hand disinfection – hygienic + refilling“, “small surface disinfection - in between disinfection - hospital room + refilling“, “small surface disinfection - in between disinfection – medical practice + refilling“, “small surface disinfection in laboratory + refilling“, “small surface disinfection in kitchens and canteens + refilling“ and “disinfection of food processing machinery + refilling“ is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % at the latest after Tier 2 consideration.

Local effects

The local toxicity profile of the active substance propan-2-ol is also considered. The active substance propan-2-ol has eye irritating properties and therefore leads to classification of the biocidal product Antisept A with H319 (Causes serious eye irritation). In addition, the biocidal product Antisept A has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking). Therefore a qualitative risk assessment for local effects regarding skin and eye contact is necessary. The allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) is “low” (Table 62).

Table 62 Relevant classification and resulting hazard categories

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 (2015)
100 (RTU) (64,73 % (w/w) a.s.)	Eye Irrit. 2, (H319) EUH066	low

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 (2017) Table 63 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of the biocidal product Antisept A for the intended uses “hand disinfection – hygienic“, “small surface disinfection - in between disinfection - hospital room“, “small surface disinfection – in between disinfection – medical practices“, “small surface disinfection in laboratory“, “small surface disinfection in kitchens and canteens“, “disinfection of food processing machinery“ as well as “refilling“. With the proposed protection measures the reduction of dermal and eye contact minimizes the anticipated health risk to an acceptable level for the intended uses.

Table 63 Summary of qualitative conclusions for local risk assessment for the biocidal product Antisept A

PT	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 [per day]	Potential degree of exposure of mucosa membranes (e.g. eyes)	Relevant RMM & PPE	Acceptability
1	Hand disinfection - hygienic	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	25 tasks per day; duration of dermal exposure: about 1 min per task	Eye contact not expected, dermal exposure (hands) intended	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Acceptable
2	Small surface disinfection - in between disinfection - hospital room	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	8 tasks per day; duration of dermal exposure: 1 min per task	Eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Acceptable
2	Small surface disinfection – in between – disinfection – medical pratices	RTU (64.73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	8 tasks per day; duration of dermal exposure: 1 min per task	Eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Acceptable

2	Small surface disinfection in laboratory	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	10 tasks per day; duration of dermal exposure: 1 min per task	Eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Acceptable
4	Small surface disinfection in kitchens and canteens	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	4 tasks per day; duration of dermal exposure: 2 min per task	Eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Acceptable
4	Disinfection of food processing machinery	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	4 tasks per day; duration of dermal exposure 5 min per task	Incidental eye contact expected, dermal exposure expected	Eye protection recommended. Regular cleaning of equipment and work area. Good standard of personal hygiene.	Acceptable
2, 4	Refilling	RTU (64,73 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	1 task per day; dermal exposure, contact time: 0,5 min.	Incidental eye contact expected, dermal exposure expected	Eye protection recommended. Regular cleaning of equipment and work area. Good standard of personal hygiene.	Acceptable

Conclusion

Concerning the local eye and skin effects of biocidal product Antisept A, the intended “hand disinfection – hygienic“, “small surface disinfection - in between disinfection - hospital room“, “small surface disinfection – in between disinfection – medical practices“, “small surface disinfection in laboratory“, “small surface disinfection in kitchens and canteens“, “disinfection of food processing machinery” and “refilling” do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the intended uses and from secondary exposure of the biocidal product Antisept A is unlikely. Risk reduction measures described in chapter 2.4.3 have to be taken into account in order to ensure safe use of the biocidal product Antisept A.

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

3.6.4.6 Risk for non-professional users

Table 64 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 [1a] PT1; Intensive care or other applications in hospitals and similar areas, adult, one application	1	68.5	10.7	0.83	7.8	yes
Scenario [1b] PT1; Intensive care or other applications in hospitals and similar areas, adult, 3 applications	1	68.5	10.7	2.48	23	yes
Scenario [2a] PT1; Dialysis	1	68.5	10.7	1.86	17	yes

or any other applications in the private area, adult, one applicati-on						
Scenario [2b] PT1; Dialysis or any other applications in the private area, adult, 3 applications	1	68.5	10.7	5.58	52	yes
Scenario [2c] PT1; Dialysis, or any other applications in the private area, child, one applica-tion	1	68.5	10.7	3.37	31	yes
Scenario [2d] PT1; Dialysis, or any other applications in the private area, child, 3 applications	1	68.5	10.7	10.11	94	yes

- **Local effects**

The biocidal product is classified as Eye Irrit. 2 (H319) and STOT SE 3, H336. A human health risk from these hazards is not expected if the precautionary statements as given in section 2.3 are followed. For eye-irritating formulations eye protection (P280) is normally required to avoid eye damages by splashes. However, the biocidal products for non-professional use are for hand disinfection only. Splashes of the liquid reaching the eye are normally not expected and will be very rare events. In addition, it is assumed that effects are less severe and can be easily treated by rinsing the eyes with water. Thus, an appropriate labelling to avoid contact with eyes and to rinse eyes in case of exposure is sufficient to protect non-professional users.

H336 would trigger P304 + P340 (IF INHALED: Remove person to fresh air and keep comfortable for breathing.). According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation of the biocidal product this precautionary statement is considered not relevant for the non-professional user.

Conclusion

No human health risk from use of this biocidal product by non-professional users was identified if it is used as intended. To avoid excessive use the typical application rate in a simple form, easily understandable for the non-professional user has to appear on the label. In addition, the biocidal product has to be stored out of the reach of children since the unattended use/misuse of the biocidal product by smaller children may result in human health hazards.

Human health hazard based on the classification of the biocidal product as Eye Irrit. 2, H319 and STOT SE 3, H336 can be sufficiently controlled by the corresponding precautionary statements listed in section 2.3. In addition, a labelling advice to avoid contact to eyes is required.

3.6.4.7 Risk for the general public

Table 65 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 [3a] PT1; Secondary exposure from hand disinfection (adult)	1	68.5	10.7	0.65	6.1	yes
Scenario [3b] PT1; Secondary exposure from hand disinfection (child)	1	68.5	10.7	1.72	16	yes
Scenario [3c] PT1; Secondary exposure from hand disinfection (toddler)	1	68.5	10.7	3.94	37	yes
Scenario [4a] PT2: Secondary exposure from disinfection of small surfaces	1	68.5	10.7	10.69	99.9	yes

by professional users, healthcare and institutional areas, adult						
	2	68.5	10.7	3.56	33	yes
Scenario [4b] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, child	1	68.5	10.7	20.13	188	no
	2	68.5	10.7	6.71	63	yes
Scenario [4c] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional area, toddler	1	68.5	10.7	32.08	300	no
	2	68.5	10.7	10.69	99.9	yes
Scenario [5a] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, adult	1	68.5	10.7	0.78	7.3	yes
Scenario [5b] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by	1	68.5	10.7	2.05	19	yes

professional users, child						
Scenario [5c] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, toddler	1	68.5	10.7	4.69	44	yes

Local effects
Specific local effects for bystanders (general public) are not expected. For more details refer to the local effect assessment for the non-professional user.

Conclusion

No human health risk was identified for secondary exposure of the general public resulting from professional and non-professional use of the biocidal product.
Specific risk mitigation measures are not required.

3.6.4.8 Risk for consumers via residues in food

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance Propan-2-ol and no SoC.

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

For summary of systemic risk characterisation for professional users refer to Table 61 and Table 62 and for summary of local risk assessment for professional users refer to Table 64 in section 3.6.4.5.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Table 66

Scenario, Tier	Relevant reference value [mg/kg bw/d]	Estimated uptake [mg/kg bw/d]	Estimated uptake / reference value [%]	Acceptable (yes/no)
Scenario [1a] PT1; Intensive care or other applications in hospitals and similar areas, adult, one application, Tier 1	10.7	0.83	7.8	yes
Scenario [1b] PT1; Intensive care or other applications in hospitals and similar areas, adult, 3 applications, Tier 1	10.7	2.48	23	yes
Scenario [2a] PT1; Dialysis or any other applications in the private area, adult, one application Tier 1	10.7	1.86	17	yes

Scenario [2b] PT1; Dialysis or any other applications in the private area, adult, 3 applications, Tier 1	10.7	5.58	52	yes
Scenario [2c] PT1; Dialysis, or any other applications in the private area, child, one application, Tier 1	10.7	3.37	31	yes
Scenario [2d] PT1; Dialysis, or any other applications in the private area, child, 3 applications, Tier 1	10.7	10.11	94	yes

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 67

Scenario, Tier	**Relevant reference value** [mg/kg bw/d]	**Estimated uptake** [mg/kg bw/d]	**Estimated uptake / reference value** [%]	**Acceptable** (yes/no)
Scenario [3a] PT1; Secondary exposure from hand disinfection (adult), Tier 1	10.7	0.65	6.1	yes
Scenario [3b] PT1; Secondary exposure from hand disinfecttion (child), Tier 1	10.7	1.72	16	yes
Scenario [3c] PT1; Secondary exposure from	10.7	3.94	37	yes

hand disinfection, toddler, Tier 1				
Scenario [4a] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, adult, Tier 1	10.7	10.69	99.9	yes
Tier 2	10.7	3.56	33	yes
Scenario [4b] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, child, Tier 1	10.7	20.13	188	no
Tier 2	10.7	6.71	63	yes
Scenario [4c] PT2: Secondary exposure from disinfection of small surfaces by professional users, healthcare and institutional areas, toddler, Tier 1	10.7	32.08	300	no
Tier 2	10.7	10.69	99.9	yes
Scenario [5a] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, adult, Tier 1	10.7	0.78	7.3	yes
Scenario [5a] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, child, Tier 1	10.7	2.05	19	yes
Scenario [5c] PT4: Secondary exposure from disinfection of small surfaces, canteens and kitchens by professional users, toddler, Tier 1	10.7	4.69	44	yes

3.7 Risk assessment for animal health

There is no toxicological information available implying that pets or domestic animals a more susceptible to the active substance or the biocidal product than humans. Thus, it is assumed that secondary exposure and risk assessment for the general public can be adopted to these animals. Hence, no risk is identified and no specific risk mitigation measures are required.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product Antisept A is intended to be used in product type 1, 2, and 4 for hand disinfection, both professional and non-professional, as well as disinfection of hard non-porous surfaces in health-care, pharmaceutical/cosmetic industry and institutional areas as well as in food preparation and handling (kitchen, restaurants, grocery shops, butcher, etc.) and in food production facilities (dairy, non-alcoholic beverages, alcoholic beverages (e.g. breweries), processed food (meat, deli, vegetables, fruits, etc.). For a detailed description of the single uses see section 3.8.4.
In the course of the product authorisation process, the applicant submitted an alternative dossier for the evaluation of the active substance propan-2-ol. According to CG-17 document No. AP 13.1-CG-17-2016-13 “Evaluation of alternative dossiers during product authorisation”, “the latest LoEP agreed by the BPC in the context of the (initial or reviewed) approval of the active substance should be taken into account for the product authorisation, regardless of the availability of new relevant data”, unless the data provided by the applicant would “significantly modify the conclusions of the hazard or risk assessment of the active substance”. Since this does not apply to the data provided in the alternative dossier, the evaluation of the biocidal product Antisept A will be based on data that were agreed during the approval of the active substance propan-2-ol.

3.8.2 Effects assessment

The biocidal product Antisept A does not contain substances of concern for the environment and no additional studies of relevance regarding the ecotoxicity and the environmental fate of the active substance propan-2-ol or the product Antisept A were provided. Hence, the environmental effects assessment is based on the information that is available from the CAR for the active substance propan-2-ol (2015, eCA DE).

3.8.2.1 Mixture toxicity

The biocidal product Antisept A does not contain substances of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance propan-2-ol.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

According to the CAR, acute and chronic data on effects of propan-2ol on aquatic organisms are available. For fish a 96 h LC_{50} of 8.692 mg a.s./L (*Pimephales promelas*) and for invertebrates an 48 h EC_{50} of 2.285 mg a.s./L (*Daphnia magna*) was determined. For algae, an E_rC_{50} of 10.500 mg a.s./L from a study with *Pseudokirchneriella subspicata* is described.

The information on long-term effects is limited to studies on invertebrates (*Daphnia magna*) and algae.

The lowest chronic effect value (NOEC = 141 mg a.s./L) was derived from a study with *Daphnia magna.*

Based on the chronic effect value for *Daphnia magna*, a **$PNEC_{water}$ of 2.82 mg a.s./L** was derived by applying an assessment factor of 50.

Studies on sediment dwelling organisms are not available and are not necessarily required for the intended uses. Hence, the equilibrium partitioning method (EPM) was applied to estimate a **$PNEC_{sediment}$ of 2.41 mg a.s./kg ww** (Eq. 70; Guidance on the BPR: Volume IV Part B Risk Assessment, 2015).

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

The effect of propan-2-ol on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 3 hours contact. The EC_{50} was calculated to be >1000 mg a.s./L nominal. For the risk assessment an EC_{50} value of 1000 mg/ L is used as a worst case. Applying an assessment factor of 100 to the EC_{50} of the respiration inhibition test a **$PNEC_{STP}$ of 10 mg a.s./L** was derived

3.8.2.3 Terrestrial compartment (including groundwater)

Since direct exposure of the products of the BPF to the terrestrial compartment and adsorption of the a.s. to soil must not be expected, the provision of experimentally derived data on the toxicity of the propan-2-ol to terrestrial organisms is not required. Thus, the $PNEC_{soil}$ was determined by applying EPM as described in equation 72 of the Guidance on the BPR: Volume IV Part B Risk Assessment (EU, 2015). Thus, a **$PNEC_{soil}$ of 0.496 mg a.s./kg ww** was determined.

3.8.2.4 Atmosphere

For the air compartment no ecotoxicological data are available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

3.8.2.5 Non-compartment specific effects

Due to a $logK_{OW}$ of 0.5, propan-2-ol is not expected to accumulate in the environment. Hence, the risk of non-compartment specific effects can be assumed to be negligible related to the use of the products of the BPF.

3.8.2.6 Summary of effects assessment

Table 68 Summary of the PNEC-values for the environmental risk assessment

Summary table on calculated PNEC values	
Compartment	**PNEC**
Water	2.82 mg a.s./L
Sediment	2.41 mg a.s./kg ww
STP	10 mg a.s./L
Soil	0.496 mg a.s./kg ww

3.8.3 Fate and behaviour

Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290nm and 750nm takes place. Therefore, propan-2-ol is not accessible for direct photodegradation in sunlight. Propan-2-ol is classified as readily biodegradable. Propan-2-ol has a relatively high vapour pressure at 5780 Pa at 25°C, therefore, direct evaporation is expected. The Henry's Law constant for propan-2-ol is 0.82 Pa m^3/ mol at 25°C. This indicates that propan-2-ol is moderately volatile. Propan-2-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. Based on a reaction rate constant of $5.1x10^{-12}$ cm^3/mol sec a half-life of 3.1 days can be estimated. Based on a log P_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} 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 geoaccumulation potential.

For a more detailed assessment of the environmental fate and behaviour of the active substance propan-2-ol please refer to the Assessment Report of propan-2-ol of the BPD.

Biodegradation / Metabolites

Propan-2-ol is classified as readily biodegradable. No data on biodegradation in soil, water/sediment or sewage treatment plants are available as in light of the screening test result no further studies were deemed necessary. For risk refinement purposes default half-lives of 15 days for biodegradation in surface water and 300 days in sediment can be assumed. For the soil compartment a default half-life of

30 days should be applied. For elimination estimations in sewage treatment plants a rate constant of $1h^{-1}$ was used.

3.8.3.1 Bioconcentration

In the CAR for propan-2-ol, bioconcentration factors (BCFs) were estimated according to the procedures described in Eq. 74 and 75 of the Guidance on the BPR: Volume IV Part B Risk Assessment (2015). By applying the experimentally derived $\log K_{OW}$ of 0.05 a BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww were determined. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-2-ol can be considered negligible.

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product “Antisept A” is used in product type 1, 2, and 4 for hand disinfection and disinfection of hard non-porous surfaces in the health-care sector, pharmaceutical/cosmetic industry and institutional areas as well as in food preparation and handling and in food production facilities. The ready-to-use product Antisept A contains 70% v/v (64.7% w/w equivalent) propan-2-ol as a.s. and is applied by spraying or pouring techniques followed by wiping.

Table 69: Intended uses in PT 1

Assessed PT	PT 1
Assessed Intended uses	Use 1: hand disinfection (professional user) Use 2: hand disinfection (non-professional user)
ESD(s) used	Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004) Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV 39, ENV 42 and ENV-A6
Approach	Use 1: average consumption / tonnage based Use 2: average consumption / tonnage based
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017) Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	n.a.
Confidential Annexes	YES: In the confidential Annex 5.2 the tonnage based local emission for use 1 and 2 are provided.
Life cycle steps assessed	All Intended Uses:

	Production: No Formulation No Use: Yes Service life: No
Remarks	For sake of completeness the average consumption based approach for use 1 and 2 are also presented in the following chapter. But for the environmental risk assessment the worst case approach (tonnage based) is used.

Table 70: Intended use in PT 2

Assessed PT	PT 2
Assessed Intended uses	Use 3: surface disinfection - professional
ESD(s) used	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; JCR, 2011 Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV 39, ENV 46 and ENV-A6
Approach	Use 3: average consumption / tonnage based
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017) Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	n.a.
Confidential Annexes	YES: In the confidential Annex 5.2 the tonnage based local emission for use 3 is provided.
Life cycle steps assessed	All Intended Uses: Production: No Formulation No Use: Yes Service life: No
Remarks	For the completeness the consumption based approach for use 3 is also presented in the following chapter. However, for the environmental risk assessment the worst-case approach, which turns out to be the tonnage based approach, is used.

Table 71: Intended use in PT 4

Assessed PT	PT 4
Assessed Intended uses	Use 4: surface disinfection (food industry), (professional user)
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 39 and ENV-A6
Approach	Use 4: consumption based

Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017) Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	n.a.
Confidential Annexes	NO
Life cycle steps assessed	Use 4: Production: No Formulation No Use: Yes Service life: No
Remarks	

3.8.4.2 Local emission estimation for relevant environmental compartments

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the a.s. is released to air and 10% of the a.s. is released to water. 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. In case of the ready-to-use (RTU) product Antisept A containing 70% v/v propan-2-ol, the disinfection is finished when the treated surface completely dried, aka the product has evaporated completely. This is facilitated by the relatively high vapour pressure of propan-2-ol. Nearly the whole amount of substance applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to waste water – via leakages or rinse off – cannot be excluded for liquid products. Therefore, for the environmental risk assessment of the biocidal product Antisept A, the distribution used during the assessment of the active substance is maintained since it is plausible that the main emission path will be via air.

3.8.4.2.1 PT 1: Intended use 1 [Hand disinfection – professional user]

The emission scenario for disinfectants used for skin and hand application is described in detail in chapter 4 of the Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004); for input and output values see following tables.
Two approaches are calculated: (1) based on consumption and (2) based on tonnage.

(1) consumption based approach

Table 72: Emission scenario for disinfectants used for skin and hand application in hospitals, calculations based on consumption

Determinants of the emission scenario according to chapter 4, table 4.5; Environmental Emission Scenarios for PT 1 (Royal Haskoning, 2004)	Value
A) Number of beds in model hospital (D)	400
Occupancy rate (D)	0.75
B) Number of occupied beds in model hospital (D)	300
Fraction released to waste water (CAR)	0.1
Fraction released to air (CAR)	0.9
C) Consumption of a.s. per bed (D)	15 g/d
D) Consumption of a.s. per occupied bed (D)	20 g/d
Emission rates according to equation A+C, A+D or B+D; Royal Haskoning (2004) [Emission rate according to equation B+C yields to a lower result]	**Value**
Local emission rate to waste water during the use of the hand and skin disinfectant	0.6 kg/d
Local emission rate to air during the use of the hand and skin disinfectant	5.4 kg/d

(D) – Default (Royal Haskoning, 2004)

(CAR) – CAR Propan-2-ol (2014)

(2) tonnage based approach

The resulting local emission of propan-2-ol to the waste water and air from the application of the biocidal product Antisept A based on tonnage is given in Annex 5.2.

The tonnage approach represents the worst-case estimation as calculated E_{local} values are higher (see Chapter 5.2.1) compared to those ones based on the consumption approach. Thus, PECs based on tonnage were calculated and then used for the environmental risk assessment.

3.8.4.2.2 PT 1: Intended use 2 [Hand disinfection – non-professional user]

The emission scenario for disinfectants used for skin and hand application is described in detail in chapter 4 of the Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004); for input and output values see following tables.
Two approaches are calculated: (1) based on consumption and (2) based on tonnage.

(1) consumption based approach

According to the BPC opinion of propan-2-ol following element has to be taken into account when authorising products: “During product authorisation actual data about the tonnage of propan-2-ol for use

in PT 2 and for the specific use pattern for which the product should be authorised are necessary to prove the currently applied market penetration factor of 0.3 used in the refinement of environmental exposure assessment."

According to the applicant the provided tonnage information is estimated. Therefore, RefMS decided that in absence of actual data about the tonnage of propan-2-ol or the tonnage of biocidal product Antisept A for use in PT 2 not to use a market penetration factor of 0.3 as applied in CAR of propan-2-ol (2014). Hence, the environmental exposure assessment of the biocidal product Antisept A for intended use 2 in PT 2 is performed with the default market share value of 0.5 from ESD for PT 2 (2004).

Table 73: Emission scenario for disinfectants used in human hygiene biocidal products (private use), calculations based on consumption

Determinants of the emission scenario according to chapter 4, table 4.2; Environmental Emission Scenarios for PT 1 (Royal Haskoning, 2004)	**Value**
Number of inhabitants feeding one STP (D)	10000
Fraction released to waste water (CAR)	0.1
Fraction released to air (CAR)	0.9
Active substance in product: B) (S)	640.0 g/kg
Consumption per application: D1) (S)	4 mL
Number of applications (S)	3 d^{-1}
Fraction of inhabitants using product N (TAB v2.1, ENV 42)	0.5
Market share of disinfectant (D)	0.5
Specific density of product (see Table 4)	858.7 kg/m^3
Emission rates according to equation B+D1; Royal Haskoning (2004)	**Value**
Local emission rate to waste water during the use of the hand and skin disinfectant	1.649 kg/d
Local emission rate to air during the use of the hand and skin disinfectant	14.838 kg/d

(D) – Default (Royal Haskoning, 2004)

(TAB) – Technical Agreements for Biocides (Version 2.1, 2019)

(CAR) – CAR Propan-2-ol (2014)

(S) – Provided by applicant

(2) tonnage based approach

The resulting local emission of propan-2-ol to the waste water and air from the application of the biocidal product Antisept A based on tonnage is given in Annex 5.2.

The tonnage approach represents the worst-case estimation as calculated Elocal values are higher (see Chapter 5.2.2) compared to those ones based on the consumption approach. Thus, PECs based on tonnage were calculated and then used for the environmental risk assessment.

3.8.4.2.3 PT2: Intended use 3 [Surface disinfection in health care sector – professional user]

Use 3a - Health care sector

The intended use of the biocidal product Antisept A is described as surface disinfection in the health care sector, pharmaceutical/cosmetic industry and institutional areas. According to ESD for PT 2 (JRC, 2011) disinfection in primary health care areas and hospital sector is covered by the ESD PT 2 (van der Poel, 2001). In chapter 3.3 of the ESD for PT 2 (van der Poel, 2001) is stated: “If the disinfectant concerned is the same as for the disinfection of lavatories and surfaces in accommodation for humans (households, offices, public places etc.)”, which corresponds to scenario description for institutional areas in ESD for PT 2 (JRC, 2011), “the scenarios of Chapter 2 are used.” Therefore, the emission estimation for use 3a is covered by the calculations for use 3c.

Use 3b - Industrial premises

The use in industrial areas is described in ESD for PT 2 (JRC, 2011). It covers industrial premises dealing with packaging materials, biotechnology, i.e. laboratories (yeast, proteins, enzymes), production of pharmaceutics, cosmetics and toiletries and production of computers. The surfaces to be disinfected are very variable in size. For the application of small scale ready-to-use (RTU) products a default surface area of 25 m^2 should be used for emission estimation according to TAB (2019), ENV 46.

Table 74: Emission scenario for disinfection in industrial premises

Determinants of the local emission according to Chapter 2.1.4.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2011)	Value
Application rate of biocidal product (Vform) (S)	0.05 L/m^2
Concentration of active substance in the product (Cform) (S)	549.57 g/L
Surface area to be disinfected ($AREA_{surface}$) (TAB)	25 m^2
Number of applications (Nappl)	1 d^{-1}
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9

Calculation Results	Value
Local emission rate to waste water	0.069 kg/d
Local emission rate to air	0.618 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JCR 2011)

(CAR) – CAR Propan-2-ol (2014)

(TAB) – TAB (2019), ENV 46: RTU – small scale applications: Definition of default values for the size of the area to be treated

Use 3c - Institutional areas

The use in institutional areas is described in ESD for PT 2 (JRC, 2011). It covers areas in schools, shops, gyms, hotels, offices and in the sanitary sector. For the disinfection in institutional areas, two scenarios are presented by van der Poel, one based on the annual tonnage and one based on the average consumption per capita. Both scenarios can also be found in the ESD for PT 2 (JCR, 2011). According to the EU Workshop PT 1-6 Report (European Commission – Directorate General Environment, 2008), both approaches will be presented. For the environmental exposure and risk assessment, the worst-case emission estimations are chosen to be relevant. Input parameters and the respective emissions are shown in the following tables.

Tonnage-based approach

It is assumed that release to an STP takes place, therefore the STP acts as the local main source. The resulting local emission of propan-2-ol to wastewater and air from the application of the biocidal product Antisept A based on tonnage is given in Annex **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Consumption-based approach

Table 75: Emission scenario for disinfectants in institutional areas – consumption-based approach

Determinants of the local emission according to Chapter 2.1.4.2, Table 4; Environmental Emission Scenarios for PT 2 (JRC, 2011) or Chapter 2.2, Table 2.2; Environmental Emission Scenarios for PT 2 (van der Poel, 2001)	Value
Number of inhabitants feeding one STP (D)	10,000
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9

Determinants of the local emission according to Chapter 2.1.4.2, Table 4; Environmental Emission Scenarios for PT 2 (JRC, 2011) or Chapter 2.2, Table 2.2; Environmental Emission Scenarios for PT 2 (van der Poel, 2001)	Value
Concentration of active substance in the product (Cform) (S)	549.57 g/L
Consumption per capita – general purposes (D)	0.005 L/d
Penetration factor of disinfectant (D)	0.5
Calculation Results	**Value**
Local emission rate to waste water	1.374 kg/d
Local emission rate to air	12.365 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JCR 2011 and ESD PT2, van der Poel, 2001)

(CAR) – CAR Propan-2-ol (2014)

Break-even point

Based on the local emission from the consumption based approach a regional tonnage equivalent (break-even point) can be calculated. If the consumption based break-even point is larger than the regional tonnage, then the local emission from the consumption based approach should be used for further environmental exposure and risk assessment.

In case of the biocidal product Antisept A, the break-even point lies at 2507.4 t/a. Since this is less than the regional tonnage, the tonnage based approach represents the worst-case situation. Therefore, for the environmental exposure and risk assessment the emission based on tonnage is used.

3.8.4.2.4 Intended use 4 [Surface disinfection – food and feed industry, professional user]

The emission scenario for surface disinfection in food and feed areas is described in detail in chapter 2.2.4 of the Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (JRC, 2011); for input and output values see following tables.

The surface area to be disinfected by RTU products are defined at the WG ENV I 2017. Whereas large scale catering kitchens with a surface area of 50m^2 covers the realistic worst case. Consequently, an environmental risk assessment for slaughterhouses was not conducted.

It can be assumed that in food and feed producing/processing areas disinfection takes place only during the working week (260 days per year).

Table 76: Emission scenario for calculating the releases of disinfectants used in small scale catering kitchens, canteens, slaughterhouses and butcheries (IHO, 2006)

Determinants of the emission scenario according to chapter 2.2.4, table 10; Environmental Emission Scenarios for PT 4 (JRC, 2011)	**Value**
Application rate of b.p. (S)	50 mL/m^2
Concentration of a.s in b.p (S)	549.57 g/L
Application rate of the a.s. (S)	27.48 g/m^2
Surface area to be disinfected (WG ENV I 2017) Slaughterhouses Large scale catering kitchens	 10 m^2 50 m^2
Number of applications per day(S)	2
Fraction of substance disintegrated during or after application (before release to the sewer system)(D)	0
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water(D)	0
Calculation Results	**Value**
Local release to waste water	0.275 kg/d
Local release to air	2.47 kg/d

(S) – Provided by applicant

(D) – Default (JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

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

The application of the biocidal product Antisept A used for disinfection results in indirect exposure of the environment via the air (wet and dry deposition) and to a lesser extent via STP.

Table 77: Identification of relevant receiving compartments based on the exposure pathway

	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	yes
Use 3	yes	yes (indirect)	not relevant	yes
Use 4	yes	yes (indirect)	not relevant	yes

3.8.6 Fate and distribution in exposed environmental compartments

- No hydrolysis under environmental conditions.
- Photolysis in water is not applicable, no absorption maximum >290 nm.
- Tropospherical half-life of propan-2-ol: 3.1 d (according to Atkinson et al. (2006), reaction with OH radicals (global 24-hours mean), concentration: 5 x 10^5 OH/cm^3).
- K_{OC} was estimated by QSAR-model for alcohols described in EU TGD (2003): K_{OC} = 3.3 L/kg, no pH dependence

The vapour pressure of propan-2-ol is 5780 Pa at 25°C and direct evaporation is expected, consequently. The Henry's constant is 0.80 Pa m^3 mol^{-1} at 25°C. According to a suggested classification scheme after Lyman et al. (1983) the Henry's law constant indicates moderate volatility from water.

Table 78: Input parameters (only set values) for calculating the fate and distribution in the environment

Input	Value	Unit	Remarks
Molecular weight	60.09	g/Mol	
Vapour pressure (at 12°C)	2304	Pa	
Water solubility (at 25°C)	1	kg/L	complete miscible with water
Organic carbon/water partition coefficient (K_{OC})	3.3	L/kg	
Henry's Law Constant	0.80	Pa/m^3/mol	
Biodegradability			a.s. is readily biodegradable
Rate constant for STP	1	h^{-1}	
DT_{50} for degradation in soil	30	d	

The distribution in the sewage treatment plant is calculated using SimpleTreat v.4.0. This results in release fractions to air of 0.27 %, water 7.96 %, sludge < 0.1 % (0.03 %) and degraded fraction 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..

3.8.7 Calculated PEC values

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 also TAB v. 2.1, ENV-A5, 2019). Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product Antisept A.

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= C_{local_eff}) according to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B + C (2017);
- $PEC_{local\_surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR IV ENV B + C (2017);
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR IV ENV B + C (2017).

According to the proposed use of b.p. the interval between two releases is shorter than one month and therefore, the effluent concentration is representative for the exposure of microorganisms in STP. Thus,

- $PEC_{STP} = C_{local\_eff}$ referring to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B + C (2017).

The local PEC values from all intended uses are presented in Table and are used for the environmental risk assessment. As mentioned in chapter 3.8.4.2.3 the use 3a is covered by use 3c.

Table 79: Summary table on calculated PEClocal values from intended uses of the biocidal product Antisept A

Use	PT	PEC_{STP} [mg/L]	$PEC_{surface\_water}$ [mg/L]	PEC_{sed} [mg/kg_{wwt}]	PEC_{air} [mg/m^3]	$DEPtotal_{ann}$ [$mg/(m^2\ d)$]
1	1	0.282	0.028	0.024	0.018	0.026
2	1	0.081	0.008	0.007	0.005	0.007
3b	2	0.003	0.0003	0.0002	0.0002	0.0002
3c	2	0.081	0.008	0.007	0.005	0.007
4	4	0.011	0.001	0.001	0.001	0.001

Based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in a zero concentration of propan-2-ol in the sewage sludge. However, because propan-2-ol is highly volatile it will be emitted to soil indirectly by wet and dry deposition ($DEPTtotal_{ann}$), which is calculated according to the

OPS model in the Guidance BPR IV ENV B + C (2017). The groundwater exposure occurs after wet and dry aerial deposition on soil. In accordance to WG ENV IV 2019 and TAB 2.1 ENV A-5 no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product Antisept A.

3.8.7.1 Non-compartment specific effects

- **Secondary poisoning**

According to the CAR of propan-2-ol (2014), the relevance of a risk characterisation for secondary poisoning is not applicable for propan-2-ol. Due to its physical properties propan-2-ol has a low potential for bioaccumulation in the terrestrial and in the aquatic food chain (see chapter 3.8.2.5).

3.8.7.2 Aggregated exposure (combined for relevant emission sources)

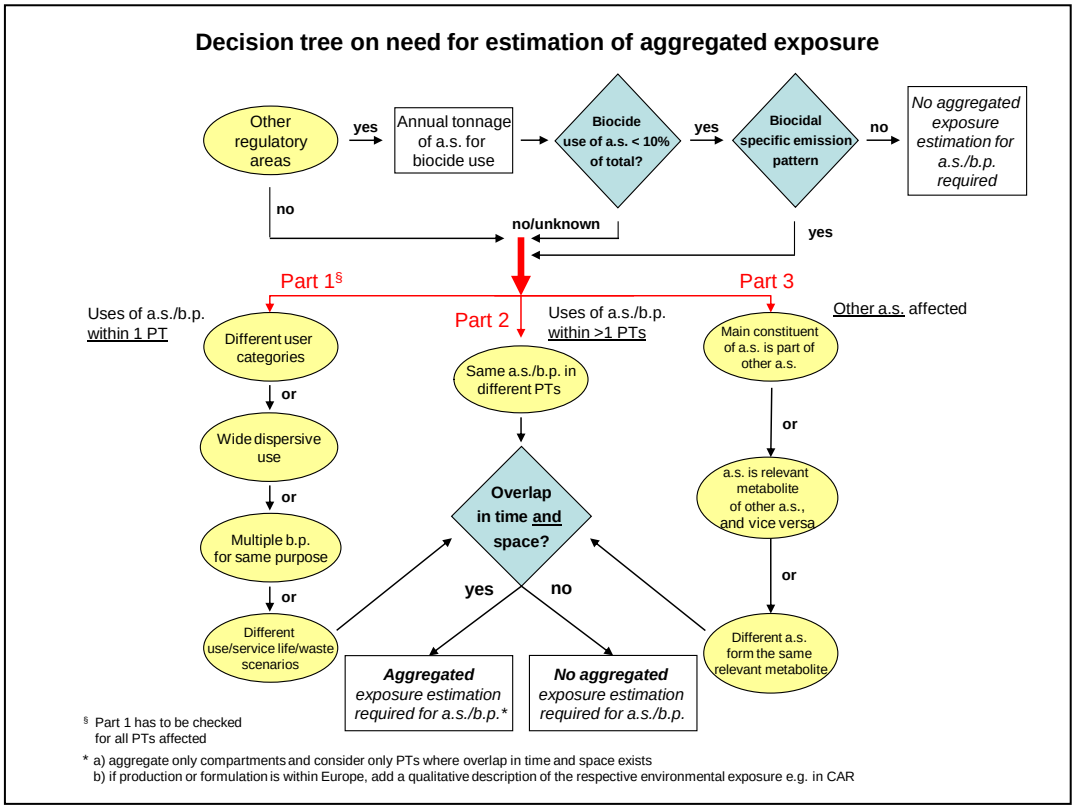

Figure 1: Decision tree on the need for estimation of aggregated exposure

According to the “Decision tree on need for estimation of aggregated exposure” the requirement for aggregated exposure estimations was checked for the biocidal products Antisept A containing propan-2-ol as active substance.

The active substance propan-2-ol is also evaluated in the frame of other regulatory areas (e.g. REACH). According to OECD SIDS Dossier of the HPV chemical Isopropanol (1997) most propan-2-ol goes into the solvent market either directly or via conversion to acetone or one of acetone’s derivates. Propan-2-ol’s major solvents uses include inks, coatings, cosmetics and pharmaceuticals. Small percentages are used for esters and as rubbing alcohol. The total European production volume of propan-2-ol in 1995 was reported to be 619000 tons (OECD 1997). According to the provided tonnage information only a small fraction (< 10 %) of the total tonnage produced is used as biocidal active substance. Therefore, no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced.

But according to the decision tree (Figure 1) it must be also examined whether specific biocidal emission patterns are available. The main (only) emission pathway for propan-2-ol is through a STP; but this

emission route is not limited to biocidal products. Specific biocidal emission patterns are not identified. Therefore, according to the decision tree it is not required to perform aggregated exposure estimation.

3.8.8 Risk characterisation

The biocidal product Antisept A comprises four uses (incl. three subuses) in three PTs that need to be assessed in the risk characterisation for the environment:

PT 1:

Use 1: Hand disinfection (professional user)
Use 2: Hand disinfection (non-professional user)

PT 2:

Use 3: Surface disinfection in the health care sector (professional user) – covered by use 3c
Use 3b: Surface disinfection in industrial premises (professional user)
Use 3c: Surface disinfection in institutional areas (professional user)

PT 4:

Use 4: Surface disinfection (food industry); (professional user)

3.8.8.1 Aquatic compartment (sediment and STP)

Table 80 PEC/PNEC ratios for surface water and sediment related to the intended uses

Summary table on calculated PEC/PNEC values			
Use	**PT**	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Use 1	1	0.010	0.010
Use 2	1	0.003	0.003
Use 3b	2	0.001	0.0001
Use 3c	2	0.003	0.003
Use 4	4	0.0004	0.0004

The PEC/PNEC-ratios for surface water and sediment related to all the intended uses of the biocidal product Antisept A are well below 1. Hence, no unacceptable risk for both compartments must be assumed due to the intended uses of the product.

- **STP**

Table 81 PEC/PNEC ratios for the STP related to the intended uses

Summary table on calculated PEC/PNEC values		
Use	**PT**	**PEC/PNEC$_{STP}$**
Use 1	1	0.028
Use 2	1	0.008
Use 3b	2	0.0003
Use 3c	2	0.008
Use 4	4	0.001

The PEC/PNEC-ratios for the STP related to all the intended uses of the biocidal product Antisept A are well below 1. Hence, no unacceptable risk for the STP must be assumed due to the intended uses of the products of the product.

3.8.8.2 Terrestrial compartment (Soil/Groundwater)

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 also TAB v. 2.1, ENV-A5, 2019). Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product Antisept A. As a consequence, no $PEC_{soil}/PNEC_{soil}$ was calculated and no PEC_{GW} was compared to the groundwater trigger value.

3.8.8.3 Atmosphere

As stated in section 3.8.2.4, ecotoxicological data for the air compartment are not available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

3.8.8.4 Non-compartment specific

As stated in section 3.8.2.5, non-compartment-specific effects are not to be expected.

3.8.8.5 PBT assessment

The conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substance propan-2-ol. Accordingly, propan-2-ol thus fulfil neither the PBT- nor the vP/vB-criteria.

3.8.8.6 Endocrine disrupting properties

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance.
Additionally, there is no indication for endocrine disrupting properties of the co-formulants of the biocidal product.
In summary, there is no indication for endocrine disrupting properties of the biocidal product.

3.8.8.7 Summary of risk characterisation

Table 82 Summary of the PEC/PNEC ratios for the concerned environmental compartments

Summary table on calculated PEC/PNEC values				
Use	**PT**	**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**
Use 1	1	0.028	0.010	0.010
Use 2	1	0.008	0.003	0.003
Use 3b	2	0.0003	0.0001	0.003
Use 3c	2	0.008	0.003	0.003
Use 4	4	0.001	0.0004	0.0004

No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal product Antisept A.

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 83

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
1	-	Umfuellen von Handdesinfektionsmitteln: hygienische und haftungsrechtliche Aspekte	Prof. Dr. Peter Heeg, P., Dr. jur. Schneider, A., Verband für angewandte Hygiene (VAH), http://www.vah-online.de/index.php?page=haendedesinfektion	04/2013
2	3.2.	Determination of the pH-value of Antisept A according to CIPAC MT 75	Hesse, M.	2016
3	3.3.	Detemination of the Density of Antisept A according to OECD 109 resp. EU A.3	Henke, W.	2016
4	3.4.1.1.	Determination of the accelerated storage of Antisept A according to CIPAC MT 46	Affolter, O.	2016

5	3.4.1.2.	Determination of the storage stability of Antisept A at room temperature (duration two years)	Affolter, O.	2016
6	3.4.1.3.	Determination of the low temperature stability of liquid formulations of Antisept A according to CIPAC MT 39.3	Affolter, O.	2016
7	3.8.	Determination of the surface tension of an aqueous solution of Antisept A according to OECD 115 resp. EU A.5	Henke, W.	2016
8	3.9.	Determination of the Viscosity of Antisept A according to OECD 114 / DIN 53015	Henke, W.	2016
9	4.17.	Abschlussbericht zum Forschungsvorhaben - Zündtemperaturen binärer Gemische bei erhöhten Ausgangsdrücken	Hirsch, W., Brandes;, E.	2015
10	5.1.	Validation of an Analytical Method using GC/FID for the determination of Isopropyl alcohol in Antisept A	Affolter, O.	2016
11	6.7.	Quantitative test method for the evaluation of bactericidal and yeasticidal activity of Antisept A on non- porous surfaces with mechanical action employing wipes in the medical area according to DIN EN 16615:2015 (Phase 2, step 2)*	Gabriel, H.	2016
12	6.7.	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of Antisept A in the medical area according to DIN EN 13624:2013 (Phase 2, step 1)	Gabriel, H.	2016
13	6.7.	Quantitative suspension test for the evaluation of basic bactericidal activity of Antisept A in the medical area according to DIN EN 13727:2015 (Phase 2, step 1)	Gabriel, H.	2016
14	6.7.	Efficacy of Antisept A in a practice-like trial with test persons Hygienic Hand rub – Test method and requirements according to DIN EN 1500:2013 (Phase 2, step 2)	Gabriel, H.	2016

15	6.7.	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of Antisept A in the medical area according to DIN EN 13624:2013 (Phase 2, step 1)	Gabriel, H.	2016
16	6.7.	Quantitative Non-Porous Surface Test for the evaluation of bactericidal and/or fungicidal activity of Antisept A in Food, Industrial, Domestic, and Institutional Areas according to DIN EN 13697:2015 (Phase 2, step 2)	Gabriel, H.	2016
17	6.7.	Quantitative suspension test for the evaluation of bactericidal activity of Antisept A in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276:2009; Phase 2, Step 1)	Gabriel, H.	2016
18	6.7.	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of Antisept A in Food, Industrial, Domestic and Institutional Areas according to DIN EN 1650:2013 (Phase 2, step 1)	Gabriel, H.	2016
19	6.7.	Evaluation of the effectiveness of Antisept A	Becker, B.	2016
20	6.7.	Expert Valuation: Seewasept Hygienic hand disinfection DIN EN 1500 Surgical hand disinfection DIN EN 12791	Schubert, R.	2010
21	6.7.	Evaluation of the effectiveness of Antisept A (adenovirus type 5)	Becker, B.	2016
22	6.7.	Evaluation of the effectiveness of Antisept A (murine norovirus)	Paulmann, D.	2017
23	6.7.	Quantitative suspension test for the evaluation of bactericidal activity of Antisept A in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276:2009; Phase 2, Step 1*)	Gabriel, H.	2017
24	6.7.	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of Antisept A in Food, Industrial, Domestic and Institutional Areas according to DIN EN 1650:2013 (Phase 2, step 1)*	Gabriel, H.	2017
25	6.7.	Bactericidal and Yeasticidal Activity of Antisept A in the quantitative surface test according to DIN EN 13697:2015 (Phase 2, Step 2)	Gabriel, H.	2017

26	6.7.	Yeasticidal Activity of Antisept A in the quantitative surface test according to DIN EN 13697:2015 (Phase 2, Step 2)	Gabriel, H.	2017
27	6.7.	Mycobactericidal Activity of Antisept A in the quantitative suspension test according to DIN EN 14348:2005 (Phase 2, Step 1)	Klock, J.	2017
28	6.7.	Gutachten zum Präparat Seewasept als Mittel zur Hautantiseptik und hygienischen Händedesinfektion	Pitten, F.-A.	2017

4.2 List of studies for the active substance(s)

4.2.1 Propan-2-ol

- The applicant provided a Letter of Access to a Third Party dossier (Stockmeier Holding GmbH) on the active substance propan-2-ol.

4.2.1.1 New information on the active substance

- The applicant submitted no new information on the active substance “propan-2-ol”.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

Details of exposure assessment (external exposure)

AntiseptA_Professional_User_Exposure

Overview about external and internal exposure and related risks

RiskCharakterisation_AntiseptA.pdf

4.3.2 Safety for non-professional users and the general public

ConsExpo 4.1 report

Scenario [1a] PT1; Intensive care or other applications in hospitals and similar areas, adult, one application, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	2.5	hour
room volume	25	m3
ventilation rate	3	1/hr
applied amount	3.43E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	11.8	mg/m3
inhalation mean concentration on day of exposure:	1.23	mg/m3
inhalation air concentration year average :	1.23	mg/m3/day
inhalation acute (internal) dose :	0.616	mg/kg
inhalation chronic (internal) dose :	0.616	mg/kg/day

Integrated (point estimates)

total external dose:	0.616	mg/kg
total acute dose (internal):	0.616	mg/kg
total chronic dose (internal):	0.616	mg/kg/day

ConsExpo 4.1 report

Scenario [1b] PT1; Intensive care or other applications in hospitals and similar areas, adult, 3 applications, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	3	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	2.5	hour
room volume	25	m3
ventilation rate	3	1/hr
applied amount	3.43E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	11.8	mg/m3
inhalation mean concentration on day of exposure:	3.7	mg/m3
inhalation air concentration year average :	3.7	mg/m3/day
inhalation acute (internal) dose :	0.616	mg/kg
inhalation chronic (internal) dose :	1.85	mg/kg/day

Integrated (point estimates)

total external dose:	0.616	mg/kg
total acute dose (internal):	0.616	mg/kg
total chronic dose (internal):	1.85	mg/kg/day

ConsExpo 4.1 report

Scenario [2a] PT1; Dialysis or any other applications in the private area, adult, one application, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	10	hour
room volume	2.	m3
ventilation rate	0.6	1/hr
applied amount	3.43E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0.67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	14.8	mg/m3
inhalation mean concentration on day of exposure:	6.15	mg/m3
inhalation air concentration year average :	6.15	mg/m3/day
inhalation acute (internal) dose :	1.65	mg/kg
inhalation chronic (internal) dose :	1.65	mg/kg/day

Integrated (point estimates)

total external dose:	1.65	mg/kg
total acute dose (internal):	1.65	mg/kg
total chronic dose (internal):	1.65	mg/kg/day

ConsExpo 4.1 report

Scenario [2b] PT1; Dialysis or any other applications in the private area, adult, 3 applications, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	3	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	10	hour
room volume	25	m3
ventilation rate	0.6	1/hr
applied amount	3.43E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0.67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	14.8	mg/m3
inhalation mean concentration on day of exposure:	18.4	mg/m3
inhalation air concentration year average :	18.4	mg/m3/day
inhalation acute (internal) dose :	1.65	mg/kg
inhalation chronic (internal) dose :	4.94	mg/kg/day

Integrated (point estimates)

total external dose:	1.65	mg/kg
total acute dose (internal):	1.65	mg/kg
total chronic dose (internal):	4.94	mg/kg/day

ConsExpo 4.1 report

Scenario [2c] PT1; Dialysis, or any other applications in the private area, child, one application, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23.9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	10	hour
room volume	25	m3
ventilation rate	0.6	1/hr
applied amount	3.44E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0.5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	14.8	mg/m3
inhalation mean concentration on day of exposure:	6.17	mg/m3
inhalation air concentration year average :	6.17	mg/m3/day
inhalation acute (internal) dose :	3.1	mg/kg
inhalation chronic (internal) dose :	3.1	mg/kg/day

Integrated (point estimates)

total external dose:	3.1	mg/kg
total acute dose (internal):	3.1	mg/kg
total chronic dose (internal):	3.1	mg/kg/day

ConsExpo 4.1 report

Scenario [2d] PT1; Dialysis, or any other applications in the private area, child, 3 applications, Tier 1

Product

Antisept A

Compound

Compound name :	propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	4	1/day
body weight	23.9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	64.7	%
exposure duration	10	hour
room volume	25	m3
ventilation rate	0.6	1/hr
applied amount	2.6	gram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0.5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	11.2	mg/m3
inhalation mean concentration on day of exposure:	18.6	mg/m3
inhalation air concentration year average :	18.6	mg/m3/day
inhalation acute (internal) dose :	2.34	mg/kg
inhalation chronic (internal) dose :	9.36	mg/kg/day

Integrated (point estimates)

total external dose:	2.34	mg/kg
total acute dose (internal):	2.34	mg/kg
total chronic dose (internal):	9.36	mg/kg/day

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

Please refer to the separate document.