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 UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

CVAS Disinfectant product based on Propan-2-ol

Product type(s) 2, 4

Propan-2-ol as included in the Union list of approved active substances

Case Number in R4BP: BC-DH025620-60

Evaluating Competent Authority: Germany

Date: [11/03/2019]

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1 CONCLUSION

The outcome of the assessment for the biocidal product CVAS Disinfectant product based on Propan-2-ol is specified in the BPC opinion following discussions at the BPC-29 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
CVAS Disinfectant product based on Propan-2-ol	-

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	CVAS Development GmbH
	Address	Dr. Albert Reimann Str. 16 a 68526 Ladenburg Germany
Pre-submission phase started on	21.12.2015 (submission to MS 12.01.2018)	
Pre-submission phase concluded on	18.02.2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr.-Albert-Reimann-Str. 16a, 68526 Ladenburg Germany
Location of manufacturing sites	Dr.-Albert-Reimann-Str. 16a, 68526 Ladenburg Germany
Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstraße 1 83115 Neubeuern Germany
Location of manufacturing sites	Pfaffensteinstraße 1 83115 Neubeuern Germany
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1 45472 Muelheim an der Ruhr Germany
Location of manufacturing sites	Am Nordseekai 22 73207 Plochingen Germany

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

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	Shamrockstraße 88 44623 Herne Germany Römerstraße 733 47443 Moers Germany
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK, Vodelingenenplaat, Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601 3196 KK, Vodelingenenplaat, Rotterdam Netherlands
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway, LA 70897, Baton Rouge, Louisana United States
Location of manufacturing sites	4999 Scenic Highway, LA 70897, Baton Rouge, Louisana United States

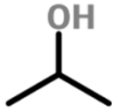
2.1.2 Product composition and formulation

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:

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Isopropyl alcohol
IUPAC or EC name	Propan-2-ol
EC number	200-661-7
CAS number	67-63-0
Index number in Annex VI of CLP	603-117-00-0
Minimum purity / content	99 %(w/w)
Structural formula	

2.1.2.2 Candidate(s) for substitution

No candidate for substitution was identified.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Isopropyl alcohol	Propan-2-ol	Active substance	67-63-0	200-661-7	61.25 (w/w) [68.8 (v/v)]

Information on the full composition is provided in the confidential[1] annex.

2.1.2.4 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 sources was established by ECHA, see asset numbers EU-0017008-0000, EU-0017009-0000, EU-0014506-0000 and EU-14505-0000)

2.1.2.5 Information on the substance(s) of concern

No substance of concern was identified.

2.1.2.6 Type of formulation

Any other liquid (ready-to-use)

[1] Access level: "Restricted" to applicant and authority

2.1.3 Hazard and precautionary statements

Classification and labelling of the biocidal product according to the Regulation (EC) 1272/2008

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

The current harmonised classification of the active substance propan-2-ol is based on Commission Regulation (EU) No 1272/2008, Annex VI, Table 3.1.

Based on the data submitted from the applicant for the third party dossier labelling with EUH066 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.1.4.

Table 1

Classification		
Hazard category	Flam. Liq.2	
	Eye irrit.2	
	STOT SE 3	
Hazard statement	H225	
	H319	
	H336	
Labelling		
Signal words	Danger	
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness and dizziness.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
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.
	P233	Keep container tightly closed.
	P261	Avoid breathing vapours.
	P264	Wash hands thoroughly after handling.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P303+P361+ P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P312	Call a POISON CENTER if you feel unwell.
	P337 + 313	If eye irritation persists: Get medical advice.
	P370+P378	In case of fire: Use alcohol-resistant foam to extinguish.
	P403 + P235	Store in well-ventilated place. Keep cool
	P405	Store locked up.
	P501	Dispose of contents to /container in accordance with local regulations.
Note	Pictogram  GHS02  GHS07	

In fact H319 would trigger P280 (Wear eye protection/face protection.). However, for non-professional use correct use 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 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is also not required since propan-2-ol and the formulated biocidal product 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.

2.1.4 Authorised use(s)

2.1.4.1 Use 1 appropriate for authorisation – Disinfection of small surfaces in product type 2 by non-professional users

Product Type(s)	02
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of non-porous surfaces in domestic areas
Application method(s)	Spraying (with trigger sprayer or pump spray) Spraying (with trigger sprayer or pump spray) and wiping Pouring and wiping
Application rate(s) and frequency	Ready-to-use 40-50 mL/m^2
Category(ies) of users	non-professional user
Pack sizes and packaging material	• Bottle: HDPE, 250 - 1000 mL • Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL

2.1.4.1.1 Use-specific instructions for use

- The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:
  - Trigger spray: Apply 20 spray strokes per 0.5 m^2.
  - Pump spray: Apply 3 jets per 100 cm^2.
  - Bottle: Apply one measuring cup per m^2

2.1.4.1.2 Use-specific risk mitigation measures

- The product must only be applied for disinfection of small surfaces (< 1m^2).

2.1.4.1.3 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 2.1.4.5

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

See chapter 2.1.4.5

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

See chapter 2.1.4.5

2.1.4.2 Use 2 appropriate for authorisation – Disinfection of small surfaces in product type 2 by professional users

Product Type(s)	02
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of non-porous surfaces in industry, small enterprises, institutions and domestic areas
Application method(s)	Spraying (with trigger sprayer or pump spray) Spraying (with trigger sprayer or pump spray) and wiping Pouring and wiping
Application rate(s) and frequency	Ready-to-use 40-50 mL/m^2
Category(ies) of users	professional user
Pack sizes and packaging material	• Bottle: HDPE, 250 - 1000 mL • Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL • IBC: HDPE, 720 L • Drum: Steel, zinc coated and painted, 200 - 220 L • Canister: HDPE, 5 - 50 L

2.1.4.2.1 Use-specific instructions for use

See chapter 2.1.4.5

2.1.4.2.2 Use-specific risk mitigation measures

- The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is recommended.
- The product must only be applied for disinfection of small surfaces.

2.1.4.2.3 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 2.1.4.5

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

See chapter 2.1.4.5

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

See chapter 2.1.4.5

2.1.4.3 Use 3 appropriate for authorisation – Disinfection of small surfaces in product type 4 by non-professional users

Product Type(s)	04
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of non-porous surfaces in kitchens. Disinfection of gardening equipment for human hygiene purpose only.
Application method(s)	Spraying (with trigger sprayer or pump spray) Spraying (with trigger sprayer or pump spray) and wiping Pouring and wiping
Application rate(s) and frequency	Ready-to-use 40-50 mL/m^2
Category(ies) of users	non-professional user
Pack sizes and packaging material	• Bottle: HDPE, 250 - 1000 mL • Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL •

2.1.4.3.1 Use-specific instructions for use

- For use at room temperature (20±2°C).
- The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:
  - Trigger spray: Apply 20 spray strokes per 0.5 m^2.
  - Pump spray: Apply 3 jets per 100 cm^2.
  - Bottle: Apply one measuring cup per m^2
- Disinfection of gardening equipment for human hygiene purpose only.
- Disinfect gardening equipment only indoors.

2.1.4.3.2 Use-specific risk mitigation measures

- The product must only be applied for disinfection of small surfaces (< 1m^2).

2.1.4.3.3 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 2.1.4.5

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

See chapter 2.1.4.5

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

See chapter 2.1.4.5

2.1.4.4 Use 4 appropriate for authorisation – Disinfection of small surfaces in product type 4 by professional users

Product Type(s)	04
Where relevant, an exact description of the use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of non-porous surfaces in canteens or kitchens, food processing industry (including breweries). Disinfection of gardening equipment for human hygiene purpose only.
Application method(s)	Spraying (with trigger sprayer or pump spray) Spraying (with trigger sprayer or pump spray) and wiping Pouring and wiping
Application rate(s) and frequency	Ready-to-use 40-50 mL/m^2
Category(ies) of users	professional user
Pack sizes and packaging material	• Bottle: HDPE, 250 - 1000 mL • Bottle with fine mist spray pump or trigger spray head: HDPE, 250 - 1000 mL • IBC: HDPE, 720 L • Drum: Steel, zinc coated and painted, 200 - 220 L • Canister: HDPE, 5 - 50 L

2.1.4.4.1 Use-specific instructions for use

- For use at room temperature (20±2°C).
- Disinfection of gardening equipment for human hygiene purpose only.
- Disinfect gardening equipment only indoors.

2.1.4.4.2 Use-specific risk mitigation measures

- Provide adequate ventilation (industrial ventilation or keeping windows and doors open).
- The product must only be applied for disinfection of small surfaces.
- The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is recommended

2.1.4.4.3 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 2.1.4.5

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

See chapter 2.1.4.5

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

See chapter 2.1.4.5

2.1.4.5 General directions for use

2.1.4.5.1 Instructions for use

- Clean surfaces before use.
- Apply the product to the surface undiluted by spraying. Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes.
- Apply the product to the surface undiluted by spraying / pouring the product and wiping of the surface afterwards. Make sure to wet surfaces completely. Allow to take effect for at least 5 minutes.
- Do not apply more than 50 mL/m^2.
- Used wipes must be disposed in a closed container.
- For non-professional users only: Do not use for more than 4 applications per day.

2.1.4.5.2 Risk mitigation measures

- Keep out of reach of children and pets.
- Avoid contact with eyes.
- Do not apply in the presence of small children.
- Keep children and pets away from rooms, where disinfection is taking place. Provide adequate ventilation before children enter treated rooms.For refilling a funnel must be applied.

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

First aid:

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

2.1.4.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

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

Store cool (not above 30°C) and protect from frost.

Shelf-life: 24 month.

2.1.4.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m^3 for the active

substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.1.5 Packaging

Table 2

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 (Yes/No)"
IBC	720 L	HDPE	HDPE	professional user	Yes
Drum	200 - 220 L	Steel, zinc coated and painted	Stopper, steel, zinc coated and painted	professional user	Yes
Canister	5 - 50 L	HDPE	HDPE	professional user	Yes
Bottle	250 - 1000 mL	HDPE	HDPE	professional user, non-professional user	Yes
Bottle	250 - 1000 mL	HDPE	Fine mist spray pump, PP, PE, PBT, EVA	professional user, non-professional user	Yes
Bottle	250 - 1000 mL	HDPE	Trigger sprayer, PP, PE, EPE, EBA, POM	professional user, non-professional user	Yes
Tin plate spray can with valve pouch (bag-in-box system)	400 mL	Tin plate	can: tin plate; pouch: PP-OPA-ALU-PET - PP, POM, Buna, tin plate, butyl	professional user, non-professional user	Yes

The packaging "Tin plate spray can with valve pouch (bag-in-box system)" is a pressurized system applied as an aerosol. Therefore, it will be deleted from the authorised uses. For details please refer to chapter 2.2.3 Flamable aerosols.

2.1.6 Documentation

2.1.6.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 of this PAR

2.1.6.2 Access to documentation

The applicant provided a letter of access to the dossier for the active substance "propan-2-ol" recorded under the asset no. EU-0011803-0000. This dossier is satisfying the requirements set out in Annex II of Regulation (EU) No 528/2012 for use in PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

2.1.6.3 Similar conditions of use

Communication D(2016)0694, dated 18.02.2016, from ECHA and addressed to CVAS Development GmbH states the following;

The biocidal product "CVAS Disinfectant products based on Propan-2-ol" is deemed to be eligible for Union authorisation.

Reasons:
"No objections were raised from either the Commission or the Member States Competent Authorities (MSCA5) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product "CVAS Disinfectant products based on Propan-2-ol" falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union"
This document can be found in section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product

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

Table 3. Intended use # 1 – Disinfection of small surfaces in product type 02

Product Type(s)	2
Where relevant, an exact description of the authorised use	Disinfection of small surfaces by professionals in product type 02 (e. g. working bench in laboratory, clean room) Disinfection of small surfaces by non-professionals in product type 02
Target organism (including development stage)	Bacteria (vegetative cells) Yeasts (vegetative cells)
Field of use	Indoor use
Application method(s)	Spraying (with trigger sprayer, pump spray or spray can) Spraying (with trigger sprayer, pump spray or spray can) and wiping Pouring and wiping
Application rate(s) and frequency	40-50 mL/m2
Category(ies) of user(s)	professional user non-professional user
Pack sizes and packaging material	IBC: HDPE, 720 L (only for professional user) Drum: Steel, zinc coated and painted, 200 - 220 L (only for professional user) Canister: HDPE, 5 - 50 L (only for professional user) Bottle: HDPE, 250 - 1000 mL Bottle with or without spray head: HDPE, 250 - 1000 mL Tin plate spray can with valve pouch: tin plate and PP-OPA-ALU-PET, 400 mL

Table 4. Intended use # 2 – Disinfection of small surfaces in product type 04

Product Type(s)	4
Where relevant, an exact description of the authorised use	Disinfection of small surfaces by professionals in product type 04 – canteens or kitchens Disinfection of small surfaces by professionals in product type 04 – food processing industry Disinfection of small surfaces by professionals in product type 04 – gardening equipment Disinfection of small surfaces by non-professionals in product type 04 – kitchens

	Disinfection of small surfaces by non-professionals in product type 04 – gardening equipment
Target organism (including development stage)	Bacteria (vegetative cells) Yeasts (vegetative cells)
Field of use	Indoor use
Application method(s)	Spraying (with trigger sprayer, pump spray or spray can) Spraying (with trigger sprayer, pump spray or spray can) and wiping Pouring and wiping
Application rate(s) and frequency	40-50 mL/m2
Category(ies) of user(s)	professional user non-professional user
Pack sizes and packaging material	IBC: HDPE, 720 L (only for professional user) Drum: Steel, zinc coated and painted, 200 - 220 L (only for professional user) Canister: HDPE, 5 - 50 L (only for professional user) Bottle: HDPE, 250 - 1000 mL Bottle with or without spray head: HDPE, 250 - 1000 mL Tin plate spray can with valve pouch: tin plate and PP-OPA-ALU-PET, 400 mL

2.2.2 Physical, chemical and technical properties

The different names of the test products Alpha Septin, Bactozol I, Disinfect Home and Calgonit DS – 622 are different trade names for the product "CVAS Disinfectant product based on Propan-2-ol" with different packaging e.g. bottle and different spraying devices.

Table 5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual inspection	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	liquid (homogenous solution).	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	liquid (homogenous solution)	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	liquid (homogenous solution)	Manka, S. (2016), Report No.: Mo5468
Colour at 20 °C and 101.3 kPa	visual inspection	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	clear, colourless	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	clear, colourless	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	clear, colourless	Manka, S. (2016), Report No.: Mo5468

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Odour at 20 °C and 101.3 kPa	olfactory inspection	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	solvent odour	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	solvent odour	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	solvent odour	Manka, S. (2016), Report No.: Mo5468
Acidity / alkalinity	CIPAC MT 75.3 (Determination of pH values)	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	Undiluted product: pH = 7.7 Testing for acidity/alkalinity is not applicable, according to the table of Annex III title 1 of the BPR, as the pH of the biocidal product is inside the pH range 4-10.	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	Undiluted product: pH = 7.8	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	Undiluted product: pH = 8.0	Manka, S. (2016), Report No.: Mo5468
Relative density	EU Method A.3 (Relative Density) oscillating densitometer	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	The relative density was determined to be 0.882.	Manka, S. (2016), Report No.: Mo5466
		Bactazol I	The relative density was determined	Manka, S. (2016),

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch No.: 40716-BA [61.3% (w/w) a.s.]	to be 0.882.	Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	The relative density was determined to be 0.873.	Manka, S. (2016), Report No.: Mo5468
Storage stability test – **accelerated storage**	-	-	As the biocidal product is a highly flammable liquid, it is not recommended to store the biocidal product at temperatures above 30°C. A label phrase stating that the biocidal product must not be stored at higher temperatures will be attached to the label.	Waiving[2]
Storage stability test – **long term storage at ambient temperature**	Please refer to results.	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	**24 months storage test at 20°C** packaging: Bag-in-Box Spray can (tin plate can with valve pouch) **a.s. content:** ▫ initial: 60.7% ▫ after 3 months (20°C): 60.2% (-0.8 %) ▫ after 12 months (20°C): 60.6% (-0.2 %) ▫ after 24 months (20°C): 59.0% (-2.8%) **Appearance (visual/olfactory inspection):** ▫ initial: Clear, colourless,	Manka, S. (2016), Report No.: Mo5466

[2] 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
			homogeneous solution with solvent odour ▫ after 3, 12 and 24 months (20°C): Clear, colourless, homogeneous solution with solvent odour **Stability of Packaging:** - initial: test item in sound condition, sealed and without leakages - after 3 months (20°C): test item in sound condition, sealed and without leakages - after 12 months (20°C): test item in sound condition, sealed and without leakages - after 24 months (20°C): test item in sound condition, sealed and without leakages **weight loss:** ▫ initial: n.a. ▫ after 3 months (20°C): -0.03 % ▫ after 12 months (20°C): -0.01 % ▫ after 24 months (20°C): -0.03 % **pH-Value, undiluted (according to CIPAC MT 75.3):** ▫ initial: 7.7 ▫ after 3 months (20°C): 7.4 ▫ after 12 months (20°C): 7.5 ▫ after 24 months (20°C): 7.4	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Relative Density (according to EU Method A.3): ▫ initial: 0.882 ▫ after 3, 12 and 24 months (20°C): 0.882 **Viscosity – Dynamic (analogous to CIPAC MT 192) 20 °C:** ▫ initial: 5.6 min-1: 7.68 mPa s 11.3 min-1: 5.76 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.80 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.08 mPa s ▫ after 3 months (20°C): 5.6 min-1: 7.68 mPa s 11.3 min-1: 4.80 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.56 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.08 mPa s ▫ after 12 months (20°C): 5.6 min-1: 3.48 mPa s 11.3 min-1: 4.80 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.08 mPa s 90.5 min-1: 4.08 mPa s 181 min-1: 3.96 mPa s ▫ after 24 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 3.84 mPa s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			22.6 min-1: 3.84 mPa s 45.2 min-1: 4.56 mPa s 90.5 min-1: 4.08 mPa s 181 min-1: 3.96 mPa s **Discharge Rate (analogous to FEA 643):** ▫ initial: 1.825 g/s ▫ after 3 months (20°C): 1.866 g/s ▫ after 12 months (20°C): 1.831 g/s ▫ after 24 months (20°C): 1.881 g/s **Clogging of Aerosol Dispenser Valves (analogous to WHO/FAO):** ▫ initial: no clogging observed after 3, 12 and 24 months (20°C): no clogging observed **Residue after Use (analogous to WHO/FAO):** ▫ initial: 3.30 g ▫ after 3 months (20°C): 3.00 g ▫ after 12 months (20°C): 3.11 g **Spray Diameter:** ▫ initial: 17.5-20.0 cm ▫ after 3 months (20°C): 17.0-23.0 cm ▫ after 12 months (20°C): 22.5 cm ▫ after 24 months (20°C): 20 -21	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			cm **Spray Pattern:** ▫ initial: circular spray pattern / pear shape spray pattern ▫ after 3 months (20°C): pear shape spray pattern ▫ after 12 months (20°C): pear spray spray pattern ▫ after 24 months (20°C): circular spray pattern	
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	**24 months storage test at 20°C** packaging: pump spray (HDPE, with spray head) **a.s. content:** ▫ initial: 60.0% ▫ after 3 months (20°C): 58.8% (-2.0%) ▫ after 12 months (20°C): 59.5% (-0.8%) ▫ after 24 months (20°C): 61.0% (+ 1.6%) **Appearance (visual/olfactory inspection):** ▫ initial: Clear, colourless, homogeneous solution with solvent odour ▫ after 3, 12 and 24 months (20°C): Clear, colourless, homogeneous solution with solvent odour	Manka, S. (2016), Report No.: Mo5467

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Stability of Packaging: - initial: test item in sound condition, sealed and without leakages - after 3 months (20°C): test item in sound condition, sealed and without leakages - after 12 months (20°C): test item in sound condition, sealed and without leakages - after 24 months (20°C): test item in sound condition, sealed and without leakages **weight loss:** ▫ initial: n.a. ▫ after 3 months (20°C): -0.01 % ▫ after 12 months (20°C): -0.05 % ▫ after 24 months (20°C): -0.01 % **pH-Value, undiluted (according to CIPAC MT 75.3):** ▫ initial: 7.8 ▫ after 3 months (20°C): 7.6 ▫ after 12 months (20°C): 7.5 ▫ after 24 months (20°C): 8.1 **Relative Density (according to EU Method A.3):** ▫ initial: 0.882 ▫ after 3, 12 and 24 months (20°C): 0.882	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Viscosity – Dynamic (analogous to CIPAC MT 192) 20 °C: ▫ initial: 5.6 min-1: 3.84 mPa s 11.3 min-1: 4.80 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.80 mPa s 90.5 min-1: 4.20 mPa s 181 min-1: 4.08 mPa s ▫ after 3 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 5.76 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.80 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.02 mPa s ▫ after 12 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 5.76 mPa s 22.6 min-1: 4.32 mPa s 45.2 min-1: 4.56 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.02 mPa s ▫ after 24 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 3.84 mPa s 22.6 min-1: 3.84 mPa s 45.2 min-1: 4.32 mPa s 90.5 min-1: 4.08 mPa s 181 min-1: 3.96 mPa s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Discharge Rate (analogous to FEA 643): ▫ initial: 0.162 g/jet ▫ after 3 and 12 months (20°C): 0.164 g/jet ▫ after 24 months (20°C): 0.168 g/jet **Clogging of Aerosol Dispenser Valves (analogous to WHO/FAO):** ▫ initial: no clogging observed after 3, 12 and 24 months (20°C): no clogging observed **Residue after Use (analogous to WHO/FAO):** ▫ initial: 5.77 g ▫ after 3 months (20°C): 2.88 g ▫ after 12 months (20°C): 2.99 g ▫ after 24 months (20°C): 5.28 g **Spray Diameter:** ▫ initial: 9.5-10.0 cm ▫ after 3 months (20°C): 11.0 cm ▫ after 12 months (20°C): 9.0 cm ▫ after 24 months (20°C): 9.0 - 10 cm **Spray Pattern:** ▫ initial: circular spray pattern	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ after 3 months (20°C): circular spray pattern ▫ after 12 months (20°C): circular spray pattern ▫ after 24 months (20°C): circular spray pattern	
		Disinfect Home Batch No.: 40716-DH [61.3% (w/w) a.s.]	**24 months storage test at 20°C** packaging: trigger spray (HDPE, with spray head) **weight loss:** ▫ initial: n.a. ▫ after 3 months (20°C): 0.01-0.04 % ▫ after 12 months (20°C): 0.16-0.17 % ▫ after 24 months (20°C): 0.01-0.35 % **Spray Diameter:** ▫ initial: 19.0-30.0 cm ▫ after 3 months (20°C): 28.0-33.0 cm ▫ after 12 months (20°C): 34.5-36.0 cm ▫ after 24 months (20°C): 27.0-28.0 cm **Spray Pattern:** ▫ initial: circular spray pattern ▫ after 3 months (20°C): circular spray pattern ▫ after 12 months (20°C): circular	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			spray pattern after 24 months (20°C): circular spray pattern	
		Disinfect Home Batch No.: 40716-DH and 12918-DH [61.3% (w/w) a.s.]	**Discharge rate (analogous to FEA 643):** ▫ initial (20°C ± 2°C): 1.066 g/stroke ▫ after 34 months (20°C ± 2°C): 1.06 g/stroke **Clogging of Dispenser Valves (analogous to WHO/FAO):** ▫ initial (20°C ± 2°C): no solid deposits on the sprayheads and on the trigger mechanism were observed. ▫ after 34 months (20°C ± 2°C): no solid deposits on the sprayheads and on the trigger mechanism were observed. **Residue after Use (analogous to WHO/FAO):** ▫ initial (20°C ± 2°C): 1.52 g ▫ after 34 months (20°C ± 2°C): 1.46	Manka, S. (2018), Report No.: Mo6394 Remark: These measurements are done additionally after finalisation of the storage stability test. Tested is the same Batch 40716-DH as in storage stability test (values after 34 months storage) and a new Batch 12918-DH (initial values, tested 5 month after production)
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	**24 months storage test at 20°C** packaging: bottle (HDPE) **a.s. content:**	Manka, S. (2016), Report No.: Mo5468

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ initial: 63.8% ▫ after 3 months (20°C): 61.6% (-3.4%) ▫ after 12 months (20°C): 64.1% (+0.5%) ▫ after 24 months (20°C): 63.8% (+0.0%) **Appearance (visual/olfactory inspection):** ▫ initial: Clear, colorless, homogeneous solution with solvent odor ▫ after 3, 12 and 24 months (20°C): Clear, colorless, homogeneous solution with solvent odor **Stability of Packaging:** - initial: test item in sound condition, sealed and without leakages - after 3 months (20°C): test item in sound condition, sealed and without leakages - after 12 months (20°C): test item in sound condition, sealed and without leakages - after 24 months (20°C): test item in sound condition, sealed and without leakages **weight loss:**	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ initial: n.a. ▫ after 3 months (20°C): -0.01 % ▫ after 12 months (20°C): -0.01 % ▫ after 24 months (20°C): -0.01 % **pH-Value, undiluted (according to CIPAC MT 75.3):** ▫ initial: 8.0 ▫ after 3 months (20°C): 8.2 ▫ after 12 months (20°C): 8.0 ▫ after 12 months (20°C): 7.8 **Relative Density (according to EU Method A.3):** ▫ initial: 0.873 ▫ after 3, 12 and 24 months (20°C): 0.873 **Viscosity – Dynamic (analogous to CIPAC MT 192) 20 °C:** ▫ initial: 5.6 min-1: 3.84 mPa s 11.3 min-1: 3.84 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.32 mPa s 90.5 min-1: 4.08 mPa s 181 min-1: 4.08 mPa s ▫ after 3 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 4.80 mPa s 22.6 min-1: 4.32 mPa s 45.2 min-1: 4.56 mPa s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			90.5 min-1: 4.20 mPa s 181 min-1: 4.08 mPa s ▫ after 12 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 5.76 mPa s 22.6 min-1: 3.84 mPa s 45.2 min-1: 3.84 mPa s 90.5 min-1: 3.84 mPa s 181 min-1: 3.90 mPa s ▫ after 24 months (20°C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 3.84 mPa s 22.6 min-1: 3.84 mPa s 45.2 min-1: 4.32 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.08 mPa s	
Storage stability test – **low temperature stability test for liquids**	-	-	Storage at low temperatures is not foreseen. A label phrase will be attached not to store the product at temperatures below 0 °C.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Effects on content of the active substance and technical	-	-	Opaque packaging, therefore no impact on a.s. content due to exposure to light expected.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product - **light**				Nov. 2014.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Temperature: As the biocidal product is a highly flammable liquid, it is not recommended to store the biocidal product at temperatures above 30 °C. A label phrase stating that the biocidal product must not be stored at higher temperatures will be attached to the label.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
			Humidity: The biocidal product is packed in water-tight packaging. Moreover since the biocidal product is a water-based formulation and since the a.s. propan-2-ol is unlimitedly soluble in water and does not react with water, humidity is not expected to influence the content of the a.s. during storage.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Effects on content of the active substance and technical characteristics of the biocidal product			HDPE and zinc-coated and painted steel are resistant to Isopropyl alcohol (Propanol-2) Information in the Database Dangerous goods: Isopropanol (2-Propanol):	Dangerous Goods Database http://www.dgg.bam.de/en/ BAM-Nr.: 734

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
- **reactivity towards container material**			-HDPE is evaluated as resistant at a temperature up to 60 °C if the pH-value of isopropanol: 6,5 -7,5 -Zinc and carbon steel are evaluated as resistant at a temperature up to 50°C if the pH-value of isopropanol: 6,5 -7,5	
Wettability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Wet sieve analysis and dry sieve test	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Disintegration time	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 (particle size determination of the droplets. The test item will be shaken and sprayed 5 seconds into the laser beam) Alpha Septin (pressurized tin plate can with valve pouch, pouch: PP-OPA-ALU-PET, 400 mL) and Disinfect Home (HDPE bottle with trigger spray head, 250 mL) Bactazol I (HDPE bottle with pump spray head, 500 mL).	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	Dv (10%): 34 µm Dv (50%): 70 µm Dv (90%): 156 µm	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	Dv (10%): 32 µm Dv (50%): 59 µm Dv (90%): 116 µm	Manka, S. (2016), Report No.: Mo5467
		Disinfect Home Batch No.: 12918-DH [61.3% (w/w) a.s.]	Dv (10%): 38 µm Dv (50%): 108 µm Dv (90%): 355 µm	Manka, S. (2018), Report No.: Mo6394
Persistent foaming	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				"Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Flowability/Pourability/Dustability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Burning rate — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Burning completeness — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Composition of smoke — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols	Please refer to results. Alpha Septin (pressurized tin plate can with valve pouch, pouch: PP-OPA-ALU-PET, 400 mL) and Disinfect Home (HDPE bottle with trigger spray head, 250 mL) Bactazol I (HDPE bottle with pump spray head, 500 mL).	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	packaging: Bag-in-Box Spray can (tin plate can with valve pouch) **Discharge Rate (analogous to FEA 643):** ▫ 1.825 g/s **Clogging of Aerosol Dispenser Valves (analogous to WHO/FAO):** ▫ no clogging observed **Residue after Use (analogous to WHO/FAO):** ▫ 3.30 g **Spray Diameter:** ▫ 17.5-20.0 cm	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	packaging: pump spray (HDPE, with spray head) **Discharge Rate (analogous to FEA 643):** ▫ 0.162 g/jet **Clogging of Aerosol Dispenser Valves (analogous to WHO/FAO):** ▫ no clogging observed **Residue after Use (analogous to WHO/FAO):** ▫ 5.77 g	Manka, S. (2016), Report No.: Mo5467

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Spray Diameter: ▫ 9.5-10.0 cm	
		Disinfect Home Batch No.: 40716-DH [61.3% (w/w) a.s.]	packaging: trigger spray (HDPE, with spray head) **Spray Diameter:** ▫ initial: 19.0-30.0 cm after 3 months (20°C): 28.0-33.0 cm after 24 months (20°C): 27.0-28.0 cm	
Physical compatibility	-	-	The biocidal product is a ready-to-use liquid product, which is not recommended to be used with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Chemical compatibility	-	-	The biocidal product is a ready-to-use liquid product, which is not recommended to be used with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Degree of dissolution and dilution stability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	EU Method A.5	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	1.0 g/L solution of the biocidal product: 70.9 mN/m at 20 °C	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	1.0 g/L solution of the biocidal product: 69.0 mN/m at 20 °C	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	1.0 g/L solution of the biocidal product: 71.1 mN/m at 20 °C	Manka, S. (2016), Report No.: Mo5468
Viscosity	CIPAC MT 192 rotational viscometer (dynamic)	Alpha Septin Batch No.: 40716-ALPHA [61.3% (w/w) a.s.]	Viscosity – Dynamic (20 °C): 5.6 min-1: 7.68 mPa s 11.3 min-1: 5.76 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.80 mPa s 90.5 min-1: 4.32 mPa s 181 min-1: 4.08 mPa s	Manka, S. (2016), Report No.: Mo5466
		Bactazol I Batch No.: 40716-BA [61.3% (w/w) a.s.]	Viscosity – Dynamic (20 °C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 4.80 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.80 mPa s 90.5 min-1: 4.20 mPa s 181 min-1: 4.08 mPa s	Manka, S. (2016), Report No.: Mo5467
		calgonit DS – 622, Batch No.: 46011401 [61.3% (w/w) a.s.]	Viscosity – Dynamic (20 °C): 5.6 min-1: 3.84 mPa s 11.3 min-1: 3.84 mPa s 22.6 min-1: 4.80 mPa s 45.2 min-1: 4.32 mPa s 90.5 min-1: 4.08 mPa s 181 min-1: 4.08 mPa s	Manka, S. (2016), Report No.: Mo5468

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
The viscosity was only measured at 20° because due to the nature of the active substance, 2-propanol, the measurement at 40°C will not deliver reliable data, as the substance starts to slowly evaporate. This would lead to variations in the measured values.				

Conclusion on the physical, chemical and technical properties of the product
The data provided by the applicant was acceptable. The product, a clear colourless liquid with a solvent like odour, is market in different packaging e.g. bottle and different spray devices. Therefore the storage stability studies are performed in different packaging's and with different technical characteristics based on the packaging (with or without spraying device). The density was determined with 0.882 and a surface tension of ca. 70 mN/m was determined. The measured pH is in the range 7.5 – 8.1, therefore no acidity and alkalinity test is necessary. No clogging was observed for both spraying devices. The spray diameter was 17.5-20.0 cm (Alpha Septin), 9.5-10.0 cm (Bactazol I) and 19.0-30.0 cm cm (Disinfect Home), the discharge rate 1.825 g/s (Alpha Septin), 0.162 g/jet (Bactazol I), 1.06 g/stroke (Disinfect Home) and the residue after use was < 5.77 g for all three spraying devices. The low and the accelerated storage stability test are waived, but the final reports of the long term storage stability tests are submitted. These tests show that all products are chemically and physically stable for two years. The content of 2-propanol remains stable during the storage with a maximum decrease of -2.8% for the product Alpha Septin. Based on this data a shelf life of 24 month together with the label phrase "Store cool (not above 30°C) and protect from frost." can be granted. The submitted data for Alpha Septin (packaging: Bag-in-Box Spray can (tin plate can with valve pouch)) are acceptable. As Aerosol dispenser are not covered by this authorization this packaging (Bag-in-Box Spray can (tin plate can with valve pouch)) will be deleted, please also refer to chapter 2.2.3 Flamable aerosols.

2.2.3 Physical hazards and respective characteristics

Table 6

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Not applicable. The biocidal product is a solution of the active substance propan-2-ol in water. As there are no chemical groups associated with explosive properties present, performing a study on explosive properties for the biocidal product is not scientifically justified.	IUCLID[3]
Flammable gases	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Flammable aerosols	study scientifically unjustified			The product "CVAS Disinfectant based on Propan-2-ol" is not formulated as an aerosol according to the definition in Annex I of the CLP Regulation, chapter 2.3.1. When assessing the hazardous properties, the type of formulation is given as "AL -Any other liquid" for the biocidal product. Consequently, the type as aerosol dispenser or the propellant was not included within the composition of the biocidal product. Information on packaging for one packaging type was erroneously indicated as "spray can" and not as "aerosol dispenser" (packaging: "Tin plate spray can with valve pouch (bag-in-box system): tin plate and	IUCLID[3]

[3] 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
				PP-OPA-ALU-PET, 400 mL"). Aerosols cover the flammability and the pressure hazard. In view of the CLP regulation, it must be concluded that the packaging for in a pressurized "Tin plate spray can with valve pouch (bag-in-box system): tin plate and PP-OPA-ALU-PET, 400 mL" falls under the definition of "Aerosols" (please also refer to the study report Manka 2016; Determination of physico-chemical Properties and Storage Stability Tests for Alpha Septin; especially p.10 and 24). Such aerosols would need special considerations in regard to classification and labelling. Aerosols shall be considered for classification in one of the three categories of this hazard class (see criteria in Annex I, Section 2.3.2.1 of CLP) and they do not fall additionally within the scope of the hazard class for flammable liquids. In summary, the CVAS Disinfectant product based on Propan-2-ol which is packaged and used as an aerosol (packaging "Tin plate spray can with valve pouch (bag-in-box system): tin plate and PP-OPA-ALU-PET, 400 mL" in has to been taken out of the scope of this authorization.	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Oxidising gases	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid. r	IUCLID[3]
Gases under pressure	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Flammable liquids	Calculation method acc. to 2.6.4.3.of Annex I, Part 2 of CLP-Regulation	60 % (w/w) propan-2-ol, 40 % (w/w) water	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			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Self-reactive substances and mixtures	study scientifically not necessary			Not applicable. 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[3]
Pyrophoric liquids	study scientifically not necessary			Not applicable. The biocidal product is a solution of the active substance propan-2-ol in water. Experience in manufacture or handling shows that propan-2-ol does not ignite spontaneously on coming into contact with air at normal temperatures.	IUCLID[3]
Pyrophoric solids	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-heating substances and mixtures	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Not applicable. The product is a solution of the active substance propan-2-ol in water. Propan-2-ol is known to be unlimitedly soluble in water to form stable mixtures. From the structural formula and composition of the product it can be concluded that the substance does not evolve any flammable gases in contact with water or humid air.	IUCLID[3]
Oxidising liquids	study scientifically not necessary			Not applicable. The study does not need to be conducted because the product is flammable.	IUCLID[3]
Oxidising solids	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Organic peroxides	study scientifically not necessary			Not applicable. The biocidal product is a solution of the active substance propan-2-ol in water. Propan-2-ol does not meet the definition of organic peroxide.	IUCLID[3]
Corrosive to metals	study scientifically not necessary			Not applicable. The study does not need to be conducted on the basis of the theoretical assessment of the chemical structure because none of the compounds contains chemical groups which could initiate an irreversible electrochemical reaction with metals which could lead to considerable damage or destruction.	IUCLID[3]
Auto-ignition temperature	DIN 51794		Auto-ignition temperature: 425 °C	Worse-case scenario: Assuming that the lowest available autoignition temperature of	CHEMSAFE (2016)

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
(liquids and gases)			(for pure propan-2-ol)	propan-2-ol (425 ° C) can be regarded as the worst case, this value is considered sufficient for the use of the product.	
Relative self-ignition temperature for solids	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]
Dust explosion hazard	study scientifically unjustified			Not applicable. The study does not need to be conducted because the product is a liquid.	IUCLID[3]

Conclusion on the physical hazards and respective characteristics of the product

The data provided by the applicant was acceptable.
Assuming that the lowest available autoignition temperature of propan-2-ol (425 ° C) can be regarded as the worst case, this value is considered sufficient for the use 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 product properties the flashpoint is below 23 °C for a mixture of 60 % (w/w) propan-2-ol and 40 % (w/w) 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 which results in H225: Highly flammable liquid and vapour.

2.2.4 Methods for detection and identification

Table 7

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
a.s. Propan-2-ol in Test item 3 "2-Propanol 65" (containing 65 % 2-Propanol)	gas chromatography with flame ionization detection	specific, interference from other substances < 3% of total peak	Linearity range: 2-Propanol: 0.2000 - 3.200 mg/mL; $R^2 = 1$	70-130% w/w (9 measurements, 3 samples per fortification Level) ▫ Level 1: 70% (1.400 mg/mL) ▫ Level 2: 100% (2.000 mg/mL) ▫ Level 3: 130% (2.600 mg/mL)	Level 1: 99.7-101.2 Level 2: 100.3-101.1 Level 3: 99.2-101.8	Level 1: 100.6 Level 2: 100.8 Level 3: 100.9 Overall mean (n=9): 100.7	Level 1: 0.8 Level 2: 0.4 Level 3: 1.5 Overall mean (n=9): 0.9	LOD and LOQ are not required, because the method will be used only for testing of specification limits.	Manka, S., Validation of Method: MV134 – BG: GC-Determination of Ethanol, 1-Propanol and 2-Propanol in Formulations, 2016, Study No.: Mo5421

Precision was demonstrated and the relative standard deviation amounts to RSD = 0.53 %.

Table 8

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 9

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 -	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	99.2-101 102-103.6 102.7-104.9	100.2 102.9 103.6 103.2	0.8 0.8 1.0 1.1	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997

			12.56 mg/mL R^2=0.9998	983 mg/m³ / 6 1966 mg/m³ / 6 Dry air (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	102.1-104.8 103.2-104.3 102.6-104.6 101.1-103.4 102.3-104.5 102.5-104.4 104-106.1 103.3-105.3 103.1-107.3	103.7 103.8 102.5 103.3 103.4 104.8 104.5 105.4	0.3 0.7 1.0 0.9 0.7 0.8 0.7 1.7	of 0.05 * OSHA target concentration of 983 mg/m³)	
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 / 5 250 mg/m³ / 4 750 mg/m³ / 5	97.3-103 106-115 105-110 104-110	99.2 111 107 107	2.6 3.1 2.1 2.3	LOQ of the method is dependent on sampling volume: the lowest concentration of 0.025 mg/mL corresponds to 3.1 mg/m³ propan-2-ol in air at the maximum sampling	DocIIIA, 4.1; 11/2015 Alcohol Task Force, 2015

								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 10

Data waiving was acceptable for the following information requirements	
Information requirement	1. Soil, Water, Food, Body fluids and tissues: Data waiving is accepted, Please also refer to the AR. 2. Air: For analytical methods for air; the applicant refers to the 3rd party active substance dossier for propan-2-ol, which was submitted by the ASD Consortium Alcohol for Inclusion into the List of Active Substances and Suppliers according to Article 95 (1) of the BPR.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Conclusion on the methods for detection and identificationof the product
The method(s) provided regarding the active substance(s) was acceptable. The information provided regarding the residues was acceptable. Methods regarding substances of concern were not necessary

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product "CVAS Disinfectant product based on Propan-2-ol" is a surface disinfectant within product-type (PT) 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and 4 (Food and feed area). The biocidal product is used for the disinfection of non-porous, pre-cleaned, small surfaces in industry, small enterprises, institutions and domestic area (PT2) as well as in kitchens, canteens, food processing industry (including breweries) and for the disinfection of gardening equipment (PT4). The product is a ready-to-use product with an intended use concentration of 61.25 % (w/w) propan-2-ol. It can be applied manually by spraying, spraying and wiping or pouring and wiping, by professionals and non-professionals.

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

The product "CVAS Disinfectant product based on Propan-2-ol" is intended to have bactericidal and yeasticidal activity. The product is applied in order to increase the hygienic status of surfaces.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Application of the biocidal product "CVAS Disinfectant product based on Propan-2-ol" leads to reduction in the number of target organisms by irreversible inactivation of bacterial and yeast cells.

2.2.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of effect. 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. 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.
After thorough contact of the active substance with the target organisms, a continuous contact of the active substance with the target cells is not required since the initial contact already results in non-reversible damage of the cells, that triggers biological processes which ultimately kill the target organism.

2.2.5.5 Efficacy data

To substantiate the claims for bactericidal and yeasticidal activity of the biocidal product, the efficacy of the biocidal product Calgonit DS 622 was assessed using currently available efficacy guidelines (EN guidances). The name "Calgonit DS 622" is one trade name for the CVAS Disinfectant product based on Propan-2-ol (see endpoint 2.1 "Trade name or proposed trade name" in IUCLID). Therefore, the composition is the same.
As the biocidal product is intended to be applied for disinfection, the formulation was tested in a tiered approach with quantitative suspension tests (phase 2, step 1 tests) and by simulating practical conditions (phase 2, step 2 tests).
The ready-to-use liquid is intended to be sprayed onto a surface (disinfection without mechanical action), poured onto a surface and wiped afterwards or sprayed onto a surface and wiped afterwards (disinfection with mechanical action).

Bactericidal efficacy
A phase 2, step 1 test (EN1276) and two phase 2, step 2 tests (EN 13697, EN16615) have been submitted to prove the bactericidal efficacy of the product. In all studies, efficacy under clean conditions at 20°C has been assessed (additionally the EN1276 was also performed under dirty conditions).
Bactericidal efficacy in phase 2, step 1 test has been proven at 50% product concentration after 5 minutes (EN 1276). *Efficacy according to EN 13697* (EN 13697), efficacy has been shown after 5 minutes at 50% product concentration. For disinfection with mechanical action (EN16615), efficacy has been shown after 5 minutes at 70 % product concentration.

Yeasticidal efficacy
Two phase 2, step 1 tests (EN1650) and two phase 2, step 2 tests (EN 13697, EN16615) have been submitted to prove the yeasticidal efficacy of the product. In all studies, efficacy under clean conditions at 20°C has been assessed (additionally the EN1650 was also performed under dirty conditions).
Yeasticidal efficacy in phase 2, step 1 tests has been proven at 50% product concentration after 5 minutes (EN 1650). Additionally, efficacy has been demonstrated for brewery specific yeast under for breweries obligatory soiling after 5 minutes at a 25% product concentration.
For disinfection without mechanical action, efficacy has been shown for 100% product concentration after 15 min which was the minimum contact time tested (EN13697).
For disinfection with mechanical action, yeasticidal efficacy has been shown after 5 minutes at 70% product concentration (EN16615). No EN 13697 for brewery specific yeast was submitted, since the results of the EN 1650 test demonstrated that the brewery specific yeast are more susceptible to the tested product than *C. albicans*.

Table 11

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test sub-stance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Product-type 2 and 4, bactericidal	Surface disinfection	Calgonit DS 622	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae*	EN 1276: 2010 (phase 2, step 1)	Quantitative suspension test Interfering substances: 0.3 g/l bovine albumin (low level soiling conditions) and 3.0 g/l bovine albumin (high level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 25% (v/v), 50% (v/v), 80% (v/v)	Bactericidal efficacy according to EN 1276 under dirty conditions (3 g/L BSA) has been shown for the product at 50% (v/v) product concentration with a contact time of 5 minutes	*Höffler, Dr. J.; Leske, J. (2011) calgonit DS 622, EN1276*
Product-type 2 and 4,	Surface disinfection	Calgonit DS 622	*Candida albicans*	EN 1650: 2008 (phase 2,	Quantitative suspension test	Yeasticidal efficacy according	*Höffler, Dr. J.; Leske, J.*

yeasticidal				step 1)	Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions) 3.0 g/l bovine albumin (high level soiling conditions) Test temperature: 20°C Contact time: 5 and 15 minutes Test concentrations: 25% (v/v), 50% (v/v), 80% (v/v)	to EN 1650 under dirty conditions (3 g/L BSA) has been shown for the product at 50% (v/v) product concentration with a contact time of 5 minutes	*(2011) calgonit DS 622, EN1650*
Product-type 2 and 4, bactericidal	Surface disinfection	Calgonit DS 622	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae*	prEN 13697: 2012 (phase 2, step 2)	Quantitative surface test Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions); 8.5 g/l skimmed milk (low level soiling conditions) for *P. aeruginosa* Test temperature: 18-25°C Contact	Bactericidal efficacy according to EN 13697 was shown after 5 min at 50% (v/v) product concentration.	*Höffler, Dr. J.; Ludwig, C. (2014) calgonit DS 622, prEN13697*

					time: 5 minutes Test concentrations: 25% (v/v), 50% (v/v), 100% (v/v)		
Product-type 2 and 4, yeasticidal	Surface disinfection	Calgonit DS 622	*Candida albicans*	prEN 13697:2012 (phase 2, step 2)	Quantitative surface test Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions) Test temperature: 18-25°C Contact time: 15 minutes Test concentrations: 25% (v/v), 50% (v/v), 100% (v/v)	Yeasticidal efficacy according to EN 13697 was shown after 15 min at 100% (v/v) product concentration.	*Höffler, Dr. J.; Ludwig, C. (2014) calgonit DS 622, prEN13697*
Product-type 4, yeasticidal	Surface disinfection	Calgonit DS 622	*Saccharomyces cerivisiae DSM 1333 Saccharomyces cerecisiae var. diastaticus DSM 70487*	EN 1650: 2013 (phase 2 step 1)	Quantitative suspension test Interfering substance: 10 g/l yeast extract Test temperature: 20°C Contact time: 5 and	Yeasticidal efficacy according to EN 1650 was shown after 5 min at 25% (v/v) product concentration.	*Lüking, Dr. A. (2017), calgonit DS 622, EN 1650*

					15 minutes Test concentrations: 25% (v/v), 50% (v/v), 70% (v/v)		
Product-type 2 and 4, bactericidal	Surface disinfection	Calgonit DS 622	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae*	EN 16615: 2015	Quantitative surface test Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 10% (v/v), 70% (v/v)	Bactericidal efficacy according to EN 16615 was shown after 5 min at 70% (v/v) product concentration.	*Lüking, Dr. A. (2017), calgonit DS 622, EN 16615*
Product-type 2 and 4, yeasticidal	Surface disinfection	Calgonit DS 622	*Candida albicans*	EN 16615: 2015	Quantitative surface test Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes	Yeasticidal efficacy according to EN 16615 was shown after 5 min at 70% (v/v) product concentration.	*Lüking, Dr. A. (2017), calgonit DS 622, EN 16615*

					Test concentrations: 10% (v/v), 70% (v/v)		

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of 2-propanol, the development of resistance is not expected and not reported. A natural resistance against 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-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.

2.2.5.7 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 biocidal product "CVAS Disinfectant product based on Propan-2-ol.

2.2.5.8 Evaluation of the label claims

The following biocidal label claims are considered to be suitable for product labels of the „CVAS Disinfectant product based on Propan-2-ol" (non-biocidal label claims have not been evaluated):

All uses:
For disinfection of non-porous, pre-cleaned surfaces at room temperature (20±2°C)

Spraying:
Bactericidal (contact time: at least 5 min at 20°C)
Yeasticidal (contact time: at least 15 min at 20°C)

Spraying and wiping / pouring and wiping:
Bactericidal and yeasticidal (contact time: at least 5 min at 20°C)
Yeasticidal (contact time: 5 min at 20°C)

The required contact times should be mentioned on the product label.

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

The "CVAS Disinfectant product based on Propan-2-o"l is not intended to be authorised for use in combination with other biocidal products.

2.2.5.10 Data waiving and conclusion

Table 12

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	
Conclusion on the efficacy	
It can be concluded that the ready-to-use biocidal product "CVAS Disinfectant product based on Propan-2-ol" shows sufficient bactericidal and yeasticidal activity on pre-cleaned, non-porous surfaces at room temperature (20±2°C) as substantiated according to European Standards (EN) for the disinfection of surfaces in industry, small enterprises, institutions and domestic area (PT2) as well as in kitchens, canteens, food processing industry (including breweries) and for gardening equipment (PT4). in PT 2 and 4 under the following conditions: Spraying: Bactericidal (contact time: 5 min at 20°C) Yeasticidal (contact time: 15 min at 20°C) Spraying and wiping / pouring and wiping: Bactericidal and yeasticidal (contact time: 5 min at 20°C) Yeasticidal (contact time: 5 min at 20°C) Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of the "CVAS Disinfectant product based on Propan-2-ol" have been met. To ensure the efficacy of the products, the following use conditions have to be indicated on the product label: "Clean surfaces before use" "Make sure to wet surfaces completely". The contact time always has to be indicated on the product label.	

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Table 13

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 chapter III, section 8.1 "Skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 14

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 propan-2-ol Annex VI 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 for skin dryness and cracking 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).

Eye irritation

Table 15

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 chapter III, section 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2014), "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 16

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 (61.25 %, 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.)

Respiratory tract irritation

Table 17

Data waiving	
Information requirement	Annex III of BPR (Regulation (EU) 528/2012), 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 18

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.

Skin sensitization

Table 19

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 chapter III, section 8.3 Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2014), "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 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.

Respiratory sensitization (ADS)

Table 21

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 the components are not available.

Table 22

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 product or their components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

Acute toxicity

Acute toxicity by oral route

Table 23

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 chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2014), "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 24

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.

Acute toxicity by inhalation

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2014), "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

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 be also above these limits.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

Acute toxicity by dermal route

Table 27

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 chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2014), "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 28

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.

Specific target organ toxicity after single exposure

Table 29

Value used in the Risk Assessment – Specific target organ toxicity after single exposure	
Value/conclusion	May cause drowsiness or dizziness.
Justification for the selected value	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
Classification of the product according to CLP	STOT SE 3, H336

Information on dermal absorption

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	The applicant has access to a third 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 third party dossier. Hence, conclusions from the CAR are also

	valid for this dossier. From the publication of Boatman et al. (1998) a dermal flux rate of 0.85 mg/cm^2/h was derived for a 70 % aqueous dilution on rat skin. The composition of the test formulation and the biocidal product are very similar. It is not expected that the slightly lower concentration in the biocidal product 61.25 % vs. 70 % has a significant effect.

Table 31

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	All scenarios with dermal contact Concentration a.s.: 61.25 % (w/w)
Value(s)	0.85 mg/cm^2/h
Justification for the selected value(s)	Boatman et al.(1998); see the table above

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

Not relevant.

Available toxicological data relating to a mixture

Not required.

Other

Not relevant

Summary of effects assessment

Table 32

Endpoint	**Brief description**
Skin corrosion and irritation	Based on the intrinsic properties of 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 single components. Irritating to the eyes (Eye Irrit. 2, H319).
Respiratory tract irritation	Based on the intrinsic properties of single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of single components. Not skin-sensitising.
Respiratory sensitization (ADS)	Based on the known intrinsic properties of single components. Not sensitising to the respiratory tract.

Acute toxicity by oral route	Based on the known intrinsic properties of single components. No acute toxicity via the oral route.
Acute toxicity by inhalation	Based on the known intrinsic properties of single components. No acute toxicity via the inhalation route.
Acute toxicity by dermal route	Based on the known intrinsic properties of 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/cm^2/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).

2.2.6.2 Exposure assessment

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

Table 33

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	Yes	n.a.	Yes	Yes	n.a.
Dermal	n.a.	Yes	Yes	n.a.	Not expected	No	n.a.
Oral	n.a.	n.a.	No	n.a.	n.a.	No	No

List of scenarios

Table 34 Summary table: scenarios for professional user

Scenario no.	Use no. (Product type)	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.2	2 (PT02)	Small surface disinfection - in between disinfection	Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in naturally ventilated rooms e.g. a patient room in a hospital. Secondary exposure of a professional bystander who is present in the patient room where the surface disinfection is carried out.	Professional
2	2 (PT02)	Small surface disinfection in laboratory	Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) 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.	Professional
3	all uses	Refilling	Decanting/Refilling of disinfectant from canisters (5 - 50 L), drums (200 - 220 L), or IBC (720 L) into handy sized packages (manually or with hand pumps, connecting lines). Secondary exposure of a professional bystander is expected.	Professional
4	4 (PT04)	Small surface disinfection in kitchens and canteens	Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) 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. Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out.	Professional

5	4 (PT04)	Disinfection of food processing machinery	Primary exposure of a professional user resulting from application (pouring & wiping, spraying & wiping, spraying) 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 of e.g. a bakery (20° C), including lower temperatures e.g. in a meat processing factory (10 °C).	Professional
6	4 (PT04)	Small surface disinfection of gardening equipment	Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on for disinfection of gardening equipment. Secondary exposure of a professional bystander who is present in the room where the disinfection of gardening equipment is carried out.	Professional

Table 35 Summary table: scenarios for non-professional user, general public and bystanders

Scenario no.	Use no. (Product type)	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.	1 (PT02)	Application: small surface disinfection in bathrooms	Primary exposure of the non-professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces	non-professionals
2.	3 (PT04)	Application: small surface disinfection in kitchens and of gardening equipment	Primary exposure of the non-professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces	non-professionals
3a.	1 (PT02)	Secondary exposure: small surface disinfection in bathrooms	Secondary exposure of a person of the general public (adult) who is present the room where the surface disinfection is carried out	general public, bystanders
3b.	1 (PT02)	Secondary exposure: small surface disinfection in bathrooms	Secondary exposure of a person of the general public (child) who is present in the room where the surface disinfection is carried out	general public, bystanders
3c.	1 (PT02)	Secondary exposure: small surface disinfection in bathrooms	Secondary exposure of a person of the general public (toddler) who is present in the room where the surface disinfection is carried out	general public, bystanders
4a.	3 (PT04)	Secondary exposure: small surface disinfection in kitchens and of gardening equipment	Secondary exposure of a person of the general public (adult) who is present the room where the surface disinfection is carried out	general public, bystanders
4b.	3 (PT04)	Secondary exposure small surface disinfection in kitchens and of gardening equipment	Secondary exposure of a person of the general public (child) who is present in the room where the surface disinfection is carried out	general public, bystanders

4c.	3 (PT04)	Secondary exposure small surface disinfection in kitchens and of gardening equipment	Secondary exposure of a person of the general public (toddler) who is present in the room where the surface disinfection is carried out	general public, bystanders

According to the applicant the biocidal product is also for use by non-professionals to disinfect gardening equipment by spraying or by pouring and wiping. It is assumed that this exposure is also covered by the corresponding scenario of PT4 (surface disinfection in kitchens). Gardening equipment will be disinfected in a garage, a garden shed or outdoors. The volume of such housings will not be significantly smaller than kitchen but will have in any case an increased ventilation rate. The surface of such equipment will not exceed a surface of $1m^2$ as assessed for the disinfection in kitchen. Hence, disinfection in kitchens (scenario 2 and scenario 4) represents a worst case for gardening equipment.
The biocidal product can be applied by pouring and wiping. Before pouring the liquid on a surface it has to be poured into a measuring cup. This task is considered as a part of the application scenarios and does not need to be assessed as a separate scenario. The exposure by pouring is covered by the application scenarios 1 and 2.

Professional exposure

CVAS Disinfectant is a propan-2-ol based disinfectant.
Within PT02 it is used for disinfection of small surfaces, e.g. in the health and institutional sector.
Within PT04 it is used for disinfection of small surfaces in food contact areas in kitchen and canteens, of food processing machinery and also for gardening equipment.

CVAS Disinfectant is a ready-to-use solution containing the active substance Propan-2-ol (CAS-No.: 63-67-0; 61.25 % (w/w))
The biocidal product is marketed in different package sizes:

- Bottle containing 250 ml to 1000 ml
- Bottle with fine mist spray pump or trigger spray head containing 250 ml to 1000 ml
- Canister containing 5 L to 50 L
- Drum containing 200 L to 220 L
- IBC containing 720 L.

The exposure to the a.s. is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. 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.
In Annex 3.2, the details of the exposure calculations for the a.s. for the professional user are laid out.

The inhalation exposure to propan-2-ol (CAS-No 63-67-0) from the different application techniques is assessed using the consumer exposure model ConsExpo Web "Inhalation exposure to vapour - evaporation model" which is applicable to assess the volatile substance. The presentation of the referring individual calculations is provided in Annex 3.2.

Scenario 1.2 - Small surface disinfection – in-between disinfection

Description

The following scenario covers the disinfection of small surfaces with an alcohol based disinfectant in a naturally ventilated room. This scenario is introduced because the scenarios from the CAR for propan-2-ol consider disinfection in technically ventilated rooms, only. Alcohol based RTU products are used on surfaces which require rapid and effective in-between infection control such as: door handles, cabinets, tables and general equipment (e.g. telephones, trolleys).

The eCA assessed based on the decision of Working Group Human Health VII 2018 two different types of professional users representing the worst case for non medical use (e.g. in institutions and industry):

Scenario 1.1: Small surface disinfection – in patient rooms by specialised cleaning personal
Scenario 1.2: Small surface disinfection – in-between disinfection by nurses or health care worker

The complete exposure assessments of both types of users are available in Annex 3.2. Based on the results the scenario 1.2 "Small surface disinfection – in-between disinfection by nurses or health care worker" is the worst case. Therefore scenario 1.2 is described in more details in the following section and is brought to the risk characterisation.

The CVAS disinfectant product is a ready-to-use surface disinfectant solution which may be decanted from a canister into a smaller unit prior to application.
For 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 on the surface, 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.

Based on HEAdhoc recommendation 9, during the working day a nurse/carer is expected to stay 20 minutes in every room to perform their duties. After visiting 4 rooms they are expected to repeat the process throughout the day revisiting each room in turn (therefore, 2 visits per room per day).

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. So it can be assumed that the area of one palm is exposed to the biocidal product during the application procedure.

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. Calculation of 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.

Based on HEAdhoc recommendation 9 the inhalation exposure can be estimated from the following outputs in ConsExpo – evaporation model:
Mean air concentration from disinfection (mg/m3): during 20 minute visit in the room, a small area 0.5 m^2 is disinfected for 1 minute per room.

Remaining air concentration after 240 min: extrapolation from ConsExpo graph plot.

Inhalation exposure =
4 rooms (1st treatment) x mean air conc (xx mg/m3) x 20mins x inhalation rate (1.25m3/hr) + 4 rooms (2nd treatment) x (mean air conc xx mg/m3 + residual air conc xx mg/m3) x 20mins x inhalation rate (1.25m3/hr)

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 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 patient 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 36

Details of Scenario 1.2	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25 % (w/w)
Density of the b.p.	0.882 g/cm³
Number of surface disinfections per day	8
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	50 ml/m²
ConsExpo web parameters	
Room volume	80 m^3
Ventilation rate	1.5 / h
Treated surface area	0.5 m²
Product amount per application	22 g
Frequency of use	4 rooms visited (2 visits per room per day)
Exposure duration (in one room)	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 42 and Table 43. For details of the calculation of

dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

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.
The classification of the b.p requires additional assessment of local risks (see chapter 2.2.6.3: Risk for professional users). 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 eye is not expected. Anyway, contact with eyes should be avoided.
The scenario 1.2 "Small surface disinfection – in-between disinfection by nurses or health care worker" represents a realistic worst case scenario and also covers scenario 1.1 "Small surface disinfection in patient rooms" performed by specialised cleaning personal. This scenario describes disinfection of small surfaces in hospital rooms where one disinfection of 0.5 m² is carried out by e.g. a specialised cleaning personal who visits 10 different hospital rooms during the shift and stays five min in each room to perform routine cleaning tasks.
For further details please refer to Annex 3.2.

The used paper towel has to be discarded into a closed container after use to prevent secondary inhalation exposure to the a.s. which evaporates from the towel.

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

Scenario 2 – Small surface disinfection in laboratory

Description

The exposure assessment of small surface disinfection in technically ventilated rooms (e.g. laboratories) is based on the approach described in the 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 CVAS disinfectant product is a ready-to-use surface disinfectant solution which may be decanted from a canister into a smaller unit prior to application. Please refer to scenario 3 for a more detailed description.

For 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 on the surface, 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 disinfectant is used e.g. in laboratories and cleanrooms.

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 realistic worst case scenario, it is assumed that one person disinfects

its working bench every 45 minutes in a small room and that the persons does not leave the room in-between (according art.19, para.2, lit.a, Reg. (EU) No. 528/2012).

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. So it can be assumed that the area of one palm is exposed to the biocidal product during the application procedure.

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 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 37

Details of Scenario 2	
Parameter	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25 % (w/w)
Density of the b.p.	0.882 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
ConsExpo web parameters	
Room volume	25 m3
Ventilation rate	8 / h
Treated surface area	0.5 m2
Product amount per application	22 g
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 42 and Table 43. For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

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.

The classification of the b.p requires additional assessment of local risks (see chapter 2.2.6.3: Risk for professional users). For disinfection of small horizontal surfaces by professional users the product is usually applied from a short distance on the surface in downwards direction so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

The used paper towel has to be discarded into a closed container after use to prevent secondary inhalation exposure to the a.s. which evaporates from the towel.

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

Scenario 3 – Refilling

Description

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 which requires the use of an adequate funnel. After refilling the person closes the bottles with a screw cap and lifts the bottle to put it aside, which 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. The calculation is based on "Mixing and loading model 4" (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG) and included for information in the Annex 3.2 only (not used for the risk assessment due to use of dermal flux).

Inhalation exposure

Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the active substance 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. A calculation of the 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 the decanting procedure. It is further assumed that the relatively small size of the canister opening and the bottle opening reduces the contact between the b.p. and adjacent air. The 75^{th} percentile is used instead of the 90^{th} percentile since the scenario is already a worst case assumption using a small room size, low ventilation and the nearfield. Moreover the 75^{th} percentile of an ART model was already agreed for HEADhoc recommendation 3 "Spraying models for assessing exposure to insecticides for low pressure downward uses".

Exposure of the eyes

Accidental splashes to the eyes cannot be excluded during manual decanting. 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
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 38

Details of Scenario 3	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25 % (w/w)
Density of the b.p.	0.882 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ART 1.5 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 42 and Table 43. For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

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.
The classification of the b.p requires additional assessment of local risks (see chapter 2.2.6.3: Risk for professional users). Local risk assessment indicated a risk for eye irritation. 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.

It is assumed that refilling from canisters larger than 10 L, drums or IBCs is carried out by the help of dosing pumps or connecting lines leading to less exposure as manual decanting.

Scenario 4 – Small surface disinfection in kitchens and canteens

The exposure assessment of 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.

CVAS is a ready-to-use surface disinfectant solution which may be decanted from a canister into a smaller unit prior to application.

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 on the surface, 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 disinfectant is used for disinfection in kitchen and canteens.

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. The ventilation rate of 15/h is based on the propan-2-ol CAR and information according to the Engineering ToolBox (https://www.engineeringtoolbox.com/air-change-rate-room-d_867.html). 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.

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. So it can be assumed that the area of one palm is exposed to the biocidal product during the application procedure.

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 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
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 39

Details of Scenario 4 - Small surface disinfection in kitchens and canteens	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25 % (w/w)
Density of the b.p.	0.882 g/cm³
Number of surface disinfections per day	4 per day
Exposed skin area (one palm)	205 cm²
Duration of one application	2 min
Application rate	50 ml / m2
ConsExpo web parameters	
Room volume	25 m3
Ventilation rate	15 / h
Surface area	1 m²
Product amount per application	44 g
Exposure duration of one application	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 42 and Table 43. For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

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.

The classification of the b.p requires additional assessment of local risks (chapter 2.2.6.3: Risk for professional users). 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. canteens or supermarkets which have a larger room volume but a lower air exchange rate.

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 smaller application bottles from larger storage containers, please refer to scenario 3.

Scenario 5 – 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 CAR for propan-2-ol.

CVAS is a ready-to-use surface disinfectant solution which has to be decanted from a canister into a smaller unit prior to application.

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 on the surface, 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 disinfectant is used for disinfection in the food processing industry.

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 (T = 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 substances). 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 stays in the production hall for the complete working day and performs disinfections 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 as, in contrast to the CAR for propan-2-ol in which 10 °C were used, disinfections are also intended for 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. It is assumed that both hands are used for wiping of the food processing machinery and its parts which may not be easily accessible. Thus, the palms of both hands are exposed to the product.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the 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 by wiping with a wetted wipe 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 (e.g. splashes). 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 or canteen 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 40

Details of Scenario 5: Disinfection of food processing machinery	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25% (w/w)
Density of the b.p.	0.882 g/cm³
Number of surface disinfections	4 per day
Exposed skin area (two palms)	410 cm²
Application duration	5 min
ConsExpo web parameters	
Room volume	300 m^3
Surface area	4.6 m²
Ventilation rate	20/ h
Application rate	50 ml/m²
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 42 and Table 43. For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

Further information and considertations
Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required.

The classification of the b.p requires additional assessment of local risks (see chapter 2.2.6.3: Risk for professional users). Local risk assessment has indicated a risk for eye irritation. For disinfection of food processing machinery the product is applied on surfaces and also in eye height.
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.

This scenario also covers 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 into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

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

Scenario 6 – Disinfection of gardening equipment

The applicant describes a scenario for disinfection of tools and gardening equipment: The respective tool is cleaned from soil and then placed on a table in a naturally ventilated room and treated with the RTU-product by spraying.
To get the alcoholic disinfectant effectively on the equipment, 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, not the spraying (aerosol formation).

It is assumed that a professional user performs 4 disinfections of tools or gardening equipment, per day. The professional user stays in the room for 15 minutes to treat the equipment with the disinfectant. It is assumed that the disinfectant is applied on the equipment by spraying and then distributed by subsequent wiping to achieve a thorough disinfection of the tools. It is assumed that a total surface of 1 m² maximum is disinfected during the application time of 2 min.

Dermal exposure
During the application phase dermal exposure can be expected if the biocidal product is distributed by wiping with e.g. a single use paper towel in one hand. So it can be expected that the area of one palm is exposed to the biocidal product during the application procedure.

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. Calculation of 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 treatment of tools a small amount of the application liquid is directly applied 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
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 the equipment is carried out. Inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 41

Details of Scenario 6: Disinfection of gardening equipment	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	61.25% (w/w)
Density of the b.p.	0.882 g/cm³
Number of surface disinfections per day	4
Exposed skin area (one palm)	205 cm²
Application duration	2 min
Application rate	50 ml/m²
ConsExpo web parameters	
Room volume (e.g. workshop, garden shed)	25 m^3
Surface area of tools and gardening equipment	1 m²
Ventilation rate	0.5/ h (Tier 1), 2.5 / h (Tier 2)
Product amount per application	44 g (50 ml)
Exposure duration	15 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 42 and Table 43. For details of the calculation of

dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.3.

Further information and considerations

The quantitative exposure assessment has indicated significant inhalation exposure. As a consequence, a refined exposure assessment was performed, taking the following safety measure into account for Tier 2 to address systemic risks: Increase of the air exchange rate to 2.5 per hour (windows and doors open).

The classification of the b.p requires additional assessment of local risks (chapter 2.2.6.3: Risk for professional users). For disinfection of gardening equipment by professional users the product is usually applied from a short distance on the equipment which is placed on a table before the professional user, 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 application bottles from larger storage containers, please refer to scenario 3.

- **Summary of professional exposure**

The following tables give an overview of the assessed exposure values. The exposure data include all phases of application.
In Table 42 the estimated external inhalation exposure are listed. In Table 43 the values of the assumed exposed skin area and application time for dermal exposure are summarised. In chapter 2.2.6.3, Table 43, the internal total exposure values (total uptake) are available. In Annex 3.2 the external and internal exposure values are available for the scenarios.

Table 42

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/m^3]**

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Scenario 1.2 Small surface disinfection – in-between disinfection	1 (PT 02)	Tier 1	39.41
Scenario 2 Small surface disinfection in laboratory	1 (PT 02)	Tier 1	84.00
Scenario 3 Refilling		Tier 1	1.500
Scenario 4 Small surface disinfection in kitchens and canteens	2 (PT 04)	Tier 1	36.20
Scenario 5 Disinfection of food processing machinery	2 (PT 04)	Tier 1	10.300
Scenario 6 Small surface disinfection of gardening equipment	2 (PT 04)	Tier 1 (ventilation rate of 0.5/h)	105.38
		Tier 2 (ventilation rate of 2.5/h)	86.125

Table 43

Summary table: Exposed skin area and application time for dermal exposure.						
Scenario	**Product type**	**Application time [min]**	**Application frequency/ day**	**Exposed skin area [cm^2]**	**Exposed hand (palm) surfaces**	**Application time/day [min]**
Scenario 1.2 Small surface disinfection – in-between disinfection	PT 02	1	10	205	1 palm	10
Scenario 2 Small surface disinfection in laboratory	PT 02	1	10	205	1 palm	10
Scenario 3 Refilling	all	0.49	1	205	1 palm	0.49
Scenario 4 Small surface disinfection in kitchens and canteens	PT 04	2	4	205	1 palm	8
Scenario 5 Disinfection of food processing machinery	PT 04	5	4	410	2 palms	20
Scenario 6 Small surface disinfection of gardening equipment	PT 04	2	4	205	1 palm	8

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

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 44

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/m^3]**

Scenario 1.2: Small surface disinfection - in-between disinfection and Scenario 3: Refilling	1 (PT 02)	Tier 1	40.91
Scenario 2: Small surface disinfection in laboratory and Scenario 3: Refilling	1 (PT 02)	Tier 1	85.500
Scenario 4: Small surface disinfection in kitchens and canteens and Scenario 3: Refilling	2 (PT 04)	Tier 1	37.70
Scenario 5: Disinfection of food processing machinery and Scenario 3: Refilling	2 (PT 04)	Tier 1	11.800
Scenario 6: Small surface disinfection of gardening equipment and Scenario 3: Refilling	2 (PT 04)	Tier 1 ventilation rate of 0.5/h)	106.875
		Tier 2 (ventilation rate of 2.5/h)	87.625

Non-professional exposure

The exposure assessments for non-professional users according to the CAR are based on the TNsG models/defaults and Consexpo 4. Although CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal product that new agreements on some parameters such as HEEG opinions / HEAdhoc recommendations are applicable. Therefore, the exposure assessments for non-professional users are amended accordingly.
Exposure and risk assessment is based on the reference product directly applied as a liquid in accordance to the corresponding CARs for propan-2-ol (PT 2 and 4) and the third party dossier. For non-professionals the use of the product as a spray and as a liquid, which is poured on a surface and subsequently wiped, is relevant. It is assumed that direct use of liquids as assessed in the CAR/third party dossier represents a worst case for the proposed application methods. For application by spraying also exposure to aerosols could be assessed. However, the exposure assessment for vapours of the active substance is considered as a worst case also covering potential exposure by aerosols. More details are given in the Description of Scenarios in Table 42 and Table 43.
The applications assessed according to the listed scenarios are considered to represent also a realistic worst case for all other potential applications.

- **Scenario [1]**

Table 45

Description of Scenario [1]
PT2: Primary exposure, disinfection of small surfaces, bath rooms: The biocidal product is used by non-professional users to disinfect surfaces during household cleaning. Usually this may occur in maximum once per day. If the biocidal product is used as spray it can subsequently be wiped on the surface. It can also be used as a liquid, which is poured and subsequently wiped on the surface. The exposure by direct application of the liquid is considered as a worst case. Furthermore, due to the high vapour pressure of the active substance inhalation exposure may occur if the person stays in the room during and after application. Exposure by aerosols is considered not relevant. The inhalation exposure assessment to vapour is based on an event concentration of more than 1000 mg/m^3 the concentration for exposure to aerosols is about 10.5 mg/m^3 (Consumer spraying and dusting model 2 TNsG part 2, p 197) and therefore 100-fold lower. It is expected that non-professional exposure is limited to a short time interval, usually once per day for 5 min. It is further assumed that disinfection is performed after regular cleaning and that the person cleaning the surface in bathrooms, for example, will leave the room shortly after disinfection. The maximum application frequency of 5 d^{-1} was adapted from the CAR. Based on a decision taken at the BPC-WGVII-2018 exposure from non-professional use in PT2 and PT4 has to be combined. Based on this combined assessment a human health risk is identified for non-professional user. Hence, in an additional exposure assessment the use frequency is reduced to 3 applications d^{-1}. Inhalation exposure The applicant informed in its application that the applied amount is about 40 to 50 mL per m^2. The maximum value is twice the application rate used in the CAR. The exposure assessment from the CAR has been revised accordingly. It is assumed that the biocidal product is applied to a total surface of 1 m^2 within 5 minutes. A small room volume of

Description of Scenario [1]		
10 m^3 and a ventilation rate of 2.0 h^{-1} (default value for bathrooms) have been chosen for calculations according to the General Fact Sheet for Consexpo (2014). The mass transfer rate from the surface to the room volume has been assumed as 0.335 m/min according to Consexpo 4.1 (Thibodeaux's method). As a worst case it is assumed that application is performed 5 times a day. <u>Dermal exposure</u> For dermal exposure as a worst case scenario it is assumed that the biocidal product covers completely the surface of the hands (820 cm^2) with a thin liquid layer of 0.01 cm (according to TGD on Risk Assessment, 2003) resulting in 8.2 mL biocidal product (equivalent to 7.2 g biocidal product with a density of 0.882 g/cm^3 and 4430 mg propan-2-ol). As a worst case scenario it is assumed that the time for evaporation is about 130 s and that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70 % aqueous dilution on rat skin has been estimated as 0.85 $mg/cm^2/h$ (Boatman et al. 1998).		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	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)	5 d^{-1}
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Weight fraction compound (applicant)	61.25 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	5 min
	Room volume (CAR, propan-2-ol, 2014 Consexpo General Fact Sheet, 2014)	10 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.0 hr^{-1}
	Applied amount (applicant), based on a density of 0.882 g/cm^3	44.1 g (50 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mol weight matrix (water)	18 g mol
	Mass transfer rate (Consexpo, Thibodeaux)	0.335 m/min
	Inhalation rate, adult (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m^3/h (0.021 m^3/min)
	Uptake fraction (inhalation absorption)	100 %

Description of Scenario [1]		
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	130 s per application/event (rounded)
	Frequency (CAR, propan-2-ol, 2014)	5 d^{-1}
	Exposed area (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	820 cm^2 (two hands)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 mg/cm^2/h

Calculations for Scenario [1]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

Inhalation exposure = 3.01 mg/kg bw/d (1 application)
= 9.03 mg/kg bw/d (3 applications)
= 15.05 mg/kg bw/d (5 applications)

For dermal exposure the evaporation time is calculated according to the following equation:

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 123 s

t: time [s]
m: mass of propan-2-ol on surface: 4430 mg
R: gas constant: 8.314 J/K/mol
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g/mol
β: mass transfer coefficient, for calculation see TGD: 8.7 m/h
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 x 0.0361 h x 820 cm^2 / 60 kg
= 0.42 mg/kg bw/d (1 application)
= 1.26 mg/kg bw/d (3 applications)
= 2.10 mg/kg bw/d (5 applications)

Total systemic exposure = 3.43 mg/kg bw/d (1 application)
= 10.29 mg/kg bw/d (3 applications)
= 17.15 mg/kg bw/d (5 applications)

- **Scenario [2]**

Table 46

Description of Scenario [2]

PT4: Primary exposure, disinfection of small surfaces, kitchens:
The biocidal product is used by non-professionals to disinfect surfaces in kitchens. Usually this may occur once per day. If the biocidal product is applied as spray it can subsequently be wiped on the surface. It can also be used as a liquid, which is poured and subsequently wiped on the surface. The exposure by direct application of the liquid is considered as a worst case. Furthermore, due to the high vapour pressure of the active substance inhalation exposure may occur if the person stays in the room during and after application. Exposure by aerosols is considered not relevant. The inhalation exposure assessment to vapour is based on an event concentration of more than 1000 mg/m^3 the concentration for exposure to aerosols is about 10.5 mg/m^3 (Consumer spraying and dusting model 2 TNsG part 2, p 197) and therefore 100-fold lower.
Disinfection is usually performed after conventional cleaning of the kitchen. Thus, it is assumed that persons will leave the kitchen briefly after use within 15 min. Dermal exposure is expected in the moment when the operator applies the spray. It is assumed that the total surface of the hands will be covered with the biocidal product for a short time interval until the active substance is evaporated. Dermal exposure because of contact to treated surfaces is considered negligible due to rapid evaporation.

Inhalation
The applicant informed in its application that the applied amount is about 40 to 50 mL per m^2. The maximum value is twice the application rate used in the CAR. The exposure assessment from the CAR has been revised accordingly. It is assumed that the biocidal product is applied to a total surface of 1 m^2 for 5 min (application duration) and that the user leaves the kitchen after 15 minutes (exposure duration). A room volume of 15 m^3 and a ventilation rate of 2.5 h^{-1} have been chosen for calculations as default values for kitchens according to the General Fact Sheet for Consexpo (2014). The mass transfer rate from the surface to the room volume has been assumed as 0.335 m/min according to Consexpo 4.1 (Thibodeaux's method).

Dermal exposure
For dermal exposure as a worst case scenario it is assumed that the biocidal product covers completely the surface of the hands (820 cm^2) with a thin liquid layer of 0.01 cm (according to TGD on risk assessment) resulting in 8.2 mL biocidal product (equivalent to 7.2 g biocidal product with a density of 0.882 g/cm^3 and 4430 mg propan-2-ol). As a worst case scenario it is assumed that the time for evaporation is about 130 s and that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70 % aqueous dilution on rat skin has been estimated as 0.85 $mg/cm^2/h$ (Boatman et al., 1998).

According to the applicant the biocidal product is also for use to disinfect gardening equipment by spraying or by pouring and wiping. It is assumed that this exposure is also covered by this scenario. Gardening equipment will be disinfected in a garage, a garden shed or outdoors. The volume of such housings will not be significantly smaller than kitchen but will have in any case am increased ventilation rate. The surface of such equipment will not exceed a surface of $1m^2$ as assessed for the disinfection in kitchen. Hence, disinfection in kitchens represents a worst case.

	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol

Description of Scenario [2]		
	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}
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Weight fraction compound (applicant)	61.25 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	15 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	15 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.5 hr^{-1}
	Applied amount (applicant, based on a density of 0.882 g/cm^3)	44.1 g (50 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mol weight matrix (water)	18 g mol
	Mass transfer rate (Consexpo, Thibodeaux)	0.335 m/min
	Inhalation rate, adult (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m³/h
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	130 s per application/event (rounded)
	Frequency (CAR, propan-2-ol, 2014)	1 d^{-1}
	Exposed area (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	820 cm^2 (two hands)
	Dermal penetration (CAR, propan-2-ol,	0.85 mg/cm^2/h

Description of Scenario [2]		
	2014)	

Calculations for Scenario [2]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

Systemic inhalation exposure = 6.18 mg/kg bw/d (1 application)

For dermal exposure the evaporation time is calculated according to the following equation:

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 123 s

t: time [s]
m: mass of propan-2-ol on surface: 4430 mg
R: gas constant: 8.314 J/K/mol
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g/mol
β: mass transfer coefficient, for calculation see TGD: 8.7 m/h
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:

Systemic dermal exposure = dermal flux rate x evaporation time x hand surface / body weight
= 0.85 mg cm^{-2} h^{-1} x 0.0361 h x 820 cm^2 / 60 kg
= 0.42 mg/kg bw/d (1 application)

Total systemic exposure = 6.60 mg/kg bw/d (1 application)

- **Combined scenarios**

Combined exposure is considered not relevant by eCA. However, based on a decision taken at the BPC-WGVII-2018 exposure from non-professional use in PT2 and PT4 has to be combined.

Summary table: systemic exposure of the general public				
Exposure Scenario	**Tier / PPE**	**Scenario [1] (mg/kg bw/d)**	**Scenario [2] (mg/kg bw/d)**	**Scenario [1] + Scenario [2] (mg/kg bw/d)**
Scenario [1] PT2:, 1 appl. + Scenario [2] PT4	1	3.43	6.60	10.03
Scenario [1] PT2:, 3 appl. + Scenario [2] PT4	1	10.29	6.60	16.89

Scenario [1] PT2:, 5 appl. + Scenario [2] PT4	1	17.15	6.60	23.75

Secondary exposure of the general public

The exposure assessments for the general public according to the CAR are based on the TNsG models/defaults and Consexpo 4. Although the CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal product that new agreements on some parameters such as HEEG opinions/HEAdhoc are applicable. Therefore, the exposure assessments for non-professional users are amended accordingly.
Exposure and risk assessment is based on the biocidal product directly applied as a liquid in accordance to the corresponding CARs for propan-2-ol (PT 2 and 4). For the general public only exposure after non-professional use was assessed. It is assumed that this exposure represents also a worst case for secondary exposure after professional use. This is supported by the lower mean event concentrations estimated for professional use scenarios.
In addition, it is assumed that direct use of liquids as assessed in the CAR represents a worst case for all relevant applications since the assessment is based mainly on the vapour pressure and the applied amount. The method of application is not relevant. More details are given in the Description of Scenarios.

- **Scenario [3]**

Table 47

Description of Scenario [3]		
PT2: Secondary exposure from disinfection of small surfaces, bathrooms: Secondary acute (daily) non-professional exposure may occur if persons (adults or children) enter rooms after use of the biocidal product. As a worst case, inhalation exposure as presented for primary non-professional exposure assessment is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation should be in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons may stay in the same room as the person applying the biocidal product. It is expected that secondary exposure resulting from professional use is also covered by this scenario. It is assumed that a person stays in the room for 5 min.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol

Description of Scenario [3]		
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	pKow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 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 (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Body weight, toddler (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Weight fraction compound (applicant)	61.25 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	5 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	10 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.0 hr^{-1}
	Applied amount (applicant, based on a density of 0.882 g/cm^3)	44.1 g (50 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mass transfer rate (Consexpo, Thibodeaux)	0.335 m/min
	Mol weight matrix (water)	18 g/mol
	Inhalation rate, adult (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m³/h
	Inhalation rate, child (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.32 m³/h
	Inhalation rate, toddler (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [3]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

3a. Adults

Inhalation exposure = 3.01 mg/kg bw/d (1 application)

3b. Children
Inhalation exposure = 7.98 mg/kg bw/d (1 application)

3c. Toddler
Inhalation exposure = 18.20 mg/kg bw/d (1 application)

- **Scenario [4]**

Table 48

Description of Scenario [4]		
PT4: Secondary exposure from disinfection of small surfaces, kitchens: Secondary acute (daily) non-professional exposure may occur if persons (adults or children) enter rooms after use of the biocidal product. Inhalation exposure is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation are in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons stay in the same room as the person that has applied the biocidal product. It is expected that exposure from professional use is also covered by this scenario. It is assumed that a person stays in the room for 15 min. For Tier 1 the exposure assessment is based on a mean event concentration of approximately 1200 mg/m^3 (refer to the Consexpo report and the corresponding extracts from the excel sheets in section 3.2). If children do not enter the treated room within the first 15 min, the mean event concentration is reduced to approximately 750 mg/m^3. Values significantly below this concentration are also expected if adequate ventilation is provided. Using this concentration the inhalation exposure is assessed in Tier 2.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	pKow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 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 (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Body weight, toddler (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Weight fraction compound (applicant)	61.25 % (w/w)

Description of Scenario [4]		
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	15 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	15 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.5 hr^{-1}
	Applied amount (applicant, based on a density of 0.882 g/cm^3)	44.1 g (50 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mass transfer rate (Consexpo, Thibodeaux)	0.335 m/min
	Mol weight matrix (water)	18 g/mol
	Inhalation rate, adult (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m^3/h
	Inhalation rate, child (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.32 m^3/h
	Inhalation rate, toddler (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.26 m^3/h
	Uptake fraction (inhalation absorption)	100 %
Tier 2	Mean event concentration a.s. (calculated from Consexpo data, rounded up)	750 mg/m^3

Calculations for Scenario [4]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to corresponding Annex in section 4.

4a. Adults
Inhalation exposure = 6.18 mg/kg bw/d (1 application)

4b. Children
Inhalation exposure = 16.40 mg/kg bw/d (1 application)

4c. Toddler
Inhalation exposure = 37.40 mg/kg bw/d (1 application)

Tier 2
Systemic inhalation exposure = mean event concentration x inhalation rate x inhalation duration x inhalation absorption / body weight

4.a Adult = 750 mg/m^3 x 1.25 mg/m^3 x 0.25 h x 100 % / 60 kg
= 3.91 mg/kg bw/d

4.b Child = 750 mg/m^3 x 1.32 mg/m^3 x 0.25 h x 100 % / 23.9 kg
= 10.36 mg/kg bw/d

4.c Toddler = 750 mg/m^3 x 1.26 mg/m^3 x 0.25 h x 100 % / 10 kg
= 23.63 mg/kg bw/d

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**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]	1	3.01	-	-	3.01
Scenario [3b]	1	7.98	-	-	7.98
Scenario [3c]	1	18.20			18.20
Scenario [4a]	1	6.18	-	-	6.18
Scenario [4b]	1	16.40	-	-	16.40
Scenario [4c]	1	37.40			37.40
Scenario [4a]	2	3.91	-	-	3.91
Scenario [4b]	2	10.36	-	-	10.36
Scenario [4c]	2	23.63			23.63

- **Combined scenarios**

Not relevant.

Dietary exposure

The intended uses of the biocidal product containing propan-2-ol for which authorisation is sought indicate that these uses are not relevant for residues in food and feed. Nevertheless, the product may come into direct contact with food or feed during professional and non-professional surface disinfection of small surfaces in food/feed processing areas, kitchens or canteens. However, due to its high vapour pressure, the active substance completely evaporates within the application time of the biocidal product, so that no transfer of active substance residues from treated surfaces to food should take place. In the unlikely event that residue transfer occurs, the active substance evaporates from the food before being consumed. Therefore, dietary exposure to humans from the use of propan-2-ol as a biocide of PT 2 or PT 4 can be excluded.

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.

Aggregated exposure

Not applicable

Summary of exposure assessment

Table 50 Scenarios and values to be used in risk assessment for professionals (please refer to Table 34 for details on the scenarios)

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1.2 Small surface disinfection – in-between disinfection	Professionals	Tier 1	6.96
2. Small surface disinfection in laboratory	Professionals	Tier 1	14.48
3.Refilling	Professionals	Tier 1 (eye protection)	0.73
4. Small surface disinfection in kitchens and canteens	Professionals	Tier 1	6.42
5.Disinfection of food processing machinery	Professionals	Tier 1 (eye protection)	3.65

6. Small surface disinfection of gardening equipment	Professionals	Tier 2 (ventilation rate of 2.5/h)	14.74

Table 51 Scenarios and values to be used in risk assessment for non-professionals and the general public (please refer to Table 35 for details on the scenarios)

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake, (mg/kg bw/d)**
1.	PT2: Primary exposure from disinfection of small surfaces, e.g. in bath rooms	Tier 1	17.15
2.	PT4: Primary exposure by disinfection of small surfaces, in kitchens, gardening equipment	Tier 1	6.60
3a.	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult	Tier 1	3.01
3b.	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, child	Tier 1	7.98
3c.	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler	Tier 1	18.20
4a.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, adult	Tier 1	6.18
4b.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, child	Tier 1	16.40
4c.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, toddler	Tier 1	37.40
4a.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, adult	Tier 2	3.91
4b.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, child	Tier 2	10.36
4c.	PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, toddler	Tier 2	23.63

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 52.

Table 52

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). The composition of the test formulation and biocidal product are very similar. Value can be used.
Inhalative absorption	Assessment Report (RMS DE (2014)				100 %
Oral absorption	Slauter et al., 1994				Nearly complete following oral, inhalation and intravenous exposure.

Maximum residue limits or equivalent

Default MRL of 0.01 mg/kg applies according to Art 18(1)(b) Reg 396 / 2005.

Risk for industrial users

No industrial applications are intended.

Risk for professional users

General considerations

The biocidal product CVAS Disinfectant product based on Propan-2-ol 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 – quantitative

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 CVAS Disinfectant product based on Propan-2-ol 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 CVAS Disinfectant product based on Propan-2-ol.

Details of risk characterisation

Reference value
For the purpose of risk characterisation resulting from exposure of professional users to Propan-2-ol from the biocidal product CVAS Disinfectant product based on Propan-2-ol, inhalation and dermal exposure to Propan-2-ol is assessed. As reference value the $AEC_{long\text{-}term}$ 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.

Absorption by inhalation
As default inhalation absorption of 100 % is assumed for the active substance Propan-2-ol.

Dermal uptake
Due to rapid evaporation of Propan-2-ol, data on dermal flux (0.85 mg/cm^2/h) instead of data on percentage of dermal absorption is used for the calculation of the dermal uptake.

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

The inhalation and dermal uptake referring to the active substance Propan-2-ol resulting from use of the biocidal product CVAS Disinfectant product based on Propan-2-ol 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 CVAS Disinfectant product based on Propan-2-ol is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 53 gives a detailed overview of the risk assessment results referring to the active substance Propan-2-ol for the biocidal product CVAS Disinfectant product based on Propan-2-ol. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 53. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 53, the scenarios small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens and disinfection of food processing machinery yield an exposure-to-AEL ratio of less than 100 % already in TIER 1.

By contrast, the exposure-to-AEL ratio of the scenario disinfection of gardening equipment exceeds the value of 100 % after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However when risk reduction measures are implemented the risk characterisation results yield an exposure-to-AEL ratio of less than 100 % in TIER 2.

Risk assessment results for the scenarios that are shown in Table 53 are regarded as worst case assumptions for risk assessment of the respective secondary exposure.

As mentioned in chapter 2.2.6.2 dermal exposure of the bystander, i.e. secondary dermal exposure is not expected for the following scenarios: small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of gardening equipment.
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 aforementioned scenarios.

Table 53:Overview of detailed risk assessment results referring to the active substance Propan-2-ol for the biocidal product CVAS Disinfectant product based on Propan-2-ol

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)
Small surface disinfection - in between disinfection	Tier 1	17.9	6.57	0.39	6.96	38.86	yes
Small surface disinfection in laboratory	Tier 1	17.9	14.00	0.48	14.48	80.92	yes
Refilling	Tier 1	17.9	0.25	0.48	0.73	4.10	yes
Small surface disinfection in kitchens and canteens	Tier 1	17.9	6.03	0.39	6.42	35.87	yes
Disinfection of food processing machinery	Tier 1	17.9	1.72	1.94	3.65	20.41	yes
Disinfection of gardening equipment	Tier 1	17.9	17.56	0.39	17.95	100.28	no
	Tier 2	17.9	14.35	0.39	14.74	82.35	yes

Tier 1: no PPE (small surface disinfection - in between disinfection, small surface disinfection in laboratory, small surface disinfection in kitchens and canteens, disinfection of gardening equipment); eye protection (refilling, disinfection of food processing machinery);
Tier 2: air echange rate of 2.5/h (disinfection of gardening equipment)
[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 chapter 2.2.6.2

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 small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of food processing machinery, disinfection of gardening equipment as well as from secondary exposure (Disinfection of food processing machinery) is unlikely since the respective risk characterisation yields exposure-to-AEL ratios of less than 100 % at least after TIER 2 consideration. The risk characterisation for the scenarios small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of gardening equipment 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 risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % at least after TIER 2 consideration.
Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.1.4 of this PAR.

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 in chapter 2.2.6.3.

A risk for professional users referring to the active substance Propan-2-ol resulting from the combined uses of the biocidal product CVAS Disinfectant product based on Propan-2-ol is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 54 gives a detailed overview of the risk assessment results referring to the active substance Propan-2-ol for the biocidal product CVAS Disinfectant product based on Propan-2-ol. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 54. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 54, the combined scenarios considered (refilling + small surface disinfection - in between disinfection, refilling + small surface disinfection in laboratory, refilling + small surface disinfection in kitchens and canteens, refilling + disinfection of food processing machinery yield an exposure-to-AEL ratio of less than 100 % already in TIER 1. By contrast, the exposure-to-AEL ratio of the scenario refilling + disinfection of gardening equipment exceeds the value of 100 % after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However when risk reduction measures are implemented the risk characterisation results yield an exposure-to-AEL ratio of less than 100 % in TIER 2.

Table 54: Overview of detailed systemic risk assessment results referring to the active substance Propan-2-ol regarding combined scenarios for the biocidal product CVAS Disinfectant product based on Propan-2-ol

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)
Refilling + Small surface disinfection - in between disinfection	Tier 1	17.9	6.82	0.87	7.69	42.96	yes
Refilling + Small surface disinfection in laboratory	Tier 1	17.9	14.25	0.971	15.22	85.02	yes
Refilling + Small surface disinfection in kitchens and canteens	Tier 1	17.9	6.28	0.87	7.15	39.97	yes
Refilling + Disinfection of food processing machinery	Tier 1	17.9	1.97	2.42	4.39	24.51	yes
Refilling + Disinfection of gardening equipment	Tier 1	17.9	17.81	0.87	18.68	104.38	no
	Tier 2	17.9	14.60	0.87	15.48	86.45	yes

Tier 1: eye protection (refilling + small surface disinfection - in between disinfection, refilling + small surface disinfection in laboratory, refilling + small surface disinfection in kitchens and canteens, refilling + disinfection of food processing machinery)
Tier 2: air exchange rate of 2.5/h (refilling + disinfection of gardening equipment)
[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 chapter 2.2.6.2

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 refilling + small surface disinfection - in between disinfection, refilling + small surface disinfection in laboratory, refilling + small surface disinfection in kitchens and canteens, refilling + disinfection of food processing machinery, refilling + disinfection of gardening equipment is unlikely since the respective risk characterisation yields exposure-to-AEL ratios of less than 100 % at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the combined scenarios taking into account the provisions described in chapter 2.1.4 of this PAR.

- **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 CVAS Disinfectant product based on Propan-2-ol with H319 (Causes serious eye irritation). In addition, the biocidal product CVAS Disinfectant product based on Propan-2-ol 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 (December 2017) is "low" (Table 55).

Table 55: 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 (December 2017)**
100 (RTU) (61.25 % (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 (December 2017) Table 56 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of the biocidal product CVAS Disinfectant product based on Propan-2-ol for the intended uses small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of food processing machinery and disinfection of gardening equipment. 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 56: Summary of qualitative conclusions for local risk assessment for the biocidal product CVAS Disinfectant product based on Propan-2-ol

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
2	Small surface disinfection - in between disinfection	RTU (61.25 % (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.	**Yes**
2	Small surface disinfection in laboratory	RTU (61.25 % (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.	**Yes**
4	Small surface disinfection in kitchens and canteens	RTU (61.25 % (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.	**Yes**
4	Disinfection of food processing machinery (20 °C)	RTU (61.25 % (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. Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**

4	Disinfection of gardening equipment	RTU (61.25 % (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.	**Yes**
2, 4	Refilling	RTU (61.25 % (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. Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**

Conclusion
Concerning the local eye and skin effects of biocidal product CVAS Disinfectant product based on Propan-2-ol, the intended uses small surface disinfection - in between disinfection, small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of food processing machinery and disinfection of gardening equipment 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 CVAS Disinfectant product based on Propan-2-ol is unlikely. Risk reduction measures described in chapter 2.1.4 have to be taken into account in order to ensure safe use of the biocidal product CVAS Disinfectant product based on Propan-2-ol.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

Risk for non-professional users

Systemic effects

Table 57

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)
PT2: Primary exposure from disinfection of small surfaces, e.g. in bath rooms, 5 appl.	1	68.5	10.7	17.15	164	no
PT2: Primary exposure from disinfection of small surfaces, e.g. in bath rooms, 5 appl.	2	68.5	17.9	17.15	96	yes
PT4: Primary exposure by disinfection of small surfaces, in kitchens, gardening equipment	1	68.5	10.7	6.60	62	yes

The exposure estimate after 5-fold daily application of the biocidal product in PT 2 (scenario 1) is above the systemic AEL (164 % of AEL). All AEL for the general population and for workers have been derived using a chemical-specific adjustment factor for human variability in toxicokinetics according to a physiological based pharmacokinetic modelling for propan-2-ol (Clewell et al., 2001 and 2004). Using this model chemical-specific assessment factors has been derived for different life stages. The highest assessment factor (2.0) calculated for the age from birth to six month has been used for derivation of the AEL for the general population. For workers the factor for

the life stages '5 to 25 years' (1.2) was selected, which was higher than the second relevant factor for the life stage '25 to 75 years' (0.83). For non-professional user it can be generally assumed that they are adults or at least adolescents. Thus, the AEL for workers/professionals is also applicable for this sub-population and for risk characterisation of non-professional primary exposure. This is in accordance to the CAR for PT2.

- **Combined scenarios**

Based on a decision taken at the BPC-WGVII-2018 exposure from non-professional use in PT2 and PT4 has to be combined.

Table 58

Task/ Scenario	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1] PT2:, 1 appl. + Scenario [2] PT4	68.5	17.9	10.03	56	yes
Scenario [1] PT2:, 3 appl. + Scenario [2] PT4	68.5	17.9	16.89	94	yes
Scenario [1] PT2:, 5 appl. + Scenario [2] PT4	68.5	17.9	23.75	133	no

- **Local effects**

Local reference values for non-professional users are not available. However, 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 2.3.6.3 are followed. For eye-irritating formulations eye protection (P280) is normally required to avoid eye damages by splashes. Based on the application frequency and the packaging the risk of eye contact by splashes of the biocidal product is low. Based on the classification as Eye Irrit Cat. 2 it is expected that the effects on eyes are not severe and can be treated easily by rinsing the eyes. The corresponding set of precautionary statements is given in section 2.3.6.3. These statements and an appropriate labelling, which instruct the non-professional user to avoid eye contact (e.g. Avoid contact with eyes) is considered 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 biocidal product (PT2 and 4) by non-professional users was identified if the biocidal product 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.
A human health risk has been identified for combined exposure to PT 2 and PT 4 applications. Safe use is expected if application frequency for PT02 does not exceed 3 times per day. Hence, the non-professional user has to be informed on the daily maximum application frequency. Assuming that the same product is used for both PT the maximum frequency is 4 d^{-1}.
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 3.4 / 3.5. In addition, a labelling advice to avoid contact to eyes is required.
To avoid excessive exposure of non-professional users the authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label. Depending on the spray device this can be expressed as spray duration, number of strokes or number of jets. Bottles used for pouring and wiping are equipped with a measuring cup.
Based on a decision taken at the BPC-WGVII-2018 the applicant provided detailed information to define the specific instructions. The information was evaluated and considered acceptable for the relevant packagings.

The summary of the applicant is presented below:

The product based on propan-2-ol is used for the disinfection of small surfaces in product type 2 and 4. For non-professional users, the typical application rate of the product is now given in a simple, easily understandable form. This information will be included on the label.
Alpha Septin, Disinfect Home and Bactazol I were tested in the reports Mo5466, Mo6394 and Mo5467 (Manka, S., 2016 and Manka, S., 2018). The tested packaging sizes are 400 mL (Alpha Septin), 500 mL (Bactazol I) and 250 mL (Disinfect Home). For Disinfect Home and Bactazol I, all packaging sizes are equipped with the same type of spray head (see Table below). Thus, the discharge rate is not depending on the bottle size per se but on the construction of the spray head. Consequently, for all packaging sizes, the same amount of product is expulsed per operation.

Representative product	***Application form***	***Packaging size***	***Application rate***	***Type of spray head (material of spray head)***	***Discharge rate/Report***	***Calculated spray duration/spray hubs/no. of measuring cups***
Alpha Septin	*Bag-in-box system/Trigger spray*	*400 mL / 250–1000 mL*	*50 mL/m^2*	*Valve body (PP, 2139 Gel)/Trigger sprayer "Versa Plast (SP05)" (PP, PE, EPE, EBA, POM)*	*1.85075 g/s Mo5466*	*24 seconds*
Disinfect Home	*Trigger spray*	*250–1000 mL*		*Trigger sprayer "Versa Plast (SP05)" (PP, PE, EPE, EBA, POM)*	*1.063 g/stroke Mo6394*	*41 strokes*
Bactazol I	*Pump spray*	*250–1000 mL*		*Fine mist spray pump "MK VII Max" (PP, PE, PBT, EVA)*	*0.1645 g/jet*	*268 jets*
Schnell	*Bottle*	*250–1000*		*Lid (HDPE)*	*-*	*1 measuring*

*Des**		*mL*				*cup*

** The product Schnell Des is commercialized as a HDPE Bottle with volumes ranging from 250-1000 mL. For each packaging size, the bottles will be equipped with a measuring cup (50 mL) so that the non-professional user will be able to easily dose the product in the correct application rate before utilization.*

Two exemplary calculations for Alpha Septin (spray duration) and Disinfect Home (spray hubs) are given below for conformity:

Relative density (D_4^{20}) of the products: 0.882
Density of water at 4°C (PH2O): 0.99997 g/cm^3
Density of product (PProduct): 0.8819 g/cm^3

Application rate: 50 mL/m^2

Calculated product amount in 50 mL (m) = 44.095 g of product per m^2 required

For Alpha Septin:
Discharge rate per second: 1.85075 g/s
Required amount of time for 44.095 g product to be expulsed:
24 seconds/m^2

For Disinfect Home:
Discharge rate per stroke: 1.063 g
Required amount of strokes for 44.095 g product to be expulsed:
41 strokes/m^2

Note that the values proposed by the applicant and agreed by the eCA are rounded in the instructions for better compliance.
24 seconds per m^2 are rounded to 10 s per 0.5 m^2.
41 strokes per m^2 are rounded to 20 strokes per 0.5 m^2.
268 jets per m^2 to 3 jets per 100 cm^2.

Risk for the general public

Table 59: 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)
PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult	1	68.5	10.7	3.01	28	yes
PT2: Secondary exposure from disinfection of small surfaces, batrooms, child	1	68.5	10.7	7.98	75	yes
PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler	1	68.5	10.7	18.20	170	no
PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, adult	1	68.5	10.7	6.18	58	yes
PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, child	1	68.5	10.7	16.40	153	no
PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, toddler	1	68.5	10.7	37.40	350	no
PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, adult	2	68.5	10.7	3.91	37	yes
PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, child	2	68.5	10.7	10.36	97	yes

PT4: Secondary exposure from disinfection of small surfaces, kitchens, gardening equipment, toddler	2	68.5	10.7	23.63	221	no

Local effects

Specific local effects for bystanders (general public) are not expected.
The biocidal product can produce local effects on skin and eyes. However, dermal or eye contact with the biocidal product is not expected for the general public (bystander).

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 if all RMM and the instructions for use are followed. Based on the risk assessment for Scenario 4 (PT4) for children and Scenario 3 and 4 (PT2 and PT4) for toddlers, re-entry of non-involved third parties, particularly children to rooms, where treatment took place, has to be avoided before adequate ventilation reducing the active substance concentration to acceptable levels. (Based on the calculated models the acceptable aerial concentration for toddlers is about 300 mg/m^3 if exposed for 15 min. Assuming a ventilation rate of 6 h^{-1} this level is reached approximately after 20 min.). Hence, a specific advice is required on the label.

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.

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

The biocidal product contains only one active substance and no substances or substances. A risk characterisation from combined exposure is not necessary.

Summary of risk characterisation

Summary of risk characterisation for industrial user

Not applicable

Summary of risk characterisation for professional user

For the summary of risk characterisation for the professional user please refer to Table 53 and Table 54.

Summary of risk characterisation for non-professional user

For the summary of risk characterisation for the non-professional user please refer to Table 57.

Summary of risk characterisation for indirect exposure

For the summary of risk characterisation for indirect exposure of the general public please refer to Table 59Table 59.

2.2.7 Risk assessment for animal health

There is no toxicological information available implying that pets or domestic animals are 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.

2.2.8 Risk assessment for the environment

2.2.8.1 General information

The biocidal product "CVAS Disinfectant product based on propan-2-ol" is intended to be used in product type 2 and 4 for disinfection of small surfaces in private, public and industrial 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 2.2.8.3.
In the course of the product authorisation process, the applicant submitted access to an alternative dossier for 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 new data 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 "CVAS Disinfectant product based on propan-2-ol" will be based on data that were agreed during the approval of the active substance propan-2-ol.

2.2.8.2 Effects assessment

The biocidal product "CVAS Disinfectant product based on propan-2-ol" 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 "CVAS Disinfectant product based on propan-2-ol" 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).

- **Mixture toxicity**

The biocidal product "CVAS Disinfectant product based on propan-2-ol" 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.

- **Aquatic compartment (including sediment and STP)**

Aquatic toxicity:

According to the CAR, acute and chronic data on effects of propan-2-ol 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 microorganisms 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.

- **Terrestrial compartment (including groundwater)**

Since direct exposure of the product 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.

- **Atmosphere**

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

- **Non-compartment specific effects**

Due to a log K_{OW} of 0.05, 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 product.

Summary of effects assessment

Table 60 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

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 0.80 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 1 h^{-1} was used.

- **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 logK_{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.

2.2.8.3 Exposure assessment

- **General information**

The biocidal product "CVAS Disinfectant product based on propan-2-ol" is used in product type 2 and 4 for disinfection of small surfaces by professionals and non-professionals as well as in food preparation and handling and in food production facilities. The ready-to-use product "CVAS Disinfectant product based on propan-2-ol" contains 68.8% v/v (61.3% w/w equivalent) propan-2-ol as a.s. and is applied by spraying or pouring techniques.

Table 61: Intended use in PT2

Assessed PT	PT 2
Assessed scenarios	Use 2a: Disinfection of small surfaces in industrial areas – professional user Use 2b: Disinfection of small surfaces for sanitary purposes in institutional areas – professional user Use 1a: Disinfection of small surfaces for sanitary purposes – non-professional user
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal

	products (sanitary and medical sector), March 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC, 2011
Approach	Use 2a: Average consumption Use 2b: Average consumption/tonnage Use 1a: Average consumption/tonnage
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	FOCUS PEARL refinement was performed for use 1a, 2a and 2b.
Confidential Annexes	YES: In the confidential annex the tonnage based local emissions for use 2b and 1a are provided.
Life cycle steps assessed	All intended uses: Production: No Formulation No Use: Yes Service life: No
Remarks	

Table 62: Intended use in PT4

Assessed PT	PT 4
Assessed Intended uses	Use 4a: Disinfection of small surfaces in canteens/catering kitchens or food processing industry (professional user) Use 3a: Disinfection of small surfaces in kitchens (non-professional user) Use 3/4: Disinfection of gardening equipment (professional and non-professional)
ESD(s) used	Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas, JRC 2011
Approach	Use 4a & Use 3a: consumption based Use 3/4: qualitative assessment
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	FOCUS PEARL refinement was performed for use 4a & use 3a
Confidential Annexes	NO
Life cycle steps assessed	Use 4a & Use 3a: Production: No Formulation No Use: Yes Service life: No Use 3/4: qualitative assessment
Remarks	

- **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 "CVAS Disinfectant product based on propan-2-ol" containing 68.8% 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 "CVAS Disinfectant based on propan-2-ol", 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.

PT2: Intended use 2a [Disinfection of small surfaces in industrial areas – professional user]

Consumption based approach

The emission scenario for disinfectants used in industrial areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). The scenario provided in the ESD PT2 (JRC, 2011) for use in industrial areas is based on application rate, a scenario based on annual tonnage is not provided for this use in the ESD. The application rate of max. 50 mL/m^2 represents a worst-case application of the RTU solutions. It was decided at the WG ENV I 2017 that the default application frequency of 1 covers a surface area of 25 m^2 in industrial areas for RTU products in PT2 (TAB v1.3 2017, ENV38). According to the applicant, max. 10 times per day an application is foreseen. The RefMS considered this application frequency as an extreme worst case and decided to deviate from the default value of 1 and instead use a value of 2 applications per day. The resulting local emission of propan-2-ol to the waste water and air from the application of the biocidal product "CVAS Disinfectant product based on propan-2-ol" is given in Table 63.

Table 63: Emission scenario for surface disinfection in industrial areas

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2011)	Value
Application rate of b.p.(S)	50 mL/m^2
Concentration of a.s in b.p(S)	527 g/L
Surface area treated(WG ENV I 2017)	25 m^2
Number of applications per day(S)	2
Fraction of a.s. disintegration(D)	0
Fraction released to wastewater(CAR)	0.1
Fraction released to air(CAR)	0.9

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2011)	Value
Calculation Results	**Value**
Local emission rate to waste water	0.13 kg/d
Local emission rate to air	1.19 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

PT2: Intended use 2b [Disinfection of small surfaces for sanitary purposes in institutional areas – professional user]

The emission can be calculated based on the tonnage or on the specific consumption. 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.

Tonnage based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas based on tonnage is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). It can be assumed that in institutional and private health care areas disinfection takes place only during the working week. The emission days (Temission) was adapted accordingly to 260 days. The resulting local emission of propan-2-ol to the waste water and air from the application of a product "CVAS Disinfectant product based on propan-2-ol" based on tonnage is given in Annex 3.6.

Consumption based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). The default consumption per capita of the b.p for general purpose is 5 mL/d. The resulting local emission of propan-2-ol to the waste water and air from the application of a product "CVAS Disinfectant product based on propan-2-ol" is given in Table 64.

Table 64: Emission scenario for surface disinfection in institutional areas (professional users) based on consumption

Determinants of the local emission according to Chapter 2.1, Table 4; Environmental Emission Scenarios for PT 2 (JRC, 2011)	Value
Number of inhabitants feeding one STP (D)	10000
Active substance in product (S)	0.527 kg/L
Consumption per capita (D)	0.005 L/d
Fraction released to wastewater (CAR)	0.1

Determinants of the local emission according to Chapter 2.1, Table 4; Environmental Emission Scenarios for PT 2 (JRC, 2011)	Value
Fraction released to air (CAR)	0.9
Penetration factor (CAR)	0.3
Calculation Results	**Value**
Local release to waste water	0.79 kg/d
Local release to air	7.12 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

It can be assumed that in institutional and private health care areas disinfection takes place only during the working week (260 days per year). 260 emission days per year were considered for the exposure of the air compartment.

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 form the consumption based approach should be used for further environmental exposure and risk assessment. In case of "CVAS Disinfectant product based on propan-2-ol" for the environmental exposure and risk assessment the emission based on consumption is used.

PT2: Intended use 1a [Disinfection of small surfaces for sanitary purposes – non-professional user]

The emission can be calculated based on the tonnage or on the specific consumption. 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.

Tonnage based approach

The emission scenario for disinfectants used for sanitary purposes (non-professional) based on tonnage is described in Chapter 2 of the ESD for PT2 (van der Poel, 2001). The resulting local emission of propan-2-ol to the waste water and air from the application of the product "CVAS Disinfectant product based on propan-2-ol" based on tonnage is given in confidential Annex.

Consumption based approach

The emission scenario for disinfectants used for sanitary purposes (non-professional) is described in Chapter 2 of the ESD for PT2 (van der Poel, 2001). The default consumption per capita of the b.p for general purpose is 5 ml/d. The resulting local emission of propan-2-ol to the waste water and air from the application of the product "CVAS Disinfectant product based on propan-2-ol" is given in Table 65.

Table 65: Emission scenario for surface disinfection used for sanitary purpose (non-professional users) based on consumption

Determinants of the local emission according to Chapter 2, Table 2.2; Environmental Emission Scenarios for PT 2 (van der Poel, 2001)	Value
Number of inhabitants feeding one STP (D)	10000
Active substance in product (S)	0.527 kg/L
Consumption per capita (D)	0.005 L/d
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9
Penetration factor (CAR)	0.3
Calculation Results	**Value**
Local release to waste water	0.79 kg/d
Local release to air	7.12 kg/d

(S) – Provided by applicant

(D) – Default (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 "CVAS Disinfectant product based on propan-2-ol", for the environmental exposure and risk assessment the emission based on consumption is used.

PT4: Intended use 4a [Surface disinfection in 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 small-scale RTU products were defined at the WG ENV I 2017 (see also TAB v1.3 2017, ENV55). Large scale catering kitchens with a disinfected surface area of 50m^2 for small-scale applications cover the realistic worst case. Consequently, an environmental risk assessment for slaughterhouses was not conducted.

Table 66: 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 the a.s. (S)	26.3375 g/m^2
Surface area to be disinfected (TAB v1.3, ENV 55) Slaughterhouses Large scale catering kitchens	 10 m^2 50 m^2
Number of applications per day(D)	1
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	0.132 kg/d
Local release to air	1.185 kg/d

(S) – Provided by applicant

(D) – Default (JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

It can be assumed that in food and feed producing/processing areas disinfection takes place only during the working week (260 days per year). 260 emission days per year were considered for the exposure of the air compartment.

PT4: Intended use 3a [Surface disinfection in food and feed area – non-professional user]

At the point of assessment of this union authorisation, there was no emission scenario to evaluate the disinfection of small surfaces by non-professionals in kitchens. Therefore the refMS used the existing emission scenario for disinfection of small surfaces in food and feed processing areas (slaughterhouses and catering kitchens) by professionals. This emission scenario is published in the ESD for PT 4 in chapter 2.2.4 and represents the worst-case scenario for the small-scale use of disinfectants in kitchens by non-professional users.
Additionally, it can be assumed that disinfectants in kitchens by non-professional are applied on a daily basis (365 days per year).

At the WG ENV I 2018 a harmonised emission scenario for private kitchens was adopted and published in the draft TAB 1.5 ENV 70. This scenario should be used for future environmental exposure assessments.

Table 67: Emission scenario for calculating the releases of disinfectants used in kitchens

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 the a.s. (S)	26.3375 g/m^2
Surface area to be disinfected (TAB v1.3, ENV 55) Slaughterhouses Large scale catering kitchens	 10 m^2 50 m^2
Number of applications per day(D)	1
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	0.132 kg/d
Local release to air	1.185 kg/d

PT4: Intended use 3/4 [Disinfection of gardening equipment professional and non-professional user]

The biocidal product "CVAS Disinfectant product based on propan-2-ol" can be used for the disinfection of gardening equipment (e.g. secateurs), according to the applicant. The RTU-product is applied after the gardening tool has been used and before tidying up to prevent possible infection of the user by injuries due to contaminated tips, edges or cutting surfaces.
The gardening equipment is placed indoor on an impermeable surface (e.g. table in a summer house) and the RTU-product is applied to a very limited surface area by spraying or wiping.
Consequently, it can be concluded that emission into the environment is negligible. Comparably, to the other uses in PT 4, this small scale application is covered by the disinfection of large scale catering kitchens, because the considered area for canteens is 50 m^2 whereas for the disinfection of gardening equipment an area of lower than 1m^2 is mentioned by the applicant.
Thus, even if disinfection of gardening equipment is performed several times per day, emissions will be lower than for disinfection of surfaces in the food and feed industry.
Therefore, no environmental exposure assessment was performed.

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

The application of the biocidal product "CVAS Disinfectant product based on propan-2-ol" 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 68: Identification of relevant receiving compartments based on the exposure pathway

	Freshwater	Freshwater sediment	STP	Soil	Groundwater	Air
Use 2a	Yes (indirect)	Yes (indirect)	yes	Yes (indirect)	Yes (indirect)	Yes
Use 2b	Yes (indirect)	Yes (indirect)	yes	Yes (indirect)	Yes (indirect)	Yes
Use 1a	Yes (indirect)	Yes (indirect)	yes	Yes (indirect)	Yes (indirect)	Yes
Use 4a	Yes (indirect)	Yes (indirect)	yes	Yes (indirect)	Yes (indirect)	Yes
Use 3a	Yes (indirect)	Yes (indirect)	yes	Yes (indirect)	Yes (indirect)	Yes
Use 3/4	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible

- **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 69: 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

Input	Value	Unit	Remarks
Organic carbon/water partition coefficient (Koc)	3.3	l/kg	
Henry's Law Constant (at 12°C)	0.383	$Pa/m^3/mol$	Measured Henry's constant 0.8 Pa/m3/mol at 25°C
Biodegradability			a.s. is readily biodegradable
Rate constant for STP	1	h^{-1}	
DT_{50} for degradation in soil	30	d (at 12ºC)	

The distribution in the sewage treatment plant is calculated using SimpleTreat v.3.1. This results in release fractions to air of 0.3 %, water 12.5 %, sludge < 0.1 % and degraded fraction 87.1 %. For further exposure calculations the fraction released to the environment via sludge is considered as negligible.
At WG ENV VII 2018, it was agreed to derive the rate constant for volatilisation from soil (k_{volat}) according to the updated Guidance document (Guidance BPR IV ENV B+C, 2017) as different values for k_{volat} of propan-2-ol were used within the member states. A k_{volat} value of 0.0119 d^{-1} for agricultural soils and 0.0238 d^{-1} for grassland is therefore applied in this assessment.

- **Calculated PEC values**

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

- PEC_{STP} (= $Clocal_{eff}$) according to equation 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

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} = $Clocal_{eff}$ referring to equation 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015).

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

- PEC_{local_soil} according to equation 69, chapter 2.3.7.5, Guidance BPR IV ENV B+C (2017);
- $PEC_{local\_groundwater}$ according to equation 71, chapter 2.3.7.6, Guidance BPR IV ENV B+C (2017) as a first worst-case estimation.

The local PEC values from all intended uses are presented in Table 70 and are used for the environmental risk assessment.

Table 70: Summary table on calculated PEC values from intended uses of the biocidal product "CVAS"

	PT	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}	PEC_{air}	$DEPtotal_{ann}$
		[µg/L]	[µg/L]	[µg/kg_{wwt}]	[µg/kg_{wwt}]	[µg/L]	[mg/m^3]	[mg/m^2 d]
Use 2a	2	8.25	0.83	0.70	0.032	0.184	3.29 x10^{-4}	4.74 x10^{-4}
Use 2b	2	49.0	4.94	4.21	0.139	0.788	1.41 x10^{-3}	2.03 x10^{-3}
Use 1a	2	49.0	4.94	4.21	0.195	1.11	1.98 x10^{-3}	2.85 x10^{-3}
Use 4a	4	8.25	0.82	0.70	0.023	0.13	2.347 x10^{-4}	3.378 x10^{-4}
Use 3a	4	8.25	0.82	0.70	0.033	0.18	3.29 x10^{-4}	4.74 x10^{-4}
Use 3/4	4	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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 (2015). The groundwater exposure is due to wet and dry aerial deposition on soil. The estimated concentration in the groundwater is defined by the concentration of propan-2-ol in pore water of agricultural soils (Guidance BPR IV ENV B, 2015). This is a conservative approach, since degradation in soil, transformation and dilution in deeper soil layers are not taken into account. The calculated results of PEC_{GW} for PT2 (use 2a, 2b, and 1a) and PT4 (use 4a and 3a) are above the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83/EC). However, during the WG ENV VII 2018 it was agreed that for alcohols in general used in PT2 with a primary release path to air, no assessment of the groundwater is needed. Therefore, although in the current assessment concentrations in groundwater are above the groundwater trigger value of 0.1 µg/L, based on expert judgement no exceedance of the groundwater trigger value is expected.

- **Refinement of the PEC_{GW} using FOCUS PEARL**

Since the PEC_{GW} of the intended uses in PT4 exceed the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83/EC) the groundwater assessment is refined with FOCUS PEARL v.4.4.4, taking into account adsorption, distribution and degradation of propan-2-ol in soil. Calculations have been performed for all FOCUS scenarios by using the following application scheme: monthly aerial deposition (detailed description to this application scheme can be found in Klein (2011). Table 71 provides the required input parameters for FOCUS PEARL.

Table 71: Input parameters for the FOCUS PEARL of propan-2-ol

Input	Value	Unit	Remarks
Molecular weight	60.09	g/Mol	
Vapour pressure (at 25°C)	5780	Pa	
Water solubility (at 25°C)	1000000	mg/L	complete miscible with water
Half-life for degradation in soil (ref. Tab. 8, Guidance BPR IV ENV B (2015) at 12°C)	30	d	
Kom (coef. for sorption on organic matter) at 20°C	1.91	L/kg	
Freundlich exponent	0.9	-	
Plant uptake factor	0.0	-	
Aerial Deposition on Arable land and Grassland			
Application type	-	-	To soil surface
Crops	-	-	Maize and Alfalfa
Target depth	1	m	
Annual incorporation	-	-	12 applications per year at the beginning of each month
Incorporation depth	0.0	m	

In FOCUS PEARL, the amount of substance entered into the leaching model is given by the application rate expressed in kg/ha. The areal deposition rate ($DEPtotal_{ann}$) according to the Guidance BPR IV ENV B (2015) is given in mg m^2/d. The annual average total deposition flux can be converted into an application rate according to the following equation (Klein, 2011):

$$App_{rate} = DEPtotal_{ann} \cdot 365\,d \cdot 0.01 \qquad (\text{annual rate})$$

$$App_{rate} = DEPtotal_{ann} \cdot 365\,d \cdot /12 \cdot 0.01 \qquad (\text{monthly rate})$$

App_{rate} : application rate (kg/ha)
$DEPtotal_{ann}$: annual average total deposition flux (mg m^{-2} d^{-1})
0.01: unit conversion factor

For the uses under consideration, the calculated application rates for both arable and grassland are given in Table 72.

Table 72: Calculated application rate for propan-2-ol used for FOCUS PEARL simulation

Use	PT	$DEPtotal_{ann}$ [mg/(m² d)]	Application rate for propan-2-ol [kg/ha/month]	
			Arable land	Grassland
4a	4	3.378 x10^{-4}	1.03 x10^{-4}	1.03 x10^{-4}
3a	4	4.74 x10^{-4}	1.44 x10^{-4}	1.44 x10^{-4}

The results of the groundwater leaching models for the 9 EU scenarios using FOCUS PEARL v.4.4.4 are provided in Table 73 (use 4a) and Table 74 (use 3a).

Table 73: Predicted groundwater concentrations of propan-2-ol closest to the 80th percentile in the percolate at 1 m depth for intended use 4a

FOCUS Scenario	Arable land [µg/L]	Grassland [µg/L]
Châteaudun	0.01	0.01
Hamburg	0.04	0.04
Jokioinen	*	0.05
Kremsmuenster	0.02	0.01
Okehampton	0.02	0.02
Piacenza	0.02	0.02
Porto	0.01	0.01
Sevilla	0.005	0.007
Thiva	0.005	0.006

Use 4a: After refinement with FOCUS PEARL, all scenarios have groundwater concentrations below 0.1 µg/L.

Table 74: Predicted groundwater concentrations of propan-2-ol closest to the 80th percentile in the percolate at 1 m depth for intended use 3a

FOCUS Scenario	Arable land [µg/L]	Grassland [µg/L]
Châteaudun	0.01	0.02
Hamburg	0.05	0.05
Jokioinen	*	0.07
Kremsmuenster	0.02	0.02
Okehampton	0.03	0.03
Piacenza	0.02	0.02
Porto	0.02	0.02
Sevilla	0.01	0.01
Thiva	0.01	0.01

Use 3a: After refinement with FOCUS PEARL, all scenarios have groundwater concentrations below 0.1 µg/L.

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 2.2.8.2).

Aggregated exposure (combined for relevant emission sources)

Biocidal active substances are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentration of active substance to be found in the environment.

Article 19(2) of the Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." This is further elaborated in Annex VI (common principles for the evaluation of biocidal products), which states that the risks associated with the relevant individual components of the biocidal product shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs.

According to the "Decision tree on the need for estimation of aggregated exposure" (refer to Guidance BPR IV ENV B (2015)) shown in Figure 1, it is checked if aggregated exposure estimations are required for the biocidal product "CVAS Disinfectant product based on propan-2-ol" containing propan-2-ol as active substance.

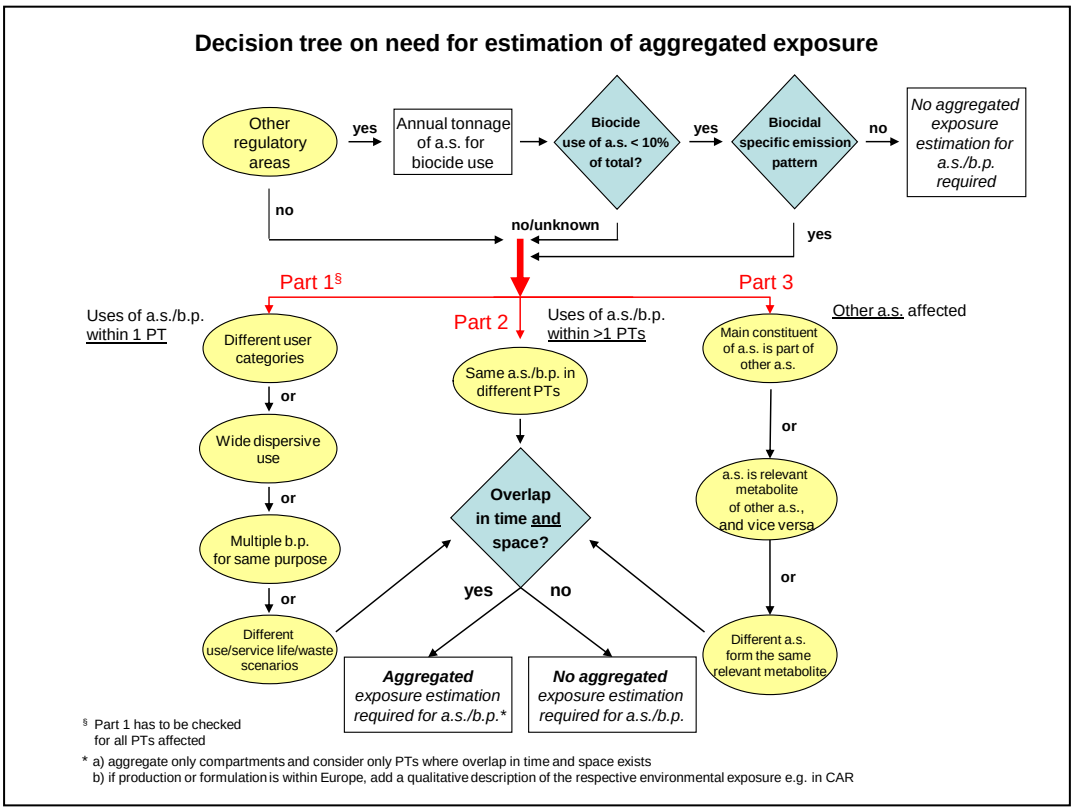


Figure 1: Decision tree on the need for estimation of aggregated exposure

Upper part of the decision tree: Relevance of aggregated exposure for the biocidal sector

The active substance propan-2-ol is notified for the list of approved substances in three products types (PT1, 2 and 4). 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. 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. A specific emission pattern for propan-2-ol due to the use of biocidal product "CVAS Disinfectant product based on propan-2-ol" cannot be identified. The occurring emissions in PT2 and 4 have been described as diffuse atmospheric emissions. This is comparable to other, non-biocidal, propan-2-ol emission sources, like e.g. solvents in inks, coatings, cosmetics and pharmaceuticals. Consequently, no aggregated exposure is required for propan-2-ol released due to the use of biocidal product "CVAS Disinfectant product based on propan-2-ol".

For a detailed description of the single uses see section 2.2.8.3.

2.2.8.4 Risk characterisation

The biocidal product "CVAS Disinfectant product based on propan-2-ol" is intended to be used in product type 2 and 4 for disinfection of small surfaces in private, public and industrial 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.).
Consequently, the following uses need to be evaluated in the environmental risk assessment to cover all the requested uses:

PT 2:

Use 2a: Disinfection of small surfaces in industrial areas – professional user
Use 2b: Disinfection of small surfaces for sanitary purposes in institutional areas – professional user
Use 1a: Disinfection of small surfaces for sanitary purposes – non-professional user

PT 4:

Use 4a: Disinfection of small surfaces in canteens/catering kitchens or food processing industry (professional user)
Use 3a: Disinfection of small surfaces in kitchens (non-professional user)

As described in section 2.2.8.3, use 3/4 [Disinfection of gardening equipment (professional and non-professional); PT 4] can be considered to be covered by the risk assessment for use 4a and use 3a.

- **Aquatic compartment (sediment and STP)**

Table 75: PEC/PNEC ratios for surface water and sediment related to the intended uses

Summary table on calculated PEC/PNEC values			
PT	**Use**	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
2	Use 2a	2.94×10^{-4}	2.9×10^{-4}
2	Use 2b	1.75×10^{-3}	1.75×10^{-3}
2	Use 1a	1.75×10^{-3}	1.75×10^{-3}
4	Use 4a	2.91×10^{-4}	2.9×10^{-4}
4	Use 3a	2.91×10^{-4}	2.9×10^{-4}

The PEC/PNEC-ratios for surface water and sediment related to all the intended uses of the biocidal product "CVAS Disinfectant product based on propan-2-ol" are well below 1. Hence, no unacceptable risk for both compartments must be assumed due to the intended uses of the biocidal product.

STP

Table 76: PEC/PNEC ratios for the STP related to the intended uses

Summary table on calculated PEC/PNEC values		
PT	Use	**PEC/PNEC$_{STP}$**
2	Use 2a	8.25×10^{-4}
2	Use 2b	4.9×10^{-3}
2	Use 1a	4.9×10^{-3}
4	Use 4a	8.25×10^{-4}
4	Use 3a	8.25×10^{-4}

The PEC/PNEC-ratios for the STP related to all the intended uses of the biocidal product "CVAS Disinfectant product based on propan-2-ol" are well below 1. Hence, no unacceptable risk for the STP must be assumed due to the intended uses of the biocidal product.

- **Terrestrial compartment (Soil/Groundwater)**

Table 77 PEC/PNEC ratios for the soil compartment related to the intended uses

Calculated PEC/PNEC values		
PT	**Use**	**PEC/PNEC$_{soil}$**
2	Use 2a	6.53×10^{-5}
2	Use 2b	2.79×10^{-4}
2	Use 1a	3.92×10^{-4}
4	Use 4a	6.05×10^{-5}
4	Use 3a	8.06×10^{-5}

The PEC/PNEC-ratios for the soil compartment related to all the intended uses of the biocidal product "CVAS Disinfectant product based on propan-2-ol" are well below 1. Hence, no unacceptable risk for the soil compartment must be assumed due to the intended uses of the biocidal product.

Groundwater

According to the conclusion of WG ENV VII 2018 no assessment for the groundwater compartment is required for biocidal products in PT2 with primary release of the active

substance to air. This applies for the uses 1a, 2a and 2b of the biocidal product "CVAS Disinfectant product based on propan-2-ol".

For the remaining uses 3a and 4a the propan-2-ol concentrations in the pore water, which were estimated in the Tier 1 groundwater assessment, were in a range from 0.13 to 0.18 µg/L. Hence, according to the Guidance on the BPR IV ENV B (2017), the exceedance of the threshold value of 0.1 µg/L in groundwater, as laid down in Council directive 98/83/EC, has to be assumed in the first instance, since the estimated concentrations in pore water are supposed to be the equivalent of the concentration in the groundwater compartment. In a second step the exceedance of the threshold value leads to the refinement of the groundwater assessment with the FOCUS PEARL 4.4.4 model.
According to the decision of ENV WG-I-2017, the modelled groundwater concentrations for all of the nine FOCUS PEARL locations must fall below the trigger value of 0.1 µg/L to approve a union authorisation. Since this is the case for the uses 3a and 4a the provisions authorisation of the biocidal product are met.

- **Atmosphere**

As stated in section2.2.8.2, ecotoxicological data for the air compartment are not available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

- **Non-compartment specific**

As stated in section 2.2.8.2, non-compartment-specific effects are not to be expected.

- **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 neither fulfil the PBT- nor the vP/vB-criteria.

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

- **Summary of risk characterisation**

Table 78: Summary of the PEC/PNEC ratios for the concerned environmental compartments

Summary table on calculated PEC/PNEC values					
PT	**Use**	**PEC/**	**PEC/**	**PEC/**	**PEC/**

		$PNEC_{STP}$	$PNEC_{water}$	$PNEC_{sed}$	$PNEC_{soil}$
2	Use 2a	8.25×10^{-4}	2.94×10^{-4}	2.9×10^{-4}	6.53×10^{-5}
2	Use 2b	4.9×10^{-3}	1.75×10^{-3}	1.75×10^{-3}	2.79×10^{-4}
2	Use 1a	4.9×10^{-3}	1.75×10^{-3}	1.75×10^{-3}	3.92×10^{-4}
4	Use 4a	8.25×10^{-4}	2.91×10^{-4}	2.9×10^{-4}	4.64×10^{-5}
4	Use 3/4	8.25×10^{-4}	2.91×10^{-4}	2.9×10^{-4}	6.65×10^{-5}

No unacceptable risks have been identified in the environmental risk assessment due to the use of the biocidal product "CVAS Disinfectant product based on propan-2-ol".

2.2.9 Measures to protect man, animals and the environment

The measures are summarised in chapter 2.1.4. Detailed information can be found in chapter 2.2.6 and 2.2.8.

2.2.10 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

2.2.11 Comparative assessment

No candidate for substitution was identified, hence a comparative assessment is not necessary.

3 Annexes

3.1 List of studies for the biocidal product

Table 79

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Data protection	Owner company
1	3.1. 3.1.1. 3.1.2. 3.1.3 3.2. 3.3. 3.4.1.2. 3.4.2.3. 3.8. 3.9.	Determination of physico-chemical Properties and Storage Stability Tests for calgonit DS - 622	Manka, S.	2016	Yes	CVAS Development GmbH
2	3.1. 3.1.1. 3.1.2. 3.1.3 3.2. 3.3. 3.4.1.2.	Determination of physico-chemical Properties and Storage Stability Tests for Disinfect Home and Bactazol I	Manka, S.	2016	Yes	CVAS Development GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Data protection	Owner company
	3.4.2.3. 3.5.6. 3.5.12. 3.8. 3.9.					
3	3.1. 3.1.1. 3.1.2. 3.1.3 3.2. 3.3. 3.4.1.2. 3.4.2.3. 3.5.6. 3.5.12. 3.8. 3.9.	Determination of physico-chemical Properties and Storage Stability Tests for Alpha Septin	Manka, S.	2016	Yes	CVAS Development GmbH
4	3.5.6 3.5.12	Determination of Spray Parameter for Disinfect Home	Manka, S.	2018	Yes	CVAS Development GmbH
4	5.1.	Validation of Method: MV134 - BG: CG-Determination of Ethanol, 1-Propanol and 2-Propanol in Formulations	Manka, S.	2016	Yes	BioGenius GmbH
5	6.7.	Test report (EN 1256, bactericidal)	Jonas, Dr. B.; Leske, J.	2011	Yes	CVAS Development GmbH
6	6.7.	Test report (EN 13697, bactericidal)	Höffler, Dr. J.; Ludwig, C.	2014	Yes	CVAS Development GmbH
7	6.7.	Test report (EN 1650, yeasticida)	Jonas, Dr. B.;	2011	Yes	CVAS Development GmbH

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Data protection	Owner company
			Leske, J.			
8	6.7.	Test report (EN 13697, yeasticidal)	Höffler, Dr. J.; Ludwig, C.	2014	Yes	CVAS Development GmbH
9	6.7.	Test report (EN 1650 *Saccharomyces*)	Lüking, Dr. A.	2017	Yes	CVAS Development GmbH
10	6.7.	Test report (EN16615, bactericidal)	Lüking, Dr. A.	2017	Yes	CVAS Development GmbH
11	6.7.	Test report (EN16615, yeasticidal)	Lüking, Dr. A.	2017	Yes	CVAS Development GmbH

3.2 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

Safety for professional users

Overview Risk characterisation (internal, external exposure values)

Overview_Risk_Assessment

Details of the exposure assessment

Results of exposure calculation.pdf

1.1_Small surface disinfection in patient

1.2_Small surface disinfection - In-betw

2-Small surface disinfection in laborat

3_Refilling.pdf

4_Small surface disinfection in kitchen

5_Disinfection of food processing mach

6_Small surface disinfection of garder

Reports and calculations


ConsExpoReport_1.1.pdf


Calculation_1.2.pdf


ConsExpoReport_1.2.pdf


ConsExpoReport_2.pdf


ARTReport_3.pdf


ConsExpoReport_4.pdf


ConsExpoReport_5.pdf


ConsExpoReport_6.pdf

Safety for non-professional users and the general public

Consexpo reports

ConsExpo 4.1 report

Scenario 1, PT2: Primary exposure, disinfection of small surfaces, bath rooms

Product

CVAS Diinfectants

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	5	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	61,3	%
exposure duration	5	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,74E3	mg/m3
inhalation mean concentration on day of exposure:	30,1	mg/m3
inhalation air concentration year average :	30,1	mg/m3/day
inhalation acute (internal) dose :	3,01	mg/kg
inhalation chronic (internal) dose :	15,1	mg/kg/day

Integrated (point estimates)

total external dose:	3,01	mg/kg
total acute dose (internal):	3,01	mg/kg
total chronic dose (internal):	15,1	mg/kg/day

ConsExpo 4.1 report

Scenario 2, PT4: Primary exposure. disinfection of small surfaces, kitchens, gardening equipment

Product

CVAS Disinfectants

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 : evaporation

weight fraction compound	61,3	%
exposure duration	15	minute
room volume	15	m3
ventilation rate	2,5	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,19E3	mg/m3
inhalation mean concentration on day of exposure:	12,4	mg/m3
inhalation air concentration year average :	12,4	mg/m3/day
inhalation acute (internal) dose :	6,18	mg/kg
inhalation chronic (internal) dose :	6,18	mg/kg/day

Integrated (point estimates)

total external dose:	6,18	mg/kg
total acute dose (internal):	6,18	mg/kg
total chronic dose (internal):	6,18	mg/kg/day

ConsExpo 4.1 report

Scenario 3a, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult

Product

CVAS Disinfectants

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 : evaporation

weight fraction compound	61,3	%
exposure duration	5	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,73E3	mg/m3
inhalation mean concentration on day of exposure:	6,02	mg/m3
inhalation air concentration year average :	6,02	mg/m3/day
inhalation acute (internal) dose :	3,01	mg/kg
inhalation chronic (internal) dose :	3,01	mg/kg/day

Integrated (point estimates)

total external dose:	3,01	mg/kg
total acute dose (internal):	3,01	mg/kg
total chronic dose (internal):	3,01	mg/kg/day

ConsExpo 4.1 report

Scenario 3b, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, child

Product

CVAS Disinfectants

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 : evaporation

weight fraction compound	61,3	%
exposure duration	5	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,32	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,73E3	mg/m3
inhalation mean concentration on day of exposure:	6,02	mg/m3
inhalation air concentration year average :	6,02	mg/m3/day
inhalation acute (internal) dose :	7,98	mg/kg
inhalation chronic (internal) dose :	7,98	mg/kg/day

Integrated (point estimates)

total external dose:	7,98	mg/kg
total acute dose (internal):	7,98	mg/kg
total chronic dose (internal):	7,98	mg/kg/day

ConsExpo 4.1 report

Scenario 3c, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler

Product

CVAS Disinfectants

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	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	61,3	%
exposure duration	5	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,74E3	mg/m3
inhalation mean concentration on day of exposure:	6,03	mg/m3
inhalation air concentration year average :	6,03	mg/m3/day

inhalation acute (internal) dose :	18,2	mg/kg
inhalation chronic (internal) dose :	18,2	mg/kg/day

Integrated (point estimates)

total external dose:	18,2	mg/kg
total acute dose (internal):	18,2	mg/kg
total chronic dose (internal):	18,2	mg/kg/day

ConsExpo 4.1 report

Scenario 4a, PT4: Secondary exposure from disinfection of small surfaces, kitchens, adult

Product

CVAS Disinfectant

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 : evaporation

weight fraction compound	61,3	%
exposure duration	15	minute
room volume	15	m3
ventilation rate	2,5	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,19E3	mg/m3
inhalation mean concentration on day of exposure:	12,4	mg/m3
inhalation air concentration year average :	12,4	mg/m3/day
inhalation acute (internal) dose :	6,18	mg/kg
inhalation chronic (internal) dose :	6,18	mg/kg/day

Integrated (point estimates)

total external dose:	6,18	mg/kg
total acute dose (internal):	6,18	mg/kg
total chronic dose (internal):	6,18	mg/kg/day

ConsExpo 4.1 report

Scenario 4b, PT4: Secondary exposure from disinfection of small surfaces, kitchens, child

Product

CVAS Disinfectant

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 : evaporation

weight fraction compound	61,3	%
exposure duration	15	minute
room volume	15	m3
ventilation rate	2,5	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute

mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,32	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,19E3	mg/m3
inhalation mean concentration on day of exposure:	12,4	mg/m3
inhalation air concentration year average :	12,4	mg/m3/day
inhalation acute (internal) dose :	16,4	mg/kg
inhalation chronic (internal) dose :	16,4	mg/kg/day

Integrated (point estimates)

total external dose:	16,4	mg/kg
total acute dose (internal):	16,4	mg/kg
total chronic dose (internal):	16,4	mg/kg/day

ConsExpo 4.1 report

Scenario 4c, PT4: Secondary exposure from disinfection of small surfaces, kitchens, toddler

Product

CVAS Disinfectant

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	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	61,3	%
exposure duration	15	minute
room volume	15	m3
ventilation rate	2,5	1/hr
applied amount	44,1	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,19E3	mg/m3
inhalation mean concentration on day of exposure:	12,4	mg/m3
inhalation air concentration year average :	12,4	mg/m3/day
inhalation acute (internal) dose :	37,4	mg/kg
inhalation chronic (internal) dose :	37,4	mg/kg/day

Integrated (point estimates)

total external dose:	37,4	mg/kg
total acute dose (internal):	37,4	mg/kg
total chronic dose (internal):	37,4	mg/kg/day

Aerial concentration

Using Consexpo 4.1 the average aerial concentration in a specific time frame is estimated by the plot function in the output menue. This information was included to the tier 2 assessment of Scenario 4. The corresponding data are imported to Excel files, and extracted below:

Aerial concentration from min 0 to min 15

graph data ConsExpo 4.1							
print date 21.09.2017							

Air concentration							
time (minute)	concentration (mg/m^3)						
0	0						
0.14999999	146.301727		5.25	1460.56091		10.3499994	1180.95154
0.29999998	282.708954		5.4000001	1451.46094		10.5	1173.59363
0.44999999	409.432526		5.54999971	1442.4176		10.6499996	1166.28149
0.59999996	526.722656		5.69999981	1433.43054		10.8000002	1159.01501
0.75	634.867249		5.8499999	1424.49951		10.9499998	1151.7937
0.89999998	734.188965		6	1415.62415		11.0999994	1144.61755
1.04999995	825.04187		6.1500001	1406.80408		11.25	1137.48608
1.19999993	907.806885		6.29999971	1398.03894		11.3999996	1130.39893
1.35000002	982.887085		6.44999981	1389.32849		11.5500002	1123.35596
1.5	1050.70166		6,5999999	1380.67224		11.6999998	1116.35693
1.64999998	1111.68115		6.75	1372.06995		11.8499994	1109.40125
1.79999995	1166.26172		6.89999962	1363.52112		12	1102.48926
1.94999993	1214.87915		7.04999971	1355.02588		12.1499996	1095.62012
2.0999999	1257.96497		7.19999981	1346.58337		12.3000002	1088.79382
2.25	1295.94141		7.3499999	1338.19348		12.4499998	1082.01013
2.39999986	1329.21765		7.5	1329.85571		12.5999994	1075.26868
2.54999995	1358.18701		7.6500001	1321.57019		12.75	1068.56921
2.70000005	1383.22412		7.79999971	1313.33618		12.8999996	1061.9115
2.8499999	1404.68359		7.94999981	1305.15332		13.0500011	1055.29529
3	1422.89819		8.09999943	1297.02148		13.1999998	1048.72009
3.14999986	1438.17847		8.25	1288.94043		13.3499994	1042.18616
3.29999995	1450.81311		8.39999962	1280.90967		13.5	1035.69263
3.44999981	1461.06812		8.55000019	1272.92896		13.6499996	1029.23987
3.5999999	1469.18835		8.69999981	1264.99805		13.7999992	1022.82715
3.75	1475.39746		8.84999943	1257.11646		1.9499998	1016.45447
3.89999986	1479.89978		9	1249.28381		14.0999994	1010.12134

4.04999971	1482.88037		9.14999962	1241.50024		14.25	1003.82782
4.19999981	1484.5072		9.30000019	1233.76501		14.3999996	997.573486
4.3499999	1484.93201		9.44999981	1226.078		14.5500002	991.358093
4.5	1484.29089		9.59999943	1218.43896		14.6999998	985.181396
4.6500001	1482.70691		9.75000095	1210.84741		14.8499994	979.043213
4.79999971	1480.29004		9.89999962	1203.30334			
4,94999981	1477.13892		10.0500002	1195.80615			
5.0999999	1469.71802		10.1999998	1188.35559		mean:	1195.24731

Aerial concentration from min 15 to min 30

graph data ConsExpo 4.1							
print date 21.09.2017							
Air concentration							
time (minute)	concentration (mg/m^3)						
15	981.440369		20.1000004	793.553772		25.1999989	641.636108
15.1499996	975.325623		20.2499981	788.609558		25.3500004	637.638367
15.3000002	969.248718		20.3999996	783.696106		25.5	633.665527
15.4499998	963.2099		20.5499992	778.813354		25.6499996	629.717529
15.5999994	957.208618		20.6999989	773.960876		25.7999992	625.794006
15.75	951.4469		20.8500004	769.138672		25.9499989	621.89502
15.8999996	945.317993		21	764.346619		26.1000023	618.020325
16.0499992	939.428162		21.1499996	759.58429		26.25	614.169739
16.1999989	933.575073		21.2999992	754.851746		26.3999996	610.34314
16.3500004	927.758362		21.4499989	750.148621		26.5499992	606.540344
16.5	921.977966		21.6000004	745.474854		26.6999989	602.761292
16.6499996	916.233582		21.75	740,830078		26.8499985	599.005859
16.7999992	910.524963		21.8999996	736.214355		27	595.273743
16.9499989	904.851929		22.0499992	731.627319		27.1499996	591.56488

17.1000004	899.214294		22.1999989	727.068909		27.2999992	587.87915
17.25	893.611694		22.3500004	722.53894		27.4499989	584.216309
17.3999996	888.044067		22.5	718.03717		27.5999985	580.576355
17.5499992	882.511047		22.6499996	713.563477		27.75	576,959045
17.6999989	877.012573		22.7999992	709.117615		27.8999996	573.364319
17.8500004	871.54834		22.9499989	704.699402		28.0499992	569.791931
18	866.118103		23.1000004	700.308777		28.1999989	566.241821
18.1499996	860.721741		23.5	695.945496		28.3500004	562.713928
18.2999992	855.35907		23.3999996	691.609375		28.5	559.207947
18.4499989	850.029724		23.5499992	687.300293		28.6499996	555.723694
18.6000004	844.733643		23.6999989	683.018066		28.7999992	552.261292
18.7500019	839.470459		23.8500004	678.762573		28.9499989	548.820435
18.8999996	834.240234		24	674.533508		29.1000004	545.401062
19.0499992	829.042419		24.1499996	670.330872		29.25	542.00293
19.1999989	823.877075		24.2999992	666.154358		29.3999996	538.625977
19.3500004	818.743896		24.4499989	662.003784		29.5499992	535.27002
19.5000019	813.642639		24.6000004	657.879211		29.6999989	531.935059
19.6499996	808.573303		24.75	653.780273		29.8500004	528.620789
19.7999992	803.535461		24.8999996	649.706909			
19.9499989	798.528992		25.0499992	645.658936		mean	732.064108

3.3 New information on the active substance

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

Access to data from active substance approval
The applicant has no access to the dossier for the approval of the active substance "propan-2-ol" for use in PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

Access to data according to for the active substance "propan-2-ol"

The applicant provided a letter of access to the dossier for the active substance "propan-2-ol recorded under the asset no. EU-0011803-0000. This dossier is satisfying the requirements set out in Annex II of Regulation (EU) No 528/2012 for use in PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

3.4 Residue behaviour

The information provided regarding the residues was acceptable.. Please refer to chapter 2.2.4.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

An IUCLID file is available. Please refer to the IUCLID file.

3.6 Confidential annex

Please refer to the separate document.

3.7 Other

No other information.