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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)

calgonit Des-H

Product type

01 (Disinfectants for human hygiene)

Propan-1-ol and Propan-2-ol as included in the Union list of approved active substances of Regulation (EU) No 528/2012

Case Number in R4BP: BC-RU051295-09

Competent Authority: DE (BAuA)

Date: 21.12.2023

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Changes history table

Application type	refMS /eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	BC-RU051295-09	21.12.2023	Initial assessment	p. 7

1 Conclusion

Calgonit Des-H is a ready to use AL-any other liquid biocidal product containing Propan-1-ol and Propan-2-ol as active substances. The product is used as a disinfectant for human hygiene (product-type 01) by professional and industrial users for the control of bacteria, yeasts, fungi and enveloped viruses.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the uses "Hygienic hand disinfection via pump dispenser" (Industrial and professional users) and "Hygienic hand disinfection via electronic dispenser" (Industrial and professional users), as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product does not contain a non-active substance (so called "co-formulant") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains Propan-1-ol and Propan-2-ol which do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered as candidates for substitution.

Therefore, a comparative assessment of the biocidal product is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended use as applied for by the applicant have been assessed and the conclusions

of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

A physical hazard was identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances, residues and relevant impurities are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

A validated analytical method is provided for monitoring of relevant components of the biocidal product and/or residues air. More information is available in section 3.4 of the PAR. No other data is required.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against bacteria, yeasts, fungi and enveloped viruses for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since no substance of concern has been identified, the human health risk assessment is based on propan-1-ol and propan-2-ol.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, and general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the use, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on Propan-1-ol and Propan-2-ol.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type	01 (Disinfectants for human hygiene)
Type of formulation	Ready to use AL-any other liquid

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
[1]	*Not relevant*	*PT 01*	*Bacteria Yeasts Fungi Enveloped viruses*	*Pump dispenser Hygienic hand rub*	*4 mL per use Max. 5 times a day **Contact times** Bacteria, Yeasts, Fungi and Viruses (enveloped viruses): 30s (clean conditions)*	*Industrial Professional*	*R*	*Refer to 3.6.11*
[2]				*Electronic dispenser Hygienic hand rub*			*R*	*Refer to 3.6.11*

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☐
not identical ☒

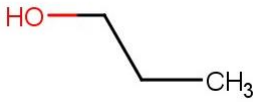
to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation (EU) No 528/2012.

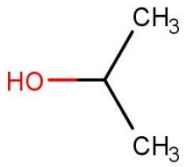
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

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

2.4 Identity of the active substances

Table 2.3 Identity of the active substances

Main constituent(s)	
Common name	Propyl alcohol
Chemical name	Propan-1-ol
EC number	200-746-9
CAS number	71-23-8
Index number in Annex VI of CLP	603-003-00-0
Minimum purity / content	99.5% (w/w)
Structural formula	

Main constituent(s)	
Common name	Isopropyl alcohol
Chemical 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	

2.5 Information on the sources of the active substances

Is the source (OQ Chemicals GmbH) of Propan-1-ol the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☐ Yes

☒ No *The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number: EU-0018321-0000)*.

Is the source (Sasol Chemie GmbH & Co. KG) of Propan-1-ol the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☐ Yes

☒ No *The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number: EU-0018878-0000)*.

Is the source (Shell Nederland Raffinaderij B.V.) of Propan-2-ol the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes

☐ No

Is the source (ExxonMobil) of Propan-2-ol the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes

☐ No

2.6 Candidate(s) for substitution

No candidate for substitution has been identified.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

More detailed information is available in the confidential annex of the PAR.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More detailed information is available in the confidential annex of the PAR.

2.8 Classification and labelling

Besides the active substances Propan-1-ol and Propan-2-ol, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substances Propan-1-ol and Propan-2-ol is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):
Propan-1-ol: Eye Dam. 1, H318; STOT SE 3, H336; Flam. Liq. 2, H225
Propan-2-ol: Eye Irrit. 2, H319, STOT SE 3, H336; Flam. Liq. 2, H225
Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

Table 2.4 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code	Eye Dam. 1 STOT SE 3 Flammable Liquid Cat 3	Eye Dam. 1 STOT SE 3 Flammable Liquid Cat 3
	 GHS02  GHS05	 GHS02  GHS05
	 GHS07	 GHS07
Signal word(s)	Danger	Danger
Hazard statements	H226: Flammable liquid and vapour H318: Causes serious eye damage. H336: May cause drowsiness or dizziness	H226: Flammable liquid and vapour H318: Causes serious eye damage. H336: May cause drowsiness or dizziness
Precautionary statements*	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P240: Ground and bond container and receiving equipment. P241: Use explosion-proof ventilating equipment. P242: Use non-sparking tools. P243: Take action to prevent static discharges. P403 + P235: Store in a well-ventilated place. Keep cool. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.

	lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. P310: Immediately call a POISON CENTER or doctor. P370 + P378: In case of fire: Use CO_2, sand, fire-extinguishing powder to extinguish. P312: Call a POISON CENTRE or doctor if you feel unwell. P405: Store locked up. P501: Dispose of contents/container in accordance with local regulations.	
Supplemental hazard statements	EUH066: Repeated exposure may cause skin dryness or cracking.	
Notes	P280 has been omitted as for hand disinfection with the assessed product, no personal protection measures are necessary. P310 should not be a stand-alone phrase but should be included in P305 + P351 + P338 according to Guidance on labelling and packaging.	

***** All P-statements listed under the first column have also been listed in the SPC.

2.9 Letter of access

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[1]) of the active substances Propan-1-ol and Propan-2-ol for use in disinfectants for human hygiene (product-type 01). Please, refer to the corresponding Assessment Report for a reference list.

2.10 Data submitted in relation to product authorisation

Not relevant (no new data on the active substances was submitted).

2.11 Similar conditions of use across the Union

Not relevant (national authorisation).

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

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	1 L	HDPE	PE	Industrial Professional	Yes
Jerrycan	5L	HDPE	HDPE	Industrial Professional	Yes

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	According to SOP-PR-015 Visual	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	Homogeneous liquid	BioGenius (2021), Study No. Mo 6415
3.1.2.	Colour at 20 °C and 101.3 kPa	According to SOP-PR-015 Visual	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	Clear, colorless	BioGenius (2021), Study No. Mo 6415
3.1.3.	Odour at 20 °C and 101.3 kPa	According to SOP-PR-015 Organileptic (comparison to other characteristic odors)	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	Solvent odor	BioGenius (2021), Study No. Mo 6415
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	pH = 5.3 (20 °C) *The determination of the acidity/ alkalinity is not necessary as the pH is in the range of 4 – 10.*	BioGenius (2021), Study No. Mo 6415

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.3.	Relative density	According to OECD 109 EC method A.3 (oscillating density meter)	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	D_4^{20} = 0.855 (20 °C) D_4^{40} = 0.838 (40 °C)	BioGenius (2021), Study No. Mo 6415
3.4.1.1.	Storage stability test – **accelerated storage**	-	-	The biocidal product is a flammable liquid. Thus, it is not recommended to store the product at temperatures above ambient temeprature. Hence, the storage condition "*Store at ambient temperature only*." and "Protect from direct sunlight" will be added to the storage conditions.	-
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**		Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	Storage in the commercial packaging (HDPE, 1 L) at 20 °C for 24 months.	BioGenius (2021), Study No. Mo 6415
		<u>Active substance content:</u> In house method (GC-FID)		**<u>Active substance content (% w/w):</u>** **0 months:** 1-Propanol: 30.6 2-Propanol: 44.43 **24 months:** 1-Propanol: 30.4 2-Propanol: 44.31	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		Appearance: According to SOP-PR-015 (visual/organileptic)		**Appearance:** **0-24 months:** Clear, colorless, homogeneous liquid with a solvent odor.	
		Weight loss: balancing		**0-24 months:** 0.03 – 0.18%	
		Stability of the packaging: According to SOP-PR-029 (visual description)		**Stability of the packaging:** **0-24 months:** Test item in sound condition, sealed and without leakages. Dimension stable.	
		pH value: CIPAC MT 75.3		**pH value:** **0-12 months:** pH = 5.3 (20 °C) **24 months:** pH = 5.1 (20 °C)	
		Viscosity: CIPAC MT 192/OECD 114 (rotational viscometer)		**Viscosity:** Shear rates: 20, 40, 60, 80, 100 s^{-1} **0 months:** 1.76 – 3.00 mPa s (20 °C) <1 – 1.55 mPa s (40 °C) **24 months:** 3.17 – 3.34 mPa s (20 °C) 1.67 – 1.95 mPa s (40 °C)	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		Relative density: EC method A.3 OECD 109 (oscillating density meter)		**Relative density:** **0-12 months:** D_4^{20} = 0.855 (20 °C) D_4^{40} = 0.838 (40 °C) **24 months:** D_4^{20} = 0.855 (20 °C) D_4^{40} = 0.819 (40 °C)	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	Storage at low temperatures is not recommended. A label phrase will recommend not storing the product at temperatures below 0 °C.	-
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	Opaque packaging, therefore no impact on a.s. content due to exposure to light expected. Further, both a.s. show no absorption between 290 nm and 750 nm. Thus, no degradation by light is expected.	-
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	**Temperature:** As the biocidal product is a flammable liquid, it is not recommended to store the biocidal product at temperatures above 30 °C. "*Do not store*	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				at temperatures above 30 °C." will be added to the storage conditions. **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-1-ol and propan-2-ol are unlimitedly soluble in water and do not react with water, humidity is not expected to influence the content of the a.s. during storage.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Storage in the commercial packaging (HDPE, 1 L) at 20 °C for 24 months. **<u>Stability of the packaging:</u>** **0-24 months:** Test item in sound condition, sealed and without leakages. Dimension stable.	BioGenius (2021), Study No. Mo 6415
3.5.1.	Wettability	-	-	Not applicable. Data is required for solid	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				preparations.	
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	Not applicable. Data is required for solid preparations or formulations forming suspensions on dilution with water.	-
3.5.3.	Wet sieve analysis and dry sieve test				
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. Data on emulsifiability, re-emulsifiability and emulsion stability is required for products that form and maintain a stable emulsion.	-
3.5.5.	Disintegration time	-	-	Not applicable. Data is required for solid preparations.	-
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable. Data is required for solid preparations. Furthermore, the product is applied directly from the bottle, no spraying is performed.	-
3.5.7.	Persistent foaming	-	-	Not applicable. The product is applied directly from the bottle, no further dilution or preparation is required.	-
3.5.8.	Flowability/pourability/dustability	-	-	Not applicable. Data is required for products that are granular, suspension	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				or applied as dust.	
3.5.9.	Burning rate — smoke generators	-	-	Not applicable. Data is required for products that are used in smoke generators.	-
3.5.10.	Burning completeness — smoke generators				
3.5.11.	Composition of smoke — smoke generators				
3.5.12.	Spraying pattern — aerosols / spray	-	-	Not applicable. The product is not sold together with a spraying device, hence testing is not necessary..	-
3.6.1.	Physical compatibility	-	-	Not applicable.The product is not recommended to be used in combination with other products.	-
3.6.2.	Chemical compatibility				
3.7.	Degree of dissolution and dilution stability (indicate the concentration tested)	-	-	Not applicable. Data is required for products in water soluble bags or as tablets.	-
3.8.	Surface tension	EC method A.5 Mean (n = 5) (ring method (Du Nouy))	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	**Undiluted:** Uncorrected: 146.9 mN/m Corrected: 139.5 mN/m **1 g/L solution:** Uncorrected: 186.2 mN/m Corrected: 174.6 mN/m The product is not surface active.	BioGenius (2021), Study No. Mo 6415

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		EC method A.5 OECD 115 (ring method (Du Nouy))	Calgonit Des-H Batch-No: KK-03-11-2023 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	**Undiluted:** 23.4 mN/m **1 g/L solution:** 69.9 mN/m The pure product should be regarded as surface active. The diluted product should not be considered as surface active.	Consilab (2023), Study No. CSL-23-1634.01
		Remark by the eCA: The APP provided data on the surface tension (BioGenius (2021), Study No. Mo6415) indicating that the product is not surface active. However, based on the composition the values were questionable. Therefore, a new study (Consilab (2023), Study No. CSL-23-1634.01) was conducted. The data are more conclusive and reveal a surface active behaviour.			
3.9.	Viscosity	CIPAC MT 192, OECD 114 (rotational viscometer)	Calgonit Des-H Batch-No: 48091301 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	**20 °C** Shear rate / s^{-1} — Viscosity / mPa s 20 — 1.76 40 — 2.60 60 — 2.83 80 — 2.93 100 — 3.00 **40 °C** Shear rate / s^{-1} — Viscosity / mPa s 20 — < 1 40 — 1.28 60 — 1.44 80 — 1.52 100 — 1.55	BioGenius (2021), Study No. Mo 6415

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
calgonit Des-H is a ready to use AL-any other liquid. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The accelerated storage stability was not carried out as the product is a flammable liquid and not recommended to store at temepratures above ambient temperature. Storage at low temperatures is not recommended. A label phrase will recommend not storing the product at temperatures below 0 °C. Based on the long term storage stability study, a shelf-life of 24 months is granted. **Implications for labelling:** *Shelf-life: 24 months.* *Store at ambient temperature only.* *Protect from direct sunlight.* *Protect from frost.*

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	-	-	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties
4.2.	Flammable gases	-	-	The study does not need to be conducted because the substance is a liquid.
4.3.	Flammable aerosols	-	-	The study does not need to be conducted because the substance is no aerosol.
4.4.	Oxidising gases	-	-	The study does not need to be conducted because the substance is a liquid.
4.5.	Gases under pressure	-	-	The study does not need to be conducted because the substance is a liquid.
4.6.	Flammable liquids	EC Method A.9, DIN EN ISO 3679 (Rapid equilibrium method in a closed cup)	Calgonit Des-H Batch No.: 41050601 45.0% w/w 2-Propanol; 30.0% w/w 1-Propanol	The test item calgonit Des-H has a flash point of 23.5 °C (corrected and rounded down to the nearest multiple of 0.5 °C). Based on the results the test item is classified as follows: **Flammable Liquid of Category 3**
4.7.	Flammable solids	-	-	The study does not need to be conducted because the substance is a liquid.
4.8.	Self-reactive substances and mixtures	-	-	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.
4.9.	Pyrophoric liquids	-	-	Not applicable. The product is a water based liquid and none of the components contained in the biocidal product are classified to have pyrophoric properties. Further, experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures.
4.10.	Pyrophoric solids	-	-	The study does not need to be conducted because the substance is a liquid.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.11.	Self-heating substances and mixtures	-	-	In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. However, if liquids are adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered.
4.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable. The product is a water based liquid and therefore does not contain any components that in contact with water emit flammable gases.
4.13.	Oxidising liquids	-	-	The study does not need to be conducted because there are no chemical groups present (the ingredients do not comprise fluorine or chlorine, oxygen is solely bound to hydrogen or carbon) in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied
4.14.	Oxidising solids	-	-	The study does not need to be conducted because the substance is a liquid.
4.15.	Organic peroxides	-	-	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria Not required as the product does not include organic peroxides.
4.16.	Corrosive to metals	-	-	The study does not need to be conducted on the basis of the chemical structure of the ingredients. None of them comprises halogens, acids, bases or complexing agents. For further information please refer to the conf. annex. Part 6 others.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	-	-	The auto-ignition temperature of propan-1-ol (385 °C) can be regarded as worst case. Therefore, testing is not required. For further information cf. section 6 of the conf. annex.
4.17.2.	Relative self-ignition	-	-	The study does not need to be conducted because the

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
	temperature for solids			substance is a liquid.
4.17.3.	Dust explosion hazard	-	-	The study does not need to be conducted because the substance is a liquid.

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is classified as Flammable Liquid of Category 3. Thus, it has to be marked with the Signal Word "Warning" and the Hazard Statement "H226: Flammable liquid and vapour".

3.4 Methods for detection and identification

For information on the analytical methods for active substance detection, please refer to the MS only annex.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method [in-house method]: Gas chromatography with flame ionization detection											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Propan-1-ol (active substance)	0.1999 – 3.198 mg/mL; r^2 = 1	Specific, interference from other substances < 3% of total peak	70% (1.399 mg/mL)	70 – 130% w/w 3 samples per fortification Level	99.5-100.2	99.9	0.4	Precision was demonstrated	RSD = 0.22%	LOD and LOQ are not required, because the method will be used only for testing of specification limits.	BioGenius (2016), Study No.: Mo5421
			100% (1.999 mg/mL)		99.6-100.2	99.9	0.3				
			130% (2.599 mg/mL)		99.1-100.5	100.0	0.8				
						Total: 100.0	Total: 0.5				
Propan-2-ol (active substance)	0.2000 – 3.200 mg/mL;	Specific, interference from other substances	70% (1.400 mg/mL)	70 – 130% w/w 3 samples per	99.7-101.2	100.6	0.8	Precision was demonstrated	RSD = 0.53%	LOD and LOQ are not required, because the method will be	BioGenius (2016), Study No.: Mo5421
			100%		100.3-	100.	0.4				

	r^2 = 1	< 3% of total peak	(2.000 g/mL)	fortification Level	101.1	8				used only for testing of specification limits.	
			130% (2.600 mg/mL)		99.2-101.8	100.9	1.5				
						Total: 100.7	Total: 0.9				

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Ananalytical method *[BioGenius, (2016), Study No.: Mo5421]* for the determination of Propan-1-ol and Propan-2-olin the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of Propan-1-ol and Propan-2-ol in air were provided and deemed acceptable at EU level. No other data is required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. As no relevant residues are expected soil and water due to the nature of the active substances, no analytical methods are required in these matrices.

3.5 Assessment of efficacy against target organisms

The efficacy assessment was conducted on the basis of the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C) (Version 1.0, 2017).

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

The biocidal product is a ready-to-use product based on the active substance Propan-1-ol and Propan-2-ol. The product is intended to be used as hygienic hand rub (PT 01) by professional and industrial users. It is applied on cleaned and dried hands.

The product is intended to have bactericidal, yeasticidal, fungicidal as well as virucidal activity against enveloped viruses. Originally, a limited spectrum virucidal activity was claimed by the applicant. However, this claim was changed by the applicant during evaluation to an enveloped virus claim.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Propan-2-ol and Propan-1-ol exhibit an unspecific mechanism of effect. They affect the cell membrane causing alteration of membrane fluidity and leakage, enter the cytoplasm and destroy the inner structure of the cell molecules and of the cytoplasm’s proteins. This process (referred to as denaturation) and the enzymes’ coagulation lead to a loss of cellular activity resulting in the cell’s death.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT 1 Use 1 & Use 2 *Hygienic hand rub*	calgonit Des-H batch No: NK 01/02/17 (Propan-1-ol 30% (w/w, Propan-2-ol 45%(w/w)))	Bactericidal *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli K12* NCTC 10538 *Pseudomonas aeruginosa* ATCC 15442	EN 13727:2012+A2:2015 Quantitative suspension test (Phase 2, step 1) Concentrations tested: 80% product concentration Interfering substances tested: Clean conditions (0.3 g/L BSA) Dirty conditions (3 g/L BSA + 3 mL/L sheep erythrocytes) Contact time: 30 and 60 sec Temperature: 20 ± 1 °C	Results showed a >5 log reduction at 80% product concentration in 30 sec under clean and dirty conditions. All controls were valid.	Chemila (2017, Test report No.: D53/2017)	*III_6.7_calgonit Des-H_PT1_Bactericidal_EN13727+A2_D53/2017.key*
PT 1 Use 1 &	calgonit Des-H	Yeasticidal/Fungicidal	EN 13624:2013 Quantitative	Results showed a >4 log	Chemila (2017,Test report	*III_6.7_calgonit Des-H_PT1_Yeasticidal_Fungicidal_EN*

Use 2 *Hygienic hand rub*	batch No: NK 01/02/17 (Propan-1-ol 30% (w/w, Propan-2-ol 45% (w/w)))	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	suspension test (Phase 2, step 1) Concentrations tested: 80% product concentration Interfering substances tested: Clean conditions (0.3 g/L BSA) Dirty conditions (3 g/L BSA + 3 mL/L sheep erythrocytes) Contact time: 30 and 60 sec Temperature: 20 ± 1 °C	reduction at 80% product concentration in 30 sec under clean and dirty conditions. All controls were valid.	No.: D53/2017)	*13624_D53/2017.key*
PT 1 Use 1 & Use 2 *Hygienic hand rub*	calgonit Des-H Batch No: 439785 (Propan-1-ol 30% (w/w, Propan-2-ol 45%(w/w)))	Virucidal Vaccinia Virus / MVA ATCC (VR-1508)	EN 14476:2019 Quantitative suspension test (Phase 2, Step 1) Concentrations tested: 80%, 50%, 5% product concentration Interfering substance tested: Dirty conditions	Results showed a >4 log reduction at 50% and 80% product concentration in 30 sec under dirty conditions. All controls were valid.	BIOTECON Diagnostics GmbH (2020, Test Report: 712.20-3_EN14476_PB_V02)	*III_6.7_calgonit Des-H_PT1_Virucidal activity against enveloped viruses_Vaccinia_EN 14476_712.20-3/2020.key*

			(3.0 g/l BSA + 3.0 g/l erythrocytes) Contact time: 30 sec contact time Temperature: 20 ± 1 °C			
PT 1 Use 1 & Use 2 *Hygienic hand rub*	calgonit Des-H batch No: NK 01/02/17 (Propan-1-ol 30% (w/w) Propan-2-ol 45% (w/w)))	Bactericidal *Escherichia coli* K12 NCTC 10538	EN 1500:2013 Phase 2, step 2 Concentrations tested: 100% product concentration Interfering substance tested: none Contact time: 30 sec <u>Application volume:</u> 4 ml/person Temperature: 20 ± 1 °C	Results showed a log reduction ≥ propan-2-ol with 4 ml of 100% product concentration in 30 s All controls were valid.	Chemila 2017 Test report No.: D53/2017	*III_6.7_calgonit Des-H_PT1_Bactericidal_EN 1500_D53/2017.key*

3.5.4 Efficacy assessment

According to the Guidance on the BPR- Volume II Efficacy - Assessment and Evaluation (Parts B&C) (Version 1.0, 2017), the product, which is intended to be applied for hygienic hand disinfection was tested in a tiered approach with phase 2, step 1 tests (quantitative suspension tests) and phase 2, step 2 tests where available. All studies have been performed based on available EN standards.

Bactericidal efficacy (PT1)

A phase 2, step 1 study (EN 13727) and a phase 2, step 2 study (EN 1500) have been submitted to prove bactericidal efficacy of the product calgonit Des-H.

The results of the study according to EN 13727 confirm bactericidal efficacy after 30 s under clean and dirty conditions at 20 °C. The results of the study according to EN 1500 demonstrated bactericidal efficacy after 30 s with 4 ml of the product.

Yeasticidal/Fungicidal efficacy (PT1)

A phase 2, step 1 study (EN 13624) has been submitted to prove yeasticidal and fungicidal efficacy of the product calgonit Des-H. The results demonstrated yeasticidal and fungicidal efficacy after 30 s under clean and dirty conditions at 20 °C.

Virucidal efficacy (PT 1)

A phase 2, step 1 study (EN 14476) with the test organism vaccinia virus (strain MVA) has been submitted to prove virucidal efficacy against enveloped viruses. The results demonstrated virucidal efficacy against enveloped viruses after 30 s under dirty conditions at 20 °C.

3.5.5 Conclusion on efficacy

The product calgonit Des-H demonstrated bactericidal, yeasticidal, fungicial and virucidal efficacy against enveloped viruses according to EN 13727, EN 13624, EN 14476 and EN 1500 under test conditions defined for hygienic hand disinfection by rubbing.

The product demonstrated efficacy for the following uses:

Use 1 & 2

Bactericidal, yeasticidal, fungicidal and virucidal against eveloped viruses –contact time 30 s, clean conditions.

It is concluded that the product is expected to be efficacious if used in accordance with the use instructions proposed in the SPC.

3.5.6 Occurrence of resistance and resistance management

According to the CARs of propan-2-ol and propan-1-ol the development of resistance is not expected and not reported due to the unspecific mode of action. A natural resistance of sporulated bacteria is known where propan-2-ol and propan-1-ol are ineffective at any concentration. Likewise, propan-2-ol and propan-1-ol are 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.

3.5.7 Known limitations

No known limitations.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

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

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

Table 3.9 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritant
Justification for the value/conclusion	The biocidal product does not contain skin-irritating or corrosive substances in relevant concentrations. However, according to the assessment reports for the active substances propan-1-ol and propan-2-ol, these substances require labelling with EUH066. Considering the high active substances concentrations in the biocidal product, EUH066 is also necessary for the biocidal product.
Classification of the product according to CLP	Classification not required. Labelling with EUH066.

Table 3.10 Data waiving

Data waiving	
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 available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

3.6.1.1 Eye irritation

Table 3.11 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye damaging
Justification for the value/conclusion	Propan-1-ol is harmonized classified as Eye Dam. 1, H318 and present in the biocidal product above the generic concentration limit of 3% for

	classification as Eye Dam. 1, H318. Therefore, the biocidal products requires classification for eye damage.
Classification of the product according to CLP	A classification of the biocidal product as Eye Dam. 1, H318 is required according to Regulation (EC) No. 1272/2008.

Table 3.12 Data waiving

Data waiving	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.2 Respiratory tract irritation

Table 3.13 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value / Conclusion	None
Justification for the conclusion	No component classified for respiratory irritation is included in the biocidal product.
Classification of the product according to CLP	Not required.

Table 3.14 Data waiving

Data waiving	
Information requirement	8.10. Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation.

3.6.1.3 Skin sensitization

Table 3.15 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin-sensitising properties are not expected.
Justification for the value/conclusion	The biocidal product does not contain components classified as skin sensitisers in relevant concentrations.
Classification of the product according to CLP	Not required.

Table 3.16 Data waiving

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not available and not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018) "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.4 Respiratory sensitization

Table 3.17 Conclusion used in Risk Assessment – Respiratory sensitisation

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

Table 3.18 Data waiving

Data waiving	
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 their components are not available.

3.6.1.5 Acute oral toxicity

Table 3.19 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	The biocidal product does not contain components classified for acute oral toxicity.
Classification of the product according to CLP	Not required.

Table 3.20 Data waiving

Data waiving	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute toxicity by oral route of the biocidal product are not available and are not required. Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.1.6 Acute inhalation toxicity

Table 3.21 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via inhalation.
Justification for the selected value	The biocidal product does not contain components classified for acute inhalation toxicity.
Classification of the product according to CLP	Not required.

Table 3.22 Data waiving

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down

	in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

3.6.1.7 Acute dermal toxicity

Table 3.23 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via dermal route.
Justification for the selected value	The biocidal product does not contain components classified for acute dermal toxicity.
Classification of the product according to CLP	Not required.

Table 3.24 Data waiving

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute toxicity by dermal route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal products, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

3.6.2 Information on dermal absorption

Table 3.25 Value(s) used in the Risk Assessment – Dermal absorption

Value used in the Risk Assessment – Dermal absorption		
Substance	Propan-1-ol	Propan-2-ol
Value	Transdermal flux: 0.85 mg/cm²/h	Transdermal flux: 0.85 mg/cm²/h

Justification for the selected value	Based on assessment report, Propan-1-ol, PT1, 2, 4, June 2017	Based on assessment reports, Propan-2-ol, PT1, 2, 4, January 2015

Table 3.26 Data waiving

Data waiving	
Information requirement	Annex III of Regulation (EC) No. 528/2012 (BPR), point 8.6 "Dermal absorption"
Justification	Studies on the dermal absorption of the biocidal product are not required. According to section 3.1.6 "Information on dermal absorption" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, May. 2018), dermal absorption can be estimated by extrapolation of experimental data obtained with a similar formulation. For the biocidal product, dermal absorption can be assessed by read-across to a dermal absorption study evaluated in the context of the active substance dossier on propan-2-ol (Boatman et al. 1998, for details see propan-2-ol ARs on PT1, 2 and 4, Germany, 2015). This study has been performed with a 70% (w/w) propan-2-ol in aqueous solution under occlusive conditions and a dermal absorption (transdermal flux) rate of 0.85 mg/cm^2/h was derived for this product. Since the composition of the biocidal product (30% (w/w) Propan-1-ol + 45% (w/w) propan-2-ol) is similar to the tested product reported in the propan-2-ol AR, the dermal absorption (transdermal flux) rate of 0.85 mg/cm^2/h is used throughout the human health exposure and risk assessment. Other co-fomulants are not considered to influence dermal absorption significantly.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Consequently, only the active substances were addressed in the human health risk assessment.

3.6.4 Other

The current harmonised classification of the active substances propan-1-ol and propan-2-ol is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):

Propan-1-ol: Eye Dam. 1, H318; STOT SE 3, H336, Flam. Liq. 2, H225
Propan-2-ol: Eye Irrit. 2, H319, STOT SE 3, H336, Flam. Liq. 2, H225

As both substances are present above the generic concentration limit of 20% for STOT SE 3, H336; the biocidal product also requires classification with STOT SE 3, H336.

3.6.4.1 Food and feeding stuffs studies

None.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

None.

3.6.4.3 Other test(s) related to the exposure to humans

None.

3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of (the) non-active substance(s), refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

Relevant guidance documents consulted for human health risk assessment
Please, consider chapter 4.4.1.

General public
Relevant exposure models or exposure studies used for human health risk assessment
Exposure of non-professional users is not relevant as intended uses are for professional use only. Exposure of the general public is not expected. Nevertheless, according to the applicant exposure of the general public is not completely ruled out according to the use description. A risk assessment for secondary exposure of the general public was not performed by the applicant. Therefore, the RMM "Not for use in areas accessible for the general public." is applied to exclude exposure of the general public.

Professional user
The evaluation of this hand disinfectant is based on Ad hoc Working Group - Human Exposure (HEAdhoc) recommendation No. 9, but deviates from the hospital scenario with regard to several parameters (e.g. frequency of hand disinfection) because the approval is applied for the food industry and gastronomy exclusively.

Relevant exposure models or exposure studies used for human health risk assessment
The volatile active substances are calculated by help of the model:

- ConsExpo for the inhalation path and by
- the flux for the dermal path.

Non-volatiles are not expected.

Strategy for human health risk assessment
Systemic quantitative risk assessment for the active substance Propan-1-ol via the dermal and inhalation route was performed with the AEL long-term of 9.2 mg/kg mg/kg bw/d.
Systemic quantitative risk assessment for the active substance Propan-2-ol via the dermal and inhalation route was performed with the AEL long-term of 17.9 mg/kg mg/kg bw/d.
A local risk assessment based on the classification of the biocidal product as well as cumulative risk characterisation from combined exposure to the active substances Propan-1-ol and Propan-2-ol was performed.

Considerations on volatility of the active substance(s) and substance(s) of concern
Propan-1-ol (CAS: 71-23-8) and propan-2-ol (CAS: 67-63-0) are volatile liquids. For hand disinfectants (PT 1), the vapour pressure at skin temperature (30° C) is considered:

- propan-1-ol: 3860 Pa
- propan-2-ol: 7770 Pa

Strategy for livestock exposure and/or dietary risk assessment
Not relevant.

Strategy for the assessment of substance(s) of concern
Not relevant, the biocidal product does not contain a substance of concern.

Strategy for disinfectant by-products assessment
Not relevant.

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

Table 3.27 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	N/A	N/A	N/A	No	No
Dermal	Yes	N/A	No*	No	N/A
Inhalation	Yes	N/A	No*	No	N/A

* In the food industry and gastronomy, bystanders are not expected for hygienic reasons. In the unlikely case that an uninvolved worker enters the kitchen or work areas in a slaughterhouse, their exposure is assumed to be less than that of the workers and is therefore covered by the scenarios of primary exposure assessed (remark: no PPE is necessary according to the risk assessment).

3.6.6.3 List of exposure scenarios

The following list contains all scenarios for professional exposure assessed according to the "Biocides Human Health Exposure Methodology Document"[2] (parts regularly updated by HEAdhoc Recommendation No. 6).

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

[2] The document is available at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure.

Table 3.28 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Primary exposure		
	Hand disinfection in food industry and gastronomy	
1-1	Hygienic hand disinfection via pump dispenser in kitchens (use 1)	Professionals
2-1	Hygienic hand disinfection via electronic dispenser in slaugtherhouses (use 2)	Professionals

3.6.6.4 Reference values to be used in risk characterisation

Table 3.29 Reference values to be used in risk characterisation

Propan-1-ol:

Reference	Value	Study	AF
$AEL_{long\text{-}term}$	9.2 mg/kg bw/d	Overall NOAEL from rat 13-week rat inhalation study (impairment in male fertility parameters)	200[1]
$AEL_{medium\text{-}term}$	18.3 mg/kg bw/d	Overall NOAEL from rat 13-week inhalation study (impairment of male fertility parameters), Assessment-Report (RMS DE (2019))	100
AEL_{acute}	27.6 mg/kg bw/d	Rat inhalation developmental toxicity studies (foetal skeletal malformations), Assessment-Report (RMS DE (2019))	100

[1] In addition to a default AF of 100, application of a separate AF of 2 for extrapolation from medium-term to long-term systemic toxicity

Propan-2-ol:

Reference	Value	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF
AEL acute/medium /long-term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Human volunteer study (Sethre et al., 2000a)	NOAEC – 200 ppm	6.4
AEL acute/medium /long-term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Human volunteer study (Sethre et al., 2000a)	NOAEC – 200 ppm; LOAEL 400 ppm [2]	3.8
AECdermal				
AECinhalation				
ARfD		Not necessary, no residues in food expected.		
ADI		Not necessary, no residues in food expected.		

[2] for acute systemic (neurological) effects (over 8 hours), based on the deterioration of postural balance

3.6.6.5 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.6.6 Professional users (including industrial users and trained professional users)

Scenario 1-1: Hygienic hand disinfection via pump dispenser in kitchens

Description and input parameters

Table 3.30 Description and input parameters

Description of Scenario 1-1: Hygienic hand disinfection via pump dispenser in kitchens
The ready to use-product is applied for use in the food industry, e.g. slaughterhouses, beverage industry and in hotel and gastronomy kitchens in 1 L bottles and 5 L jerrycans. Therefore, exposure of hand disinfectants is calculated analogue to HEAdhoc recommendation No. 9 for use in the food industry only. The applicant has foreseen two different types of dispensers for all uses, a manual pump dispenser and an electronic dispenser, both resulting in the same level of exposure. In order to cover both dispensers in the scenario discriptions, each of them has been included in one of the two scenarios, although both dispenser types are relevant for both scenarios. For pump dispensers, use in commercial kitchens is designated by the applicant. Based on the submitted data, the eCA can follow this approach. 4 mL of the biocidal product are applied to one hand, spread over the complete surface of both hands and let to dry. The evaporation time considered for dermal exposure is calculated according to annex 3 of recommendation 9, but taking into account that the product is not a pure substance but a mixture of substances with significantly different vapour pressures. For this purpose, an average vapour pressure of 6206 Pa (corresponding to the composition of 30% propan-1-ol and 45.5% propan-2-ol) and the mass of both alcohols (without water) were used (analogous to already approved products): According to Raoult's Law, the vapour pressure of an individual substance in a mixture is given by the product of molar fraction x_i and the vapour pressure of the pure substance $p_{i,\ pure}$: $p_{i,\ mix} = x_i \cdot p_{i,\ pure}$. The vapour pressure of the entire mixture is the sum of all individual vapour pressures, i.e.: $p_{mixture} = \Sigma_i\ p_i$. Consequently, a mixture of two alcohols iPA and nPA has the vapour pressure $p_{iPA\text{-}nPa\text{-}mix} = x_{iPA} \cdot p_{iPa} + x_{nPa} \cdot p_{nPa}$ It is assumed that each employee performs up to 5 hand disinfections per working day. Inhalation exposure was assessed using ConsExpo. It is assumed that 11 employees work in the commercial kitchen and that each of them performs 5 hand disinfections per working day. For the calculation, it is assumed that during a hand disinfection event all 11 employees disinfect their hands at the same time. If these events are evenly distributed over the 480 min working day, every 480 min/5=96 min a hand disinfection event takes place. The simulation performed with ConsExpo shows that the evaporated alcohols have been removed almost completely from the air by aeration before the next disinfection event takes place 96 min later. Therefore, to assess the entire working day, it is assumed that this scenartio is repeated 5 times per day, covering 480 min. Eye exposure by professional users is excluded because the liquid is applied downwards and evaporates on the hands within a very short time. Concerning connection of the canisters to the dispenser (mixing & loading phase), exposure is expected to be far lower than exposure during hand disinfection, where the product is intentionally applied to the skin, thus it is covered by the application scenarios. In addition, refilling was not applied for by the applicant as the 1 litre and 5 litre canisters are ready-to-use products, and consequently refilling was excluded in the SPC in alignement with document CA-March22-Doc.4.4 "Hand disinfectants (PT 1) to be used with dispensers and refilled containers (clarification on risk assessment, SPC and labelling/information on dispensers and refilled containers)" agreed in the 95th CA meeting.

Bystanders are not expected in the food industry and in professional kitchens for hygienic reasons.

Input parameters for Scenario 1-1 (kitchen)			
inhalation and dermal exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	concentration of propan-1-ol [% w/w]	30.151	Application for authorisation
	concentration of propan-2-ol [% w/w]	45.455	ditto
	density of b.p. [g/cm³]	0.8549	ditto
	Number of applications per person per day	5	ditto
	Number of employees (in 80 m³ room)	11	ditto
	volume of b.p. per application [ml]	4	ditto
	exposed area [cm²]	0.902	11 persons à 820 cm² (HH Recom 14)
	temperature [° C]	30	hand temperature
	ConsExpo web parameters		
	room volume [m³]	80*	commercial kitchen
	ventilation rate [air exchange per hour]	5	Heating & ventilation contractor's association: kitchen ventilation systems DW/172
	emission duration (evaporation time) [min.]	1.46**	calculated in accordance with Recom 9
	application / exposure duration [min./d]	96	480 min. / 5 times
	product amount per application [g]	3.42	calculated analogue to application for authorisation
	exposure duration per application [min.]	10	Headhoc Recom 9
	mode of release	constant rate	expert judgement
Tier 2	eye protection (goggles)	not necessary***	expert judgement
	protective gloves, coverall	not necessary	expert judgement
	inhalation protection	not necessary	expert judgement

* The applicant has suggested to consider 11 employees working in a kitchen with a size of 80 m³ and a ventilation rate of 5 /h, while in the Assessment Report (CAR) for propan-2-ol PT4-kitchen scenario 25 m³ and a ventilation rate of 15/h were assumed. We followed the applicant's suggestion, because 25 m³ might not be realistic for a commercial kitchen in which 11 people work.

** calculated evaporation time at 30 °C according to annex 3 of HEAdhoc recommendation No. 9 taking into account that the product is not a pure substance but a mixture of substances with significantly different vapour pressures (analogous to already approved products).

*** Direct eye exposure by professional users is excluded as the liquid is applied downwards. Indirect eye exposure resulting from hand-to-eye contacts is unlikely considering the hygienic setting and the quick evaporation of the alcohols. Additionally, labelling with H318 and RMM "Avoid contact with eyes" warn against eye damage. Gloves are not applicable during hand disinfection. Adequate air exchange is assumed in a commercial kitchen for hygienic reasons.

Scenario 2-1: Hygienic hand disinfection via electronic dispenser in slaugther houses

Description and input parameters

Table 3.31 Description and input parameters

Description of Scenario 2-1: Hygienic hand disinfection via electronic dispenser in slaugtherhouses
The ready to use-product is applied for use in the food industry, e.g. slaughterhouses, beverage industry and in hotel and gastronomy kitchens in 1 L bottles and 5 L jerrycans. Therefore, exposure of hand disinfectants is calculated analogue to HEAdhoc recommendation No. 9 but for use in these areas, only. For electronic dispensers, use in slaughterhouses is designated by the applicant. However, manual pump dispensers may also be used here, without affecting the exposure (see respective explanation for scenario 1-1). Based on the submitted data, the eCA can follow this approach. Electronic dispensers are large boxes at a turnstile in an anteroom from which the applicant submitted several photographs (see respective photos in the confidential PAR). Before (re)entering the working room, both hands are put into the openings at the same time. 4 mL of the biocidal product are applied, spread over the complete surface of both hands and let to dry. For slaughterhouses, the applicant assumes 300 workers who carry out routine hand disinfection by an electronic dispenser before a turnstile, twice per day (at the beginning of shift and after lunch break). In addition, he states that 10 workers may carry out an additional 3rd hand disinfection when re-entering the slaughterhouse after short breaks. As the eCA has no contradictory information and follows the applicant. The evaporation time for dermal exposure is calculated according to annex 3 of recommendation 9, but taking into account that the product is not a pure substance but a mixture of substances with significantly different vapour pressures. For this purpose, an average vapour pressure of 6206 Pa (corresponding to the composition of 30% propan-1-ol and 45.5% propan-2-ol) and the mass of both alcohols (without water) were used (analogous to already approved products). For a rationale on this approach, please see respective explanation in scenario 1-1. Although it is assumed that workers routinely disinfect twice a day, as a worst case for dermal exposure it is considered that some workers may also disinfect a third time during the day, for example after leaving for a short break. For inhalation exposure, it is assumed that all of the 300 workers pass the turnstile and disinfect their hands. For the calculation, a constant release was assumed, i.e., the total amount of product used by 300 workers (300 · 3.42 g = 1026 g) is released evenly into the anteroom. Each worker is expected to stay for 2 min in the anteroom, twice a day. The calculation was originally perfomed using ConsExpo, the assessment is provided in the accompanying document "Calgonit Des-H-Output_ProfessionalUser_Slaugtherhouse_original.xlsx". However, after discussion phase with the concerned member states, the eCA has performed a simplified exposure calculation that is easier to understand. This alternate calculation uses the 'well-mixed room model with a constant emission rate" described in "Mathematical Models for Estimating Occupational Exposure to Chemicals" published by the American Industrial Hygiene Association (AIHA). An excel spreadsheet for this model is available in the IHMOD Tool which can be downloaded at https://www.aiha.org/public-resources/consumer-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools/ihmod-tool. For this simplified approach it is considered that it takes 60 min for the 300 workers to pass the turnstile. As worst-case, it is assumed that the entire amount of product used evaporates into the anteroom during this time period. Thus, during this period the concentration of the evaporating a.s. increases in the air, consequently wokers passing at the end of this period are exposed to the highest concentrations. As a worst case, it is assumed that a worker is exposed both times to this maximum concentration. After all emoployees have passed, the concentration decreases due to aeration (more than 99% have been removed 60 min after the last disinfection took place). For this reason, the

inhalation exposure from the 2nd disinfection is not higher than from the first. Furthermore, in case that during the day few workers disinfect their hands for a third time, inhalation exposure from this single disinfection is expected to be negligible compared to the maximum value considered for the two regular events.
Since the simplified approach intentionally covers an absolute worst case by considering the maximum exposure for the same worker twice a day, the calculated exposure levels are higher than from the original approach, but they still result in the same overall conclusion (see risk assessment below).

The refined approach is provided in the accompanying document "Calgonit Des-H-Output_ProfessionalUser_revised_afterCommenting.xlsx".

Eye exposure by professional users is excluded because the liquid is applied downwards and evaporates on the hands within a very short time.

Concerning connection of the canisters to the dispenser (mixing & loading phase), exposure is expected to be far lower than exposure during hand disinfection, where the product is intentionally applied to the skin, thus it is covered by the application scenarios. In addition, refilling was not applied for by the applicant as the 1 litre and 5 litre canisters are ready-to-use products, and consequently refilling was excluded in the SPC in alignement with document CA-March22-Doc.4.4 "Hand disinfectants (PT 1) to be used with dispensers and refilled containers (clarification on risk assessment, SPC and labelling/information on dispensers and refilled containers)" agreed in the 95th CA meeting.

Bystanders are not expected in the food industry and in professional kitchens for hygienic reasons.

Concerning photographs of the turnstile with disinfectant dispenser and its opening for hand disinfection, please refer to the confidential product assessment report.

Input parameters for Scenario 2-1 (slaughterhouse)			
inhalation and dermal exposure (flux)			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	concentration of propan-1-ol [% w/w]	30.151	Application for authorisation
	concentration of propan-2-ol [% w/w]	45.455	ditto
	density of b.p. [g/cm³]	0.8549	ditto
	Number of applications per person per day	2 (for dermal exposure, 3 applications are expected)	ditto (in an anteroom / sluice)
	Number of employees (in 80 m³ room)	300	passing a turnstile
	volume of b.p. per application [ml]	4	Application for authorisation
	exposed area [cm²]	820	Headhoc Recom 14
	temperature [° C]	30	hand temperature
	ConsExpo web parameters		
	room volume [m³]	80	anteroom / sluice
	ventilation rate [air exchange per hour]	5	Heating & ventilation contractor's association, specification for kitchen ventilation systems DW/172
	emission duration (evaporation time) [min.]	1.46*	calculated in accordance with Recom 9
	product amount per application [g]	3.42	calculated analogue to application for authorisation
	exposure duration per application [min.]	10	Headhoc Recom 9
	mode of release	constant rate	expert judgement
Tier 2	eye protection (goggles)	not necessary**	expert judgement
	protective gloves, coverall	not necessary	expert judgement
	inhalation protection	not necessary	expert judgement

* calculated evaporation time at 30 °C according to annex 3 of HEAdhoc recommendation No. 9 taking into account that the product is not a pure substance but a mixture of substances with significantly different vapour pressures (analogous to already approved products).

** Direct eye exposure by professional users is excluded as the liquid is applied downwards. Indirect eye exposure resulting from hand-to-eye contacts is unlikely considering the hygienic setting and the quick evaporation of the alcohols. Additionally, labelling with H318 and RMM "Avoid contact with eyes" warn against eye damage. Gloves are not applicable during hand disinfection. Adequate air exchange is assumed in a commercial kitchen for hygienic reasons.

Outcome of systemic exposure and risk characterisation

Table 3.32 Summary table: estimated systemic exposure and risk characterisation for professional users

Propan-1-ol:

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 9.2 mg/kg bw/d	**Acceptable (Yes/No)**
1-1	1/no PPE	n.a.	0.56	2.94	3.50	38.0	Yes
	2/n.a. for hand disinfectants	n.a.	0.56	2.94	3.50	38.0	Yes
2-1 simplified approach	1/no PPE	n.a.	0.34	1.06	1.29	15.2	Yes
	2/n.a. for hand disinfectants	n.a.	0.34	1.06	1.29	15.2	Yes
2-1 original approach	1/no PPE	n.a.	0.23	0.68	0.91	9.88	Yes
	2/n.a. for hand disinfectants	n.a.	0.23	0.68	0.91	9.88	Yes

n.a.: not applicable

Propan-2-ol:

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 17.9 mg/kg bw/d	**Acceptable (Yes/No)**
1-1	1/no PPE	n.a.	0.85	4.41	5.25	29.4	Yes
	2/n.a. for hand disinfectants	n.a.	0.85	4.41	5.25	29.4	Yes
2-1 simplified approach	1/no PPE	n.a.	0.51	1.59	2.10	11.7	Yes
	2/n.a. for hand disinfectants	n.a.	0.51	1.59	2.10	11.7	Yes
2-1 original approach	1/no PPE	n.a.	0.34	2.38	2.72	15.2	Yes
	2/n.a. for hand disinfectants	n.a.	0.34	2.38	2.72	15.2	Yes

n.a.: not applicable

Combined scenarios

The combination of an eletronic dispenser in an anteroom and pump dispensers in the working hall is not assumed because if, behind an electronic dispenser at a turnstile, further hygiene measures are deemed necessary, it is customary that workers wear disposable gloves.

Outcome of combined systemic exposure and risk characterisation
Not applicable

Outcome of (semi-)quantitative local exposure and risk characterisation
Not applicable

Outcome of qualitative local risk assessment

Table 3.33 Outcome of qualitative local risk assessment

Hazard			Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
high	H318, EUH066		1	Kitchen: Hand disinfection via pump dispenser	inhalation dermal	5 events per person per day; duration, due to rapid evaporation of the alcohols, is ca. 1.46 min per event	negligible* Eye: excluded for professional users** Hands: expected	no PPE**	Acceptable	
high	H318, EUH066		1	Slaughterhouse: Hand disinfection via electronic dispenser	inhalation dermal	2 events per person per day (3 for dermal); duration, due to rapid evaporation of the alcohols, is ca. 1.46 min per	negligible* Eye: excluded for professional users** Hands: expected	no PPE**	Acceptable	

						event				

* Inhalation exposure at the moment of hand disinfection in kitchens is eliminated by room ventilation. In slaughterhouses, the anteroom is left directly after hand disinfection.
** Direct eye exposure by professional users is excluded as the liquid is applied downwards. Indirect eye exposure resulting from hand-to-eye contacts is unlikely considering the hygienic setting and the quick evaporation of the alcohols. Additionally, labelling with H318 and RMM "Avoid contact with eyes" warn against eye damage. Gloves are not applicable during hand disinfection. Adequate air exchange is assumed in a commercial kitchen for hygienic reasons.

Conclusion

Based on the systemic and local risk assessment of the individual active substances Propan-1-ol and Propan-2-ol via the dermal and inhalation route, a risk for professional users resulting from the uses of the biocidal product calgonit Des-H is unlikely after TIER 1 consideration. For risk characterisation from combined exposure to the active substances within the biocidal product, please refer to chapter 3.6.10. In summary, regarding occupational safety, there are no objections against the use taking into account the provisions described in chapter 3.6.11 of this PAR.

3.6.6.7 Non-professional users

Exposure of non-professionals is not relevant. The biocidal product is for industrial and professional use only.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

According to the applicant, exposure of the general public is not expected. Nevertheless. due to the use description, a use in other areas than professional and industrial areas, is not ruled out (e.g. in hotels and gastronomy). A risk assessment for secondary exposure of the general public was not performed by the applicant. Therefore, the RMM "Not for use in areas accessible for the general public." needs to by applied.

For professional users in the food industry and gastronomy, bystanders are not expected for hygienic reasons. In the unlikely event that an uninvolved worker enters the kitchen or work areas in a slaughterhouse, his exposure is assessed to be less than that of the workers and is therefore covered by the scenarios assessed.

Combined scenarios

The approval was applied for 1 L bottles and 5 L jerrycans only. Therefore, refilling is not necessary. Consequently, assessment of combined exposure of refilling and application is not applicable.

Outcome of qualitative local risk assessment

Not applicable for professional users.

Conclusion

Not applicable for professional users.

3.6.7 Monitoring data

None.

3.6.8 Dietary risk assessment

The intended use descriptions of the Propan-1-ol and Propan-2-ol containing biocidal product "calgonit Des-H", for which authorisation is sought, indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for hygienic hand disinfection

(PT 01) and no direct or indirect contact with food or feed is intended.
Due to its high vapour pressure, Propan-1-ol and Propan-2-ol evaporate completely within the time of application of the biocidal product, so that no transfer from hands to food should occur. In the unlikely event that residue transfer does occur, the active substances will evaporate from the food before it is eaten.
Therefore, consumers are not exposed to Propan-1-ol and Propan-2-ol residues in food and there is no risk to consumers.

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Table 3.34 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses					
	Sector of use	**Residue definition**	**Sample matrix**	**Reference regulation**	**Reference**
1.	Plant protection products (Propan-2-ol)	Propan-2-ol (default MRL of 0.01 mg/kg)	Food of plant and animal origin	Not approved as PPP under Reg. (EC) No 1107/2009 Default MRL according to Art 18(1)(b) Reg 396 / 2005.	*https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0396&from=EN

3.6.8.2 Maximum residue limits or equivalent

Table 3.35 Maximum residue limits or equivalent

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**	**Estimated food concentration (mg/kg)**	**MRL exceedance (Yes/No)**
MRLs (Propan-2-ol)	Art 18(1)(b) Reg 396 / 2005	Food of plant and animal origin	Default MRL of 0.01 mg/kg	Residues in food and feed are not expected	No

3.6.9 Aggregated exposure and risk characterisation

Not applicable for professional users.

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

Tier 1 and tier 2

Table 3.36 Tier 1 and tier 2

1-1	**Propan-1-ol**	**Propan-2-ol**	**Conclusions**
Without PPE			
Tier 1[(a)]	*38.0% AEL*	*29.4%AEL*	*Acceptable*
Tier 2[(b)]	*0.38*	*0.29*	*Acceptable*
	HI = 0.67		
2-1 simplified approach	**Propan-1-ol**	**Propan-2-ol**	**Conclusions**
Without PPE			
Tier 1[(a)]	*15.2% AEL*	*11.7% AEL*	*Acceptable*
Tier 2[(b)]	*0.15*	*0.12*	*Acceptable*
	HI = 0.27		
2-1 original approach	**Propan-1-ol**	**Propan-2-ol**	**Conclusions**
Without PPE			
Tier 1[(a)]	*9.88% AEL*	*15.2% AEL*	*Acceptable*
Tier 2[(b)]	*0.1*	*0.15*	*Acceptable*
	HI = 0.25		

a: Tier 1 here is an intermediary step to verify risk acceptability for each individual substance (active substance or SoC) used in the product and is followed by

b: Tier 2 to assess the combined exposure/toxixity of the biocidal product.

The table was amended according to Appendix 4-7 of the Guidance on the BPR: Volume III Human Health (Parts B+C).

Tier 3a

Not applicable for professional users.

Tier 3b

AEL can be refined by target organ.
Not applicable for professional users.

3.6.11 Overall conclusion on risk assessment for human health

Table 3.37 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
[1]	Hygienic hand disinfection via pump dispenser	Acceptable with the following risk mitigation measure	Not for use in areas accessible for the general public. Avoid contact with eyes.*
[2]	Hygienic hand disinfection via electronic dispenser	Acceptable with the following risk mitigation measure	Not for use in areas accessible for the general public. Avoid contact with

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
			eyes.*

*Eye exposure by professional users is excluded because the liquid is applied downwards and evaporates on the hands within a very short time. Gloves are not applicable during hand disinfection. A sufficient air exchange is assumed for hygienic reasons.

3.7 Risk assessment for animal health

Considering the use, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

3.7.1 Risk for companion animals

Not relevant, no exposure expected.

3.7.2 Risk for livestock animals

Not relevant, no exposure expected.

3.8 Risk assessment for the environment

The risk assessment for the environment was conducted according to the Guidance on the BPR: Volume IV Environment Part A (2022) as well as Parts B+C (2017).

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

No new studies have been submitted since the approval of the active substances. The risk assessment is therefore based on the list of endpoints as published in the assessment reports (Assessment report for Propan-1-ol, product types 1,2,4, June 2017 and Assessment report for Propan-2-ol, product type 1, 13 January 2015) for which Germany was the rapporteur member state. The assessment reports are available on the ECHA website.

The fate and behaviour of both active substances is briefly summarised below:

Propan-1-ol
Propan-1-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290 nm and 750 nm takes place and hence Propan-1-ol cannot undergo direct photolysis in sunlight. Propan-1-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. Based on a reaction rate constant of 5.8 x 10^{-12} cm^3/(molecule x sec) by Atkinson et al. (2006) a half-life of 2.8 days can be estimated.
The Henry´s Law constant for Propan-1-ol is 0.76 Pa m^3/ mol, which indicates a moderate volatility at 25°C.
Based on a log K_{OW} of 0.25 and the QSAR for alcohols, the K_{OC} was calculated to be 3.96 L/kg. Therefore, Propan-1-ol is expected to exhibit only a weak adsorption in soils and sediments, indicating a very high mobility of Propan-1-ol in soil and a very low geoaccumulation potential.
Propan-1-ol is considered to be 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.

Propan-2-ol
Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290 nm and 750 nm takes place. Therefore, Propan-2-ol is not accessible for direct photodegradation in sunlight. Propan-2-ol has a relatively high vapour pressure of 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 by Atkinson et al. (2006) a half-life of 3.1 days can be estimated. Based on a log K_{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 geo-accumulation potential.
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.

The endpoints applied in the environmental risk assessment are summarised in the table below.

Table 3.38 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment				
	Value		**Unit**	**Remarks**
	Propan-1-ol	**Propan-2-ol**		
Fate and behaviour in the environment				
Molecular weight	60.09	60.09	g/mol	
Melting point	-127	-89.5	°C	
Vapour pressure (at 25°C)	2760	5780	Pa	
Water solubility	Completely miscible in water Value used for risk assessment:1	Completely miscible in water Value used for risk assessment:1	kg/L	
Log Octanol/water partition coefficient (K_{ow})	0.25	0.05	Log 10	
Organic carbon/water partition coefficient (K_{oc})	3.96	3.3	L/kg	
Henry's Law Constant (at 25 °C)	0.76	0.8	Pa x m^3/mol	
Characterisation of biodegradability	readily biodegradable	readily biodegradable	-	
Rate constant for STP	1	1	h^{-1}	No measured value available, default value based on screening test
DT_{50} for biodegradation in surface water	15	15	d (at 12ºC)	No measured value available, default value based on screening test
DT_{50} for hydrolysis in surface water	No hydrolysis	No hydrolysis		
DT_{50} for degradation in soil	30	30	d (at 12ºC)	No measured value available, default value based on screening test
DT_{50} for degradation in air	2.8	3.1	d	Half-life in the troposphere
Predicted no effect concentrations (PNEC)				
Sewage treatment plant	10	10	mg/L	Values are presented in published Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015)
Surface water	2.3	2.82	mg/L	
Marine water	--	--	mg/L	
Sediment	1.99 (derived from $PNEC_{water}$ using EPM)	2.41 (derived from $PNEC_{water}$ using EPM)	mg/kg wwt	

Marine sediment	--	--	mg/kg wwt	
Soil	0.432 (derived from $PNEC_{water}$ using EPM)	0.496 (derived from $PNEC_{water}$ using EPM)	mg/kg wwt	

Neither $PNEC_{bird}$ nor $PNEC_{mammal}$ have been determined due to the low estimated BCF of the a.s. and associated low potential of accumulation in the environment.

3.8.1.2 Endpoints for the product

There are no data available for the product. The effect and exposure assessment and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substance(s).

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substances were addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

According to the CAR for Propan-1-ol (eCA: DE, 2017) and Propan-2-ol (eCA: DE, 2015), there are no indications for endocrine disrupting properties of these active substances on environmental non-target organisms. However, a comprehensive ED-assessment for the active substances according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.
For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

3.8.1.5 PBT Assessment

The conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substances for Propan-1-ol (CAR June 2017) and Propan-2-ol (CAR January 2015). Accordingly, Propan-1-ol and Propan-2-ol thus neither fulfil the PBT- nor the vP/vB-criteria.

3.8.2 Emission estimation

3.8.2.1 General information

The biocidal product "calgonit Des-H" contains products of PT1 that are used for hand disinfection by professional and industrial users. According to the applicant the ready-to-use products (hygienic hand disinfection via pump dispenser (#Use 1) or electronic dispenser (#Use 2) are primarily used in the food industry and also in the hotel and gastronomy industry. The RTU products contain 30% w/w of the active substance Propan-1-ol and 45% w/w of the active substance Propan-2-ol, respectively. Hence, these concentrations are considered in the emission estimation.

During the environmental risk assessment it was assumed, respectively, that after application 90% of the active substances are released to air and 10% 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)

products of the BP "calgonit Des-H ", the disinfection is finished when the treated skin is completely dried and the product has evaporated completely. This is facilitated by the relatively high vapour pressure of both a.s.. Nearly the whole amount of substances 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 BP, the distribution used during the assessment of the active substances is maintained since it is plausible that the main emission path will be via air.

Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario document for PT1 (ESD, release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment), the Technical Agreement on Biocides (TAB) and the model SimpleTreat 4.0 (Distribution in the sewage treatment plant (STP)) by using the default values for parameters, unless otherwise noted. In addition, the emission calculations submitted by the applicant in the dossier were taken into account. Distribution in the STP and the environment is calculated based on the physical-chemical properties as listed in section 3.2 and table 3.91.

Distribution in the STP has been recalculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance with the TAB ENV 9. Furthermore, the Henry constant was converted from 25°C to 15°C (temperature in the STP) outside of ST 4.0 according to Guidance on the BPR: Volume IV Environment (Parts B+C), Equation 23 and the following Henry constants were used for the ST 4.0 calculation: Propan-1-ol: 0.434 Pa x m^3/mol; Propan-2-ol: 0.457 Pa x m^3/mol). The following distribution was derived:

Table 3.39 Distribution of the active substances in the STP according to Simple Treat 4.0

Distribution of the active substances in the STP according to Simple Treat 4.0		
	Value [%]	
	Propan-1-ol	**Propan-2-ol**
air	0.172	0.181
water	7.979	7.977
sludge	0.037	0.031
degraded	91.81	91.81

For further exposure calculations, the fraction released to the environment via sludge is considered as not relevant, considering the low share of both active substances in sludge (<0.1%) as well as their ready biodegradability and the potential volatilisation from soil.

In addition, during the WG ENV IV 2019 it was agreed that for products containing volatile alcohols, there is no need to conduct a risk assessment for the subsequent environmental compartments (soil and groundwater) following the release path via air (see also TAB ENV-188).

Consequently, emissions to soil and groundwater were not assessed for this biocidal product considering the two aspects mentioned above.

Significant release to the environment will occur during the application of products holding the a.s.. The table below summarises the assessed emission scenarios and the receiving environmental compartments that have been identified as potentially exposed due to the use of the biocidal product. Compartments highlighted in bold are directly exposed.

Table 3.40 Environmental risk assessment

Use number	Scenario assessed	ESD applied	Maximum in-use concentration of the active substance(s)	Receiving compartments
[1] + [2]	Scenario 1.1: Professional use: release of disinfectants used for skin and hand application in hospitals based on the annual tonnage applied[1]	ESD for PT1 (2004): Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1), EUBEES, 2004	Propan-1-ol: 300 g/kg Propan-2-ol: 450 g/kg	**STP** surface water sediment **air**
	Scenario 1.2: Professional use: release of disinfectants used for skin and hand application in hospitals based on an average consumption			
	Scenario 1.3: Hygienic hand disinfection (professional, industrial user)	A new Scenario was proposed in the draft PAR by the applicant for hand disinfection in the food sector. It is also presented in the PAR, but is not taken into account for the PEC calculations, since it was not discussed and agreed at WG ENV.		

[1] *The applied scenario is based on tonnage data which are confidential. The risk assessment is consequently included in the confidential annex of the PAR.*

3.8.2.2 Emission estimation for the scenario(s)

The emission scenarios for disinfectants used for skin and hand application are described in detail in chapter 4 of the Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004); for input and output values see the following tables. Two approaches are calculated: consumption-based approach and tonnage-based approach.
Additionally, a new Scenario for the product type 1 was proposed in the dossier by the applicant for hand disinfection in the food industry sector. It is also presented in this section (Scenario 1.3), but is not taken into account for the PEC calculations, since it was not discussed and agreed at WG ENV.

Scenario 1.1- Professional use: release of disinfectants used for skin and hand application in hospitals based on the annual tonnage applied

The resulting local emissions of Propan-1-ol and Propan-2-ol to waste water and air from use of the biocidal product "calgonit Des-H" in hospitals (according to ESD PT1) based on tonnage are given in the Confidential Annex, chapter 5.

Scenario 1.2: Professional use: release of disinfectants used for skin and hand application in hospitals based on an average consumption

Table 3.41 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1.2: Professional use: release of disinfectants used for skin and hand application in hospitals based on an average consumption			
Number of beds in model hospital	400		D
Fraction released to waste water	0.1		CAR (Propan-1-ol, Propan-2-ol)
Fraction released to air	0.9		CAR (Propan-1-ol, Propan-2-ol)
Consumption of a.s. per bed	Alcohols: 15 Propan-1-ol: 6 Propan-2-ol: 9	g/d	P The consumption of alcohols per bed stated in table 3.8 of ESD PT1 was divided between the two active substances according to their share in the total amount of active substance in the BPF.

Table 3.42 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	
	Propan-1-ol	**Propan-2-ol**
Water	0.24	0.36

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	
	Propan-1-ol	**Propan-2-ol**
Air	2.16	3.24

Conclusion for Scenarios 1.1 and 1.2

The consumption-based approach (scenario 1.2) represents the worst-case estimation as calculated Elocal values are higher compared to those based on the tonnage approach. Thus, PECs based on consumption were calculated and then used for the environmental risk assessment.

Scenario 1.3: Hygienic hand disinfection (professional, industrial user)

This new Scenario was introduced by the applicant and eCA DE decided to present it also in this PAR as supportive information. However, because it was not discussed and agreed at WG ENV, it was not taken into account for the PEC calculations. In addition, for the same application (hand disinfection in the food sector) in an already discussed Union authorisation (UA) the ESD scenario for hand disinfection in hospitals was already agreed and used for the emission calculation. The following part is stated in the dossier of the applicant:

"The ready-to-use product is used for professional hand disinfection in food and beverage industry, hotels and gastronomy. An application in hospitals is not relevant. The product contains 30% propan-1-ol and 45% propan-2-ol and per application, 4 mL of disinfectant solution are applied. According to information provided by the applicant the worst case situation concerning the environmental exposure is based on companies with up to 600 employees applying the product up to 5 times per day.
The ESD for PT1 (2004) provides an emission scenario for disinfectants used for skin and hand application in table 4.5. However, this emission scenario does not fit to the specific use of the biocidal product since it is based on the use by nursing and surgical staff in hospitals. Therefore, the emission estimation is based on the information provided by the applicant and the information stated in the table below. Calculations take into account the maximum number of applications, the applied volume as well as the concentrations of the active substances. Detailed information on the used equations is provided in the calculation sheet which is attached to Annex 3.2.2 ERA, Appendix 1.
In accordance with the Assessment Report for "propan-1-ol" used in PT1, 2 and 4 (Germany, June 2017) and the Assessment Report for "propan-2-ol" used in PT1 (Germany, January 2015) it is assumed that only 10% of the active substances are released to the sewer system (i.e. via STP) whereas 90% are emitted to air."

Table 3.43 Input parameters for calculating the local emiss*ion

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1.3: *provided by the Applicant: Hygienic hand disinfection (professional, industrial user)*			
Number of employees using the hand disinfectant	600	[d^{-1}]	Based on 2 shift operation à 300 employees
Number of applications per employee	5	[d^{-1}]	
Efficient dose rate of the hand disinfectant	0.004	[L/application]	
Density of the hand disinfectant	0.8549	[kg/L]	
Fraction of a.s. in the hand disinfectant			
Propan-1-ol	0.30	[-]	
Propan-2-ol	0.45	[-]	
Fraction of a.s. emitted to			
STP	0.10	[-]	acc. to relevant Assessment Reports
Air	0.90	[-]	
Number of emission days per year	260	[d]	Based on 52 weeks à 5 working days

Table 3.44 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	
	Propan-1-ol	**Propan-2-ol**
Water	0.31	0.46
Air	2.77	4.16

The resulting local emissions based on the applicants proposed scenario are comparable to those estimated in the worst-case consumption-based approach (scenario 1.2) and no unacceptable risk for the environment was determined.

3.8.3 Exposure calculation and risk characterisation

In the following table a summary of PNEC values as well as estimated PEC values and resulting risk quotients are presented for the worst-case scenario 1.2.

Table 3.45 Summary table of PNEC, PEC and PEC:PNEC values

Summary table of PNEC, PEC and PEC:PNEC values		
	Propan-1-ol	**Propan-2-ol**
PNEC values		
PNECstp(mg/L)	10	10
PNECwater (mg/L)	2.3	2.82
PNECsed (mg/kg wwt)	1.99	2.41
SCENARIO 1.2 - -professional use		
PEC values		
PECair	6.00E-04	9.00E-04
PECstp(mg/L)	9.58E-03	1.43E-02
PECwater (mg/L)	9.58E-04	1.43E-03
PECsed (mg/kg wwt)	8.32E-04	1.23E-03
PEC/PNEC values		
PEC/PNECstp	9.58E-04	1.40E-03
PEC/PNECwater	4.17E-04	5.09E-04
PEC/PNECsed	4.16E-04	5.10E-04

Atmosphere

According to the active substance CARs of Propan-1-ol and Propan-2-ol, the half-lives for the reaction with OH radicals are 2.8 and 3.1 days, respectively. The Henry's law constants are 0.76 Pa m³/mol for Propan-1-ol and 0.82 Pa m³/mol for Propan-2-ol. The breakdown products by phototransformation are mainly water, hydrogen and carbon monoxide. Thus overall, potential interaction with atmospheric processes is assumed to be not relevant.

There are no indications that the active substances contribute to depletion of the ozone layer as the compounds are not listed as 'controlled substances' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. It is expected that the biocidal product have no global warming potential, stratospheric ozone depletion potential, no potential for tropospheric ozone formation and no acidification potential.
The environmental risk to air is therefore considered acceptable.

Sewage treatment plant (STP)

Conclusion: The estimated PEC/PNEC values for microorganism in sewage treatment plants are below the trigger of 1. Thus, the use of Propan-1-ol and Propan-2-ol as active substances in the biocidal product indicates no unacceptable risk for the sewage treatment plant.

Aquatic compartment

Conclusion: The estimated PEC/PNEC values for surface water and sediment are below the trigger of 1. Thus, the use of Propan-1-ol and Propan-2-ol as active substances in the biocidal product indicates no unacceptable risk for the aquatic compartment.

Terrestrial compartment

Conclusion: During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols, there is no need to conduct a risk assessment for the subsequent environmental compartments (soil and groundwater) following the release path via air (see also TAB ENV-188). Additionally, the fraction released to the environment via application of sewage sludge is considered as not relevant.
Consequently, emissions to soil and groundwater were not assessed for this biocidal product.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

The product is applied as a disinfectant indoors. Considering that non-target organisms do not normally reside in industrial/institutional/public areas, primary poisoning is unlikely. The risks related to primary poisoning are therefore acceptable.

3.8.4.2 Secondary poisoning

As the log K_{ow} for both active substances is <3 and the active substances are not highly adsorptive (K_{oc} <20000 L/kg in sediment and/or 50000 L/kg in soils), bioconcentration is not expected according to the trigger values presented in the guidance. Experimentally-derived bioconcentration factors (BCFs) demonstrated that the active substances does not fulfil the criteria for bioaccumulation (BCF<2000). The risk for bioconcentration in the proposed use is therefore considered not relevant. The standards for bioconcentration are met and no further assessment of secondary poisoning is deemed necessary.

3.8.5 Mixture toxicity

Mixture toxicity assessment was conducted according to the Guidance on the BPR: Volume IV Environment (Part B; Part II).

3.8.5.1 Screening step

Screening Step 1: Identification of the concerned environmental compartments

Significant release to the aquatic environment will occur during the application of product. For further information on the release pathway and the relevant compartments for the assessment of the product, see the respective chapters.

Screening Step 2: Identification of relevant substances

Besides the two active substances no substance of concern (SoC) for the environment is contained in the b.p.

Screening Step 3: Screen on synergistic interactions

There is no indication of synergistic interactions for the product or its constituents.

Table 3.46 Screening step

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

Mixture toxicity assessment is required, as two ecotoxicologically relevant components/ active substances were identified. The assessment will be provided for both substances in the subsequent section.

3.8.5.2 Tiered approach

In Tier 1 summation of PEC/PNEC quotients were conducted and results are shown in the following table.

Tier 1: PEC/PNEC summation

Summary table PEC:PNEC summation			
	Propan-1-ol	**Propan-2-ol**	**Σ**
SCENARIO 1.2 – Professional use: release of disinfectants used for skin and hand application in hospitals based on an average consumption			
PEC/PNEC values			
PEC/PNECstp	9.58E-04	1.40E-03	2.36E-03
PEC/PNECwater	4.17E-04	5.09E-04	9.26E-04
PEC/PNECsed	4.16E-04	5.10E-04	9.27E-04

Table 3.47 Tier 1

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Y	-

Conclusion: No unacceptable risk for the environment was identified by conducting Tier1-mixture toxicity assessment.

3.8.6 Aggregated exposure (combined for relevant emission sources)

As there is currently no Guidance available, no aggregated exposure assessment was conducted for the b.p. "Calgonit-DES-H".

3.8.7 Overall conclusion on the risk assessment for the environment

Table 3.48 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
[1]	Hygienic hand disinfection via pump dispenser	acceptable	Not relevant
[2]	Hygienic hand disinfection via electronic dispenser	acceptable	Not relevant

Conclusion: No unacceptable risk for the environment was identified for the b.p. "Calgonit-DES-H". Therefore no risk mitigation measures concerning the environment are necessary.

3.9 Assessment of a combination of biocidal products

Not relevant (a use with other biocidal products is not intended).

3.10 Comparative assessment

Not relevant (no candidate for substitution was identified).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Please refer to document "Calgonit Des-H-Output_ProfessionalUser_Slaugtherhouse_original.xlsx" for the original assessments of the Scenario 2-1: Hygienic hand disinfection via electronic dispenser in slaugther houses and to document "Calgonit Des-H-Output_ProfessionalUser_revised_afterCommenting.xlsx" for the assessment refined after commenting by concerned member states (including refined assessment of scenario 2-1).


231130_Calgonit Des-H - Output_Prof


231130_Calgonit Des-H - Output_Prof

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Not relevant.

4.2 New information on the active substances and substance(s) of concern

Not relevant (no new information on the active substances is available).

Not relevant (no substance(s) of concern identified).

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Anony-mous	2021	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	III_3.1_Appearance (at 20°C and 101.3 kPa)_calgonit Des-H.key.001	Determination of physic-chemical Properties and Storage Stability Tests for calgonit Des-H Report No.: Mo6415	Study report	BioGenius GmbH TechnologiePark Building 56 Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany Calvatis GmbH, Am Hafen 16 , 68526 Ladenburg, Germany	yes (incl. QA statement)	yes
		3.2 Acidity, alkalinity (pH)	III_3.2_pH_calgonit Des-H.key.001				yes (incl. QA statement)	yes
		3.3 Relative density (liquids) and bulk, tap density (solids) (relative density)	III_3.3_Relative density_calgonit Des-H.key.001				yes (incl. QA statement)	yes
		3.4.1 Storage stability tests (storage stability and reactivity towards container material)	III_3.4.1.2_Long term storage test at ambient temperature_calgonit Des-H.key.001				yes (incl. QA statement)	yes
		3.8 Surface tension (surface tension)	III_3.8_Surface tension_calgonit Des-H.key.001				yes (incl. QA statement)	yes
		3.9 Viscosity (viscosity)	III_3.9_Viscosity_calgonit Des-H.key.001				yes (incl. QA statement)	yes

Anony-mous	2022	4.6 Flammable liquids (flash point of flammable liquids)	III_4.6_Flammable liquids_calgonit Des-H.key.001	calgonit Des-H Determination of physico-chemical properties Flash Point (EC A.9.) Study No.: CSL-22-1361.01	Study report	consilab Gesellschaft für Anlagensicherheit mbH Industriepark Höchst, G830/G840 65926 Frankfurt am Main Germany Calvatis GmbH Am Hafen 16, 68526 Ladenburg, Germany	yes (incl. QA statement)	yes
Anony-mous	2016	5 Methods of detection and identification (analytical methods)	III_5.1._Analytical method_Propan-1-ol.key.001	Validation of Method: MV134 - BG: GC-Determination of Ethanol, 1-Propanol and 2-Propanol in Formulations Report No.: Mo5421	Study report	BioGenius GmbH - Analytics, Bergisch Gladbach; Germany	GLP information not provided	yes
			III_5.1._Analytical method_Propan-2-ol.key.001				GLP information not provided	yes
Anony-mous	2017	6.7 Efficacy data to support these claims (efficacy data)	III_6.7_calgonit Des-H_PT1_Bactericidal_EN13727+A2_D53/2017.key	Determination of Bactericidal (EN 13727+A2) and Fungicidal (EN 13624) activity of the product calgonit Des-H; Determination of virucidal activity (EN 14476+A1) of the product calgonit Des-H; Hygienic Handrub (EN 1500)	Study report	unpublished test report of Calvatis GmbH, Germany ; Chemila, spol. s r.o Za Drahou 4386/3, Hodonin 69501, Czech Republic Calvatis GmbH, Am Hafen 16, 68526	not specified	yes
			III_6.7_calgonit Des-H_PT1_Yeasticidal_Fungicidal_EN 13624_D53/2017.key				not specified	yes
			III_6.7_calgonit Des-H_PT1_Limited virucidal activity_Adenovirus_EN 14476+A1_D53/2017.key				not specified	yes

			III_6.7_calgonit Des-H_PT1_Bactericidal_EN 1500_D53/2017.key	of the product calgonit Des-H Report No.: D53/2017		Ladenburg, Germany	not specified	yes
			III_6.7_calgonit Des-H_PT1_Limited virucidal activity_MNV_EN 14476+A1_D53/2017.key				not specified	Yes
Anony-mous	2020	6.7 Efficacy data to support these claims (efficacy data)	III_6.7_calgonit Des-H_PT1_Virucidal activity against enveloped viruses_Vaccinia_EN 14476_712.20-3/2020.key	Test report: 712.20-3_EN14476_PB_V 02 Report No.: 712.20-3_EN14476_PB_V 02	Study report	BIOTECON Diagnostics GmbH, Hermannswerder 15, 14473 Potsdam, Germany Calvatis GmbH, Am Hafen 16, 68526 Ladenburg, Germany	not specified	yes

4.4 References

4.4.1 Guidance documents

Packaging
- Guidance on the BPR Volume I Part A,B,C Version 2.1, 2022
- Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008
- International Transportation of Dangerous Goods by Road (ADR), Volume 1,2 / 2021

Physical, chemical, and technical properties
- Guidance on the BPR: Volume I Parts A+B+C – v.2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Physical hazards and respective characteristics
- Guidance on the BPR: Volume I Parts A+B+C – v.2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Methods for detection and identification
- Guidance on the BPR: Volume I Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.1, March 2022
- Guidance on the BPR: Volume I Parts A+B+C – v.2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Efficacy
- Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), Version 1.0, 02/2017

Human health
- Regulation (EU) 528/2012
- Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C), Version 4.0, 2017, https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094
- Directive 1999/45/EC
- Regulation (EC) No 1272/2008 (CLP)
- EFSA guidance on dermal absorption, 2017
- Biocides Human Health Exposure Methodology, Version 1, BHHEM, Version 1, 2015, https://echa.europa.eu/de/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure
- CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants_final.pdf
- Recommendation no. 6 of the BPC Ad Hoc Working Group on Human Exposure, methods and models to assess exposure to biocidal products in different product types, HEAdhoc 6, Version 4, https://echa.europa.eu/documents/10162/1154636/recom6_methods_models_en.pdf/3399feed-8731-4a5b-b37f-0be2853b2f4c?t=1591272532625
- Recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure, Hand disinfection in hospitals, Version 1, 19.01.2017, https://echa.europa.eu/documents/10162/1154636/rec_9_disinfection_in_hospitals_en.pdf/81f9a6d6-f9b5-42e9-97c1-62a5eb897c11?t=1485174674139

Animal health
No guidance agreed yet.
- CG-30-2018-09 AP 7.3 Risk assessment for animal health _final

Environment
- Guidance on the BPR: Volume I Parts A+B+C – v.2.0, 2017, 2022
- Technical Agreements for Biocides (TAB) – ENV v.2.0, 2020

4.4.2 Legal texts

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.