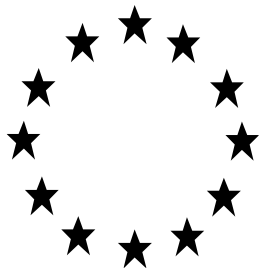
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Liv DES+45

Product type 2

Propan-2-ol

Case Number in R4BP: BC-EA025731-68

Evaluating Competent Authority: Sweden

Date: 24/April/2019

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1 CONCLUSION

1.1 Summary of decision

It is concluded after evaluation that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions.

1.1.1 Usage area and user

Product type 2 (Disinfectants and algaecides not intended for direct application to humans or animals. Indoors – Used for the disinfection of small surfaces, which are not used for direct contact with food or feeding stuffs.

Professional: For disinfection of small non-porous surfaces in medical practices and laboratories.

Non-professional: For disinfection of small surfaces (<1m^2) in bathrooms of private households.

1.1.2 Application method

Pouring and wiping.

The product should be applied undiluted either by pouring directly onto the surface and then wiped over the surface with a cloth/paper tissue or by pouring the product on a cloth/paper tissue and then wiped over the surface.

1.1.3 Pests and application rate

Target organisms are:

- Bacteria
- Fungi
- Viruses (murine norovirus and human rotavirus)

Application rate: 50 mL/m^2

Contact time:
1 minute for bactericidal and yeasticidal efficacy.
5 minutes for virucidal (murine norovirus and human rotavirus) efficacy.

1.2 Requirement for further information

None.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Liv DES+45	Sweden

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Clemondo AB
	Address	Makadamgatan 16 Box 13073 SE-250 13 Helsingborg Sweden
Authorisation number	5542	
Date of the authorisation	24-04-2019	
Expiry date of the authorisation	23-04-2029	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Clemondo AB
Address of manufacturer	Makadamgatan 16 Box 13073 SE-250 13 Helsingborg Sweden
Location of manufacturing sites	Clemondo AB Makadamgatan 16 Box 13073 SE-250 13 Helsingborg Sweden

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

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	Ineos Solvents Germany GmbH Shamrockstrasse 88 44623 Herne Germany and

	Ineos Solvents Germany GmbH Römerstrasse 733 47443 Moers Germany
Name of manufacturer	Aug. Hedinger GmbH & Co. KG
Address of manufacturer	Heiligenwiesen 26 70327 Stuttgart Germany
Location of manufacturing sites	Shell Nederland Raffinaderij B.V. Vondelingenweg 601, 3196 KK, Rotterdam The Netherlands
Name of manufacturer	Brenntag GmbH
Adress of manufacturer	Stinnes Platz 1 45472 Mülhelm an der Ruhr Germany
Location of manufacturing sites	Shell Nederland Raffinaderij B.V. Vondelingenweg 601, 3196KK, Rotterdam The Netherlands Exxon Mobil Chemical Plant 4999 Scenic Highway 70897 Baton Rouge, Louisiana United States

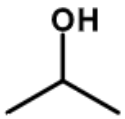
2.1.2 Product composition and formulation

The full composition of the product Liv DES+45 is provided in the Confidential Annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

The active substance propan-2-ol in the biocidal product is not a candidate for substitution since it does not meet the exclusion criteria laid down in Article 5 or the conditions in Article 10 of Regulation (EU) No 528/2012.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	37.6%
		Non-active substances			62.4%

2.1.2.4 Information on technical equivalence

The biocidal product contains the active substance propan-2-ol. The five sources of propan-2-ol were considered technical equivalent to the reference source in the assessments carried out by ECHA:

Decision number	**Asset number**
TAP-D-1271075-27-00/F	EU-0017008-0000
TAP-D-1271080-30-00/F	EU-0017009-0000
TAP-D-1208202-35-00/F	EU-0014021-0000
TAP-D-1236892-12-00/F	EU-0014506-0000
TAP-D-1236889-07-00/F	EU-0014505-0000

2.1.2.5 Information on the substance(s) of concern

No substance of concern was identified.

2.1.2.6 Type of formulation

Any other liquid (AL)

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	H225 Flam. Liq. 2 Eye Irrit. 2 STOT SE 3
Hazard statement	Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness
Labelling	
Signal words	Danger
Hazard statements	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness
Supplemental hazard information	EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. (P102 Keep out of reach of children.) P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapours. P264 Wash hands thoroughly after handling. P271 Use only in a well-ventilated area. (P280 Wear eye protection.) P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTRE if you feel unwell. P337 + P313 If eye irritation persists: Get medical advice. P405 Store locked up. P501 Dispose contents to an approved waste disposal plant for hazardous waste.
Note	P101 (If medical advice is needed, have product container or label at hand) is required for non-professional use only. H319 triggers P264 and is recommended for the general public and is optional for professional use. H319 also triggers P280 (Wear eye protection). However, based on the qualitative risk assessment for local effects the additional advice “Avoid contact with eyes” should be added on the label. This advice and P305+P351+P338 (IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing) and P337 + P313 (If eye irritation persists: Get medical advice) are considered sufficient to protect non-professional and professional users from the corresponding risk. P102 (Keep out of reach of children) is required for non-professional use. However, P405 (Store locked up) will take precedence over P102.

2.1.4 Authorised use(s)

2.1.4.1 Use #1 – Disinfection of small surfaces by wiping – professional use

Product Type	02 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	For disinfection of small non-porous surfaces in medical practices and laboratories.
Target organism (including development stage)	Bacteria Yeast Virus (murine norovirus and human rotavirus)
Field of use	Indoor
Application method(s)	Pouring and wiping
Application rate(s) and frequency	Ready to use 50 mL/m^2 Contact time: 1 minute for bacteria and yeast 5 minutes for viruses (murine norovirus and human rotavirus)
Category(ies) of users	Professionals
Pack sizes and packaging material	300 mL, 1 L and 5 L HDPE bottles

2.1.4.1.1 Use-specific instructions for use

See 2.1.5.1

2.1.4.1.2 Use-specific risk mitigation measures

- The product must only be applied for disinfection on small surfaces.

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

See 2.1.5.3

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

See 2.1.5.4

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

See 2.1.5.5

2.1.4.2 Use #2 – Disinfection of small surfaces (<1 m^2) by wiping – non-professional use

Product Type	02 – Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	For disinfection of small surfaces (<1m^2) in bathrooms of private households.
Target organism (including development stage)	Bacteria Yeast Virus (murine norovirus and human rotavirus)
Field of use	Indoor
Application method(s)	Pouring and wiping
Application rate(s) and frequency	Ready to use 50 mL/m^2 Contact time: 1 minute for bacteria and yeast 5 minutes for viruses (murine norovirus and human rotavirus)
Category(ies) of users	Non-professionals
Pack sizes and packaging material	300 mL and 1 L HDPE bottles

2.1.4.2.1 Use-specific instructions for use

See 2.1.5.1

2.1.4.2.2 Use-specific risk mitigation measures

• In order to avoid adverse health effect, the product must only be applied for disinfection of small surfaces (<1 m^2) and should maximum be applied twice daily.

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

See 2.1.5.3

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

See 2.1.5.4

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

See 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

- Clean obvious dirt from surface and allow time to dry before applying the product.
- Apply the product undiluted by pouring directly onto the surface and wipe over the surface with a cloth/paper tissue or pour the product on the cloth/paper tissue and then wipe over the surface.
- Make sure to wet the surface completely.
- Allow to take effect for at least 1 minute for bactericidal and yeasticidal efficacy and 5 minutes for virucidal (murine norovirus and human rotavirus) efficacy.
- Do not apply more than 50 mL/m^2.

2.1.5.2 Risk mitigation measures

- Avoid contact with eyes.
- Do not discharge the biocidal product into the sewage system or the environment.

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

Likely direct/indirect effects:

- Serious eye irritation.
- Drowsiness and dizziness.

First aid:

- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
- Call a POISON CENTER (Giftinformationscenralen) if you have been exposed to the product and feel unwell.
- If eye irritation persists, get medical advice.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Dispose of the product or container with product as a hazardous waste to an approved waste disposal plant.
- Only empty container can be disposed as plastic packaging.

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

- Shelf-life: 3 years.
- Store below 30 °C.
- Keep away from heat and sources of ignition.
- Keep container tightly closed.
- Keep locked up.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	300 mL	HDPE	Flip-top cap (PP)	Professional and non-professional	Yes
Bottle	1 L	HDPE	Flip-top cap (PP)	Professional and non-professional	Yes
Bottle	5 L	HDPE	Screw cap (PP)	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The applicant has submitted product specific studies to support the efficacy of the product. In addition, physico-chemical properties data and an analytical method for Liv DES+45 has been provided. The studies are included in the reference list.

2.1.8.2 Access to documentation

Clemendo AB has access to the data on the active substance propan-2-ol with a Letter of Access from Fieldfisher Waterhouse LLP representing the Alcohol Task Force ("the ATF").

The data on the active substance was evaluated by CA DE in the Competent Authority Report (CAR) on propan-2-ol (July 2014) and summarised in the Assessment Report (January 2015).

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Professional use

Product Type(s)	Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	For small-scale disinfection of surfaces such as lab benches and surfaces in medical- and healthcare for professional operation.
Target organism (including development stage)	Bacteria and yeast after 1 minute virus after 5 minutes (human rotavirus and murint Norovirus).
Field of use	Where the microbiological contamination needs to be prevented including medical- and healthcare, laboratory and other related fields. This ready for use surface disinfectant is intended for surfaces that are contaminated with body fluids and other fluids that might contaminate the surface. The product is mainly intended for professional use.
Application method(s)	The solution is intended to be spurted onto the surface. The solution is thereafter wiped over the surface with a paper tissue. An alternative way is to drown a cloth with the disinfectant which is then used to wipe the surface. The required contact time is 1 minute for bacteria and yeast and 5 minutes if virucidal action is warranted.
Application rate(s) and frequency	50 mL product/m^2 Application will occur between each patient in medical care. The treated surface should be allowed to dry for at least 5 minutes after application of the product.
Category(ies) of user(s)	Professionals.
Pack sizes and packaging material	300 mL, 1 L and 5 L HDPE bottles.

Table 2. Intended use # 2 – Non-professional use

Product Type(s)	Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	For small-scale surface disinfection in bathrooms of private households.
Target organism (including development stage)	Bacteria and yeast after 1 minute and virus after 5 minutes (human rotavirus and murint norovirus).

Field of use	This ready for use surface disinfectant is intended for disinfection of surfaces that are contaminated with body fluids and other fluids. Non-professionals could use the biocidal product for disinfection of bathroom/toilet in a household.
Application method(s)	The solution is intended to be spurted onto the surface. The solution is thereafter wiped over the surface with a paper tissue. An alternative way is to drown a cloth with the disinfectant which is then used to wipe the surface. The duration of action is 1 minute for bacteria and yeast and 5 minutes if virucidal action is warranted.
Application rate(s) and frequency	50 mL of product/m^2. Application is assumed to occur once per week. More frequent application can occur temporarily due to infection diseases.
Category(ies) of user(s)	Non-professionals.
Pack sizes and packaging material	300 mL and 1 L HDPE bottles.

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2.2.2 Physical, chemical and technical properties

The product Liv DES+45 is a ready-to-use aqueous solution for use as a disinfectant. The physical and chemical and storage stability data submitted to support the formulation are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA comments
Physical state	Visual assessment	Liv DES+45	Homogeneous liquid	1	Acceptable
Colour	Visual assessment	Liv DES+45	Colourless	1	Acceptable
Odour	Olefactory assessment	Liv DES+45	Strong alcoholic odour	1	Acceptable
pH / acidity / alkalinity		Liv DES+45	pH = 7.9 (neat) at 20 °C	1	Acceptable
Relative density / bulk density	Hydrometer AE01-LAB	Liv DES+45	0.93 at 20 °C	IUCLID 3.3	Acceptable
Storage stability test – **accelerated storage**			"Store below 30 °C" is stated on the label.		Acceptable No accelerated storage stability test performed. However, "Store below 30 °C" is stated on the label.
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No.17, 2nd edition, CropLife International	Liv DES+45	25 ºC for 3 years, 1 L HDPE bottle Packaging: no change in appearance of packaging after storage Appearance of product 3 years at 25 ºC: clear colourless liquid	1	Acceptable Ambient storage stability study was conducted for 3 years in 1 L commercial packaging. There is no significant change to the appearance,

			Active content Initial: 36% 3 years at 25 ºC: 38% pH Initial: 7.9 3 years at 25 ºC: 7.9		packaging, active substance content or pH after storage.
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Liv DES+45	4 ºC for 7 days, 1 L HDPE bottle Packaging: no change in appearance of packaging after storage Appearance of product 4 ºC for 7 days: clear colourless liquid pH Initial: 7.9 4 ºC for 7 days: 7.9	1	Acceptable There is no significant change to the appearance, packaging or pH after storage. The low temperature stability test should have been performed at 0 °C. But since propan-2-ol is fully miscible in water (1000 g/L at 25°C) and the freezing point for a 30% v/v of aqueous isopropanol solution is -15 °C, no phase separation issue is expected.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Case		For propan-2-ol a cut-off point of 210 nm is given in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption	IUCLID 3.4.2.1	Acceptable

			maximum of < 290 cannot undergo direct photolysis in sunlight. Therefore, the substance is unaccessible for direct photodegradation in sunlight.		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			-		Not tested since Liv DES+45 is an aqueous solution and “Store below 30 °C” is stated on the label. Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See “Storage stability test – long term storage at ambient temperature” above.		Acceptable
Wettability			-		Not relevant for aqueous ready-to-use formulations.
Suspensibility, spontaneity and dispersion stability			-		Not relevant for aqueous ready-to-use formulations.
Wet sieve analysis and dry sieve test			-		Not relevant for aqueous ready-to-use formulations.
Emulsifiability, re-emulsifiability and emulsion stability			-		Not relevant for aqueous ready-to-use formulations.
Disintegration time			-		Not relevant for aqueous ready-to-use formulations.

Particle size distribution, content of dust/fines, attrition, friability			-		Not relevant for aqueous ready-to-use formulations.
Persistent foaming			-		Not relevant for aqueous ready-to-use formulations.
Flowability/Pourability/Dustability			-		Not relevant for aqueous ready-to-use formulations.
Burning rate — smoke generators			-		Not relevant for Liv DES+45.
Burning completeness — smoke generators			-		Not relevant for Liv DES+45.
Composition of smoke — smoke generators			-		Not relevant for Liv DES+45.
Spraying pattern — aerosols			-		Not relevant for Liv DES+45.
Physical compatibility	Case		Des+45 is not recommended to be used in combination with other products.	IUCLID 3.6.1	Acceptable
Chemical compatibility	Case		Des+45 is not recommended to be used in combination with other products.	IUCLID 3.6.2	Acceptable
Degree of dissolution and dilution stability			-		Not relevant for aqueous ready-to-use formulations.
Surface tension	Case		The ECHA Guidance on Information requirements and chemical safety assessment, Chapter R.7.1.6	IUCLID 3.8	Acceptable

			(Endpoint specific guidance, surface tension), declare the following: Surface tension test is only required if surface activity is expected or is a desirable feature of the product. That is not the case for the product.		
Viscosity	Viscosity meter Brookfield DV AC 230	Liv DES+45	Dynamic viscosity: 1 mPas at 20 °C	1	Acceptable

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties of Liv DES+45 are acceptable for an aqueous ready-to-use solution. Acceptable ambient temperature data have been provided for Liv DES+45 and a shelf life of 3 years is supported.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA comments
Explosives	Case		The product does not fulfill the criteria in the CLP Regulation 1272/2008 to be classified as explosive.	IUCLID 4.1	Acceptable There are no substances in the product that are classified as explosive.
Flammable gases			-		Not relevant for Liv DES+45.
Flammable aerosols			-		Not relevant for Liv DES+45.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA comments
Oxidising gases			-		Not relevant for Liv DES+45.
Gases under pressure			-		Not relevant for Liv DES+45.
Flammable liquids	ISO 3679:2015 Rapid equilibrium closed cup method	Liv DES+45	Flash point 19.5°C	2	Acceptable Liv DES+45 is classified as a highly flammable liquid and vapour: H225 Flam. Liq. 2
Flammable solids			-		Not relevant for Liv DES+45.
Self-reactive substances and mixtures			-		Not relevant for Liv DES+45.
Pyrophoric liquids			-		Not relevant for Liv DES+45.
Pyrophoric solids			-		Not relevant for Liv DES+45.
Self-heating substances and mixtures			-		Not relevant for Liv DES+45.
Substances and mixtures which in contact with water emit flammable gases			-		Not relevant for Liv DES+45.
Oxidising liquids			The product does not fulfill the criteria to be classified as oxidising according to the CLP regulation 1272/2008.	IUCLID 4.4	Acceptable
Oxidising solids			-		Not relevant for Liv DES+45.
Organic peroxides			-		Not relevant for Liv DES+45.
Corrosive to metals			-		Not relevant for Liv DES+45.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA comments
Auto-ignition temperatures of products (liquids and gases)			The auto-ignition temperature for the product is >150 °C.	IUCLID 4.17.1	Acceptable
Relative self-ignition temperature for solids			-		Not relevant for Liv DES+45.
Dust explosion hazard			-		Not relevant for Liv DES+45.

Conclusion on the physical hazards and respective characteristics of the product
Liv DES+45 has a flash point of 19.5°C and is classified as flam. liq. 2 H225. Liv DES+45 does not have explosive or oxidising properties.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

Methods of analysis for the active substance and impurities have already been considered during the EU evaluation of propan-2-ol and are reported in the CAR. No further consideration is required from a chemistry perspective.

Analytical methods for the active substance in the biocidal product

An analytical method for the determination of the active substance in the product was submitted by the applicant. (Ref. no. 3)

The samples were analysed using Gas Chromatography, GC, Agilent 7890A with Flame Ionization Detection, FID, column used HP-1, 30 m * 0,53 mm * 0,88 µm, 19095Z-023 Agilent. 1,2-propanediol was used as internal standard, ISTD.

A calibration curve was prepared from six calibration standards. Stock solutions were prepared in six concentrations ranging from 25% to 50% (w/w) of isopropanol in deionized water. Internal standard (ISTD) stock solution was prepared to a concentration of 33% (w/w) 1,2-propandediol in de-ionized water. 1 g of the ISTD stock solution and 1 g of each calibration standard stock solutions were mixed together with de-ionized water to a final weight of 10 g. Six individual samples from Bottle 1 and from Bottle 2 were prepared by mixing 1 g of sample, 1 g of ISTD and add de-ionized water to a final weight of 10 g. The exact weight, using a 4-digit balance, was noted for all solutions prepared.

Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Precision (%)** RSD	**Reference**
					Range	Mean	RSD		
Propan-2-ol	GC-FID	2.5% - 5.0% 6 conc. in duplicate n = 2 x 6	r=0.9998	No interference	98.4 – 99.9	99.2	0.56	0.27 (Bottle 1) 0.35 (Bottle 2)	Arnsten S. 2018, Determination of IPA content in disinfectant samples LIV DES+45

Recovery (accuracy) – Solutions at six different concentrations were prepared containing known amounts of analyte and the recovery measured in duplicate. The recoveries ranged from 98.4 – 99.9 %. The associated %RSD value is 0.56%.
Precision (repeatability) – An assessment of the precision of the analytical method was made by determining the active substance content in individual samples (n = 6) from 2 different bottles of Liv DES+45. The associated %RSD value are 0.27% (Bottle 1) and 0.35% (Bottle 2).
Linearity – Determinations at six concentrations ranging from 2.5-5.0% of active substance content were made to determine the linearity of the detector response. The correlation coefficient (r) is 0.9998.
Specificity – No interferences from the matrix were detected.

Limit of quantification (LOQ) - The limit of quantification was not determined but was shown to be significantly lower than the concentration of the samples analyzed. A sample of the calibration stock solution ~25% that was diluted ten times, and then prepared the same way as the calibration standards, showed a signal to noise factor $>10^3$.

There are no relevant impurities in the technical grade active substance therefore no further methods for the formulated product are required.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of propan-2-ol residues in air, soil and water have previously been evaluated at active substance approval. It is stated in the CAR that analytical methods of residues in soil and water are not required since no residues are expected. It is also stated in the CAR that an acceptable method using GC-FID for the determination of residues in air is available. For confirmation, a GC-MS method is available which however has not been fully validated. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure via the intended uses.

Conclusion on the methods for detection and identification of the product
A validated GC-FID method has been provided to determine propan-2-ol in Liv DES+45. The monitoring methods for soil, air and water have previously been evaluated at active substance approval. The monitoring methods for body fluids, food/feed of plant and animal origin are not relevant for Liv DES+45.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Des+45 is intended to be used (1) by professionals for disinfection in medical practices and laboratories, and (2) by non-professionals for disinfection in bathrooms of private households (see 2.1.4).
The ready for use solution is used by either spurting it onto the surface and then wiping with paper tissues, or by wetting a cloth and then wiping the surface.

2.2.5.2 Organisms to be controlled

Efficacy data (see 1.1.1.1) support claims that Liv DES+45 is an effective disinfectant against:

- Bacteria (Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538 and Enterococcus hirae ATCC 10541)
- Yeast (Candida albicans ATCC 10231)
- Murine norovirus S99 Berlin
- Human rotavirus Wa VR-2104

2.2.5.3 Effects on target organisms

See 2.2.5.4 Mode of action.

2.2.5.4 Mode of action

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

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Quantitative suspension test, evaluation of bactericidal activity	*Disinfection of instruments used in the medical area*	Dirty conditions (3.0 g/l bovine serum albumin + 3.0 ml/l sheep erythrocytes)	Pseudomonas aeruginosa NCTC 15442, Staphylococcus aureus NCTC 6538 and Enterococcus hirae NCTC 10541	EN 13727	100% of working solution, 1 minute, 20°C	>5 log10 reduction	4
Quantitative test, evaluation of bactericidal activity	*Disinfection of non-porous surfaces*	Dirty conditions (3.0 g/l bovine albumin)	Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538 and Enterococcus hirae ATCC 10541	EN 13697	100% of working solution, 1 minute, 20°C	>6 log10 reduction	5
Quantitative suspension test, evaluation of yeasticidal activity	*Disinfection of instruments used in the medical area*	Dirty conditions (3.0 g/l bovine albumin)	Candida albicans ATCC 10231	EN 13624	100% of working solution, 1 minute, 20°C	yeasticidal activity	6
Quantitative suspension test, evaluation of virucidal activity	*Disinfection in the medical area*	Dirty conditions (3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes)	Murine norovirus S99 Berlin/Raw cells	EN 14476 2013 + A1 2015	100% of working solution, 5 minutes, 20°C	virucidal activity	7
Quantitative suspension test, evaluation of virucidal activity	*Disinfection in the medical area*	Dirty conditions (3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes)	Human Rotavirus Wa VR-2104 / CV-1 cells	EN 14476 2013 + A1 2015	100% of working solution, 5 minutes, 20°C	virucidal activity	8

2.2.5.5.1 Summary EN 13727

EN 13727 2012 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1).
According to EN 13727:2012, Liv DES+45 possesses bactericidal activity at a minimum of > 5 log reduction at a concentration of 100.00% V/V of the working concentration as tested after 1 minute at 20°C under DIRTY conditions (3.0 g/l bovine serum albumin + 3.0 ml/l sheep erythrocytes) against Pseudomonas aeruginosa NCTC 15442, Staphylococcus aureus NCTC 6538 and Enterococcus hirae NCTC 10541.

2.2.5.5.2 Summary EN 13697

EN 13697, Chemical disinfectants and antiseptics — Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2, step 2).
According to EN 13697:2015, Liv DES+45 possesses bactericidal activity at a concentration of 100.0 % V/V of the working concentration as tested after 1 minute at 20°C under DIRTY conditions (3.0 g/l bovine albumin), achieving a >6 log10 reduction against Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538 and Enterococcus hirae ATCC 10541.

2.2.5.5.3 Summary EN 13624

EN 13624, Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1).
According to EN 13624:2013, Liv DES+45 possesses yeasticidal activity at a concentration of 100% V/V of the working concentration as tested after 1 Minute at 20°C under DIRTY conditions (3.0 g/l bovine albumin against Candida albicans ATCC 10231.

2.2.5.5.4 Summary EN 14476 Murint Norovirus

EN 14476 2013 + A1 2015 Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1).
According to EN 14476:2013, Liv DES+45 possesses virucidal activity at a concentration of 100.0% V/V of the working concentration as tested after 5 minutes at 20°C under DIRTY conditions (3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes) against murine norovirus S99 Berlin/Raw cells.

2.2.5.5.5 Summary EN 14476 Human Rotavirus

EN 14476 2013 + A1 2015 Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1).
According to EN 14476:2013, Liv DES+45 possesses virucidal activity at a concentration of 100.0% V/V of the working concentration as tested after 5 minutes at 20°C under DIRTY conditions (3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes) against Human Rotavirus Wa VR-2104 / CV-1 cells.

2.2.5.5.6 Evaporation and contact time

To ascertain that the application rate of the product is sufficient to obtain contact times stipulated in label claims, an evaporation study was performed and experimental data was submitted (9). The equivalent of 50 ml/m^2 product was applied to a surface on a scale with 0.1 mg precision and left to evaporate. The remaining mass of product was recorded every minute during the first five minutes after application. The experiment was repeated three times. After five minutes, there was still product left on the surface, indicating that a contact time of at least 5 minutes will be obtained using an application rate of 50 ml/m^2.

Experimental data on the mass change of the biocidal product after application to a non-porous surface			
Time (min)	**Run 1, mass (g)**	**Run 2, mass (g)**	**Run 3, mass (g)**
0	0.0571	0.0552	0.054
1	0.0529	0.05	0.0508
2	0.0479	0.044	0.0455
3	0.0427	0.0398	0.0399
4	0.0385	0.0359	0.0372
5	0.0354	0.0334	0.034

Conclusion on the efficacy of the product

General bactericidal and yeasticidal claims are supported for Liv DES+45, with a contact time of 1 minute. Bactericidal and yeasticidal efficacy have been demonstrated using relevant representative test organisms listed in *Guidance on the BPR: Volume II Parts B+C, Version 2.0 December 2017, Appendix 3. Table of Reference Test Organisms (PT 1-5)*. An evaporation study using Liv DES+45 have demonstrated that the product will achieve a contact time of 1 minute, using the suggested application rate.

Specific virucidal efficacy of Liv DES+45 have been shown against murine norovirus and human rotavirus, using a contact time of 5 minutes, in two separate EN14476 (phase 2/step 1) quantitative suspension tests. An evaporation study using Liv DES+45 have demonstrated that the product will achieve a contact time of 5 minutes, using the suggested application rate.

No general virucidal claim can be made, as this requires efficacy to also be proven against polio virus type 1 and adenovirus type 5, apart from murine norovirus, according to the *Guidance on the BPR: Volume II Parts B+C, Version 2.0 December 2017, Appendix 3. Table of Reference Test Organisms (PT 1-5)*.

2.2.5.6 Occurrence of resistance and resistance management

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

proteinlayer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.

2.2.5.7 Known limitations

Overt dirt on the surface that is to be treated may decrease the disinfective efficacy of the biocidal product, by physically preventing the active substance from reaching the surface that is to be treated.
Excessive water or other liquid present on the surface that is to be treated may decrease the disinfective efficacy of the biocidal product, by diluting and lowering the concentration of the active substance.
Excessive heat on the surface that is to be treated may decrease the disinfective efficacy of the biocidal product, by accelerating evaporation and thereby causing an insufficient contact time between active substance and target organisms.

2.2.5.8 Evaluation of the label claims

Version 1 of the guidance on evaluating biocidal efficacy (*Guidance on the BPR: Volume II Parts B+C*) entered into force in February 2017, and version 2 in December 2017 (guidance in force). The application for authorisation of Liv DES+45 was submitted to the SE CA on the 1 July 2016. As the guidance in force cannot reasonable be applied retrospectively, expert judgement has been used in indicated areas to evaluate the claimed efficacy of Liv DES+45.

A general bactericidal claim is supported for Liv DES+45, with a contact time of 1 minute, and was demonstrated using relevant representative test organisms listed in *Appendix 3. Table of Reference Test Organisms (PT 1-5)* of the guidance in force. The test methods EN13727 (phase 2 step 1) and EN13697 (phase 2 step 2) were deemed acceptable by expert judgement.

A general yeasticidal claim is supported for Liv DES+45, with a contact time of 1 minute, and was demonstrated using a relevant representative test organism listed in *Appendix 3. Table of Reference Test Organisms (PT 1-5)* of the guidance in force. The phase 2 step 1 test method EN13624 was deemed acceptable by expert judgement. A phase 2 step 2 test is required by the guidance in force (see below).

Specific virucidal efficacy of Liv DES+45 have been shown against murine norovirus and human rotavirus, using a contact time of 5 minutes, in two separate EN14476 (phase 2 step 1) quantitative suspension tests.

The guidance in force states that there is no stipulated phase 2 step 2 test for virucidal claims in the medical area (the professional use of Liv DES+45). The same guidance states that the phase 2 step 2 virus test described in EN14476 should be used for testing products against viruses used in domestic areas (the non-professional use of Liv DES+45).

As the guidance in force cannot be retrospectively applied to this evaluation, and to indicate whether Liv DES+45 would be virucidal and yeasticidal under the use conditions described in this report, the applicant was asked to show that the applied product would indeed remain on a surface for the required contact time of 5 minutes (worst case, for virucidal claims). An evaporation study using Liv DES+45 demonstrated that the product will achieve a contact time of 5 minutes, using the suggested application rate. Lacking applicable guidance, this was found to be acceptable to support the specific virucidal label

claims for professional and non-professional use. However, upon renewal of the product authorisation all claims must be supported by the guidance in force.

In line with the guidance in force, and in the expert judgement of the SE CA, a full spectrum virucidal claim cannot be made, as this requires efficacy to also be proven against polio virus type 1 and adenovirus type 5, apart from murine norovirus (*Appendix 3. Table of Reference Test Organisms (PT 1-5)* of the guidance in force)

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

Not applicable.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on human health

Toxicolocgical data on the biocidal product is not available. Instead, information required for the human health risk assessment is based on the active substance, propan-2-ol, which is available in the CAR.

Classification of the product is based on data on the individual ingredients and their concentration in the product, according to Regulation (EC) No 1272/2008.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified Supplemental hazard statement: EUH066 Repeated exposure may cause skin dryness or cracking.

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of skin irritation. It is concluded in the CAR that the substance does not meet the criteria for classification as irritating to the skin. Hence, it can be assumed that Liv DES+45 is not irritating to the skin. However, according to the CAR, local skin effects and reactions have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. Therefore, the CAR concluded that the EUH066 statement “Repeated exposure may cause skin dryness or cracking” should be a supplemental hazard statement.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye Irritation Category 2 – H319 Causes serious eye irritation
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Eye Irritation Category 2 – H319 Causes serious eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	According to the assessment report on the active substance, propan-2-ol, propan-2-ol is assessed and classified (according to the CLP regulation) as Eye Irrit. 2; H319; Causes serious eye irritation. Based on the concentration of propan-2-ol in Liv DES+45, also the product is assessed to have the eye irritation properties. Hence, Liv DES+45 is regarded as Eye Irrit. 2; H319; Causes serious eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory tract irritation
Justification	None of the ingredients of the product are classified for respiratory irritation. Therefore, the product does not meet the criteria for classification for respiratory irritation according to Regulation (EC) No 1272/2008.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Skin sensitisation
Justification	The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of sensitisation. In a mouse local lymph node assay, concentrations of 10, 25, and 50 % propan-2-ol yielded stimulation indices that were below the classification threshold for skin sensitisation. It is concluded in the CAR that there is no indication that propan-2-ol should be a sensitizer. Hence, Liv DES+45 is not a skin sensitizer.

Respiratory sensitisation (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory system
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitisation
Justification	None of the ingredients of the product are classified for respiratory sensitisation. Therefore, the product does not meet the criteria for classification for respiratory sensitisation according to Regulation (EC) No 1272/2008.

Acute toxicity

The assessment of acute toxicity of Liv DES+45 is based on the active substance propan-2-ol. The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of acute toxicity.

The assessment regarding the acute toxicity is therefore based on the conclusions of the acute toxicity on propan-2-ol presented in the CAR. Propan-2-ol indicated low acute toxicity via the oral, inhalation and dermal route. Therefore, Liv DES+45 is not regarded as acute toxic.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic via the oral route
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity
Justification	The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of acute oral toxicity. It can be assessed from the LD50 values (4400 mg/kg/bw, rats and 7980 mg/kg bw, rabbits) that propan-2-ol show only low acute oral toxicity. Propan-2-ol does not meet the criteria in the CLP regulation to be classified as acute toxic on oral exposure. It is concluded in the CAR that the LD50 values indicate only low acute oral toxicity in rats and rabbits. Hence, Liv DES+45 is not regarded as acute toxic upon oral exposure.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic via the inhalation route
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of acute toxicity by inhalation. Propan-2-ol displayed only low acute toxicity in rats resulting from inhalative exposure. The LC50 values of 56.2 and 47.5 mg/L do not meet the criteria in the CLP regulation (10 mg/L) for classification as acute toxic by inhalation. It is concluded in the CAR that the LC50 values indicate only low acute toxicity on inhalation in rats. Hence, Liv DES+45 is not regarded as acute toxic upon inhalation.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic via the dermal route
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute dermal toxicity
Justification	From dermal exposure of rabbits to propan-2-ol for 24 h, a dermal LD50 was provided, 12900 mg/kg bw. Due to a severe lack in reporting of experimental detail, e.g. regarding the area of dermal exposure, the reliability of the rabbit dermal toxicity study is limited. However, the very high LD50 value gives an indication of the very low acute dermal toxicity from exposure to propan-2-ol. The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider in the case of acute dermal toxicity. Based on the very low acute dermal toxicity from the active substance, it can be concluded that Liv DES+45 also show low acute toxicity upon dermal exposure.

Information on dermal absorption

Value used in the Risk Assessment – Dermal absorption	
Substance	Propan-2-ol
Value	25 %
Justification for the selected value	See waiver justification

Data waiving	
Information requirement	Dermal absorption
Justification	The agreed value for dermal absorption, in the CAR for 2-propan-ol, of 0.85 mg/cm^2/h can not be applied in the risk assessment of the biocidal product Liv DES+45. First of all, Liv DES+45 is much more diluted (37.6 % a.s.) than the representative product (70 % a.s.) and secondly, it contains a small amount of a surfactant. In general, according to EFSA Guidance on Dermal Absorption (2012), surfactants may increase dermal absorption since they optimise the wetting and permeability of the skin. In addition, the dermal absorption is generally higher if a chemical is applied in a low concentration (dilution) compared to a higher concentration. Therefore, additional information on dermal absorption was required for this product. Since no such information was supplied, the default value of 25 % according to the EFSA Guidance on Dermal Absorption (2012) has been used in the risk assessment.

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

The biocidal product Liv DES+45 does not contain any substances of concern. One component of the biocidal product has a proposed classification as Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1, however it does not contribute to the classification of the biocidal product due to the low concentration.

Available toxicological data relating to a mixture

N.A.

Other

N.A.

Endocrine disrupting properties

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance. Additionally, there is no indication that the co-formulants in the biocidal product have endocrine disrupting properties based on available information developed in context of the biocidal products, plant protection products and REACH legislation.

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

2.2.6.2 Exposure assessment

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	Small surface disinfection in medical practice and laboratory (application)	Primary exposure of a professional user resulting from application (pouring from bottle and wiping of the surface) – Dermal and inhalation exposure	Professional
2	Bystander during small surface disinfection in medical practice and laboratory (application)	Secondary exposure of a professional bystander who is present when small surface disinfection is performed – Inhalation exposure	Professional bystander
3	Small surface disinfection in bathrooms (application)	Primary exposure of a non-professional user resulting from application (pouring from bottle and wiping of the surface) – Dermal and inhalation exposure	Non-professional
4	Using bathroom after small surface disinfection	Secondary exposure of a non-professional bystander entering the bathroom/toilet directly after disinfection (adult or children/toddlers) – Inhalation exposure	General public

Industrial exposure

Liv DES+45 is only intended for professional and non-professional use and no industrial exposure is foreseen.

Professional exposure

Scenario 1: Professional primary exposure

Description of Scenario 1

The disinfectant is used to wipe surfaces where hygiene is important (indoor use), for instance in laboratories and medical practice in between patients. Disinfection of a small-scale surface by applying onto working bench and wiping the surface with tissue paper or cloth. During a normal working day of 8 hours, the professional will be exposed to the disinfectant 10 times (wiping every 45 min). The exposure time is estimated to 45 minutes (as a worst case if the professional stays in the room after disinfection). The concentration of the active substance in the air depends on the applied amount, volume of the room, temperature and the ventilation rate. The concentration reaches the maximum level quickly and declines due to the air exchange in the room.

The inhalation exposure assessment was made using default values according HEAdhoc recommendation 15 (scenario A: Laboratories) and calculated by ConsExpo Web (version 1.0.3) "Inhalation – Exposure to vapour – Evaporation".

In accordance with the CAR, the dermal exposure was calculated based on the 75th percentile value of the model from BEAT ("small scale wiping"; Hughson and Aitken, 2004).

The possible dermal exposure during disinfection is the palm of the hand during wiping of the biocidal product. It is recommended that the professional use personal protective equipment (PPE) when handling the biocidal product (however, this is not considered in the calculations of dermal exposure (Tier 1).

	Parameters[1]	Value
Tier 1	Concentration of propan-2-ol	37.6 % w/w
	Density of the solution	0.93 g/mL
	Area disinfected	small surface 0.5 m^2
	Application rate	50 mL/m^2
	Event exposure duration	45 minutes
	Frequency of use	10 times/day
	Application duration	1 min
	Product amount per application	23.25 g
	Temperature	25 °C
	Ventilation rate	8/h
	Room volume	25 m^3
	Mass transfer rate	10 m/h (default ConsExpo)
	Inhalation rate (adult, light exercise)	1.25 m^3/h
	Body weight (adult)	60 kg

[1] Default values taken from HEAdhoc Recommendation 15 "Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile substances by RTU wipes and trigger sprays".

Calculations for Scenario 1

Professional inhalation exposure:
The ConsExpo-report of the calculation of inhalation exposure is included in Annex 3.2. Based on the assumptions made in the scenario an estimated concentration (mean event concentration) of 58 mg 2-propan-ol/m^3 is obtained for professional use during disinfection. If the person does not leave the room during the day, the inhalation exposure will be 9.0 mg/kg bw/day.

Professional dermal exposure:
The potential hand exposure (75th percentile; BEAT (Hughson and Aitken, 2004)) is 214 µl/min. The potential professional dermal exposure during application is calculated as follows:

214 µL/min x 0.93 g/mL x 10 min x 37.6% = 748 mg propan-2-ol/day

As the default value of 25% is used for dermal absorption, the systemic dermal exposure will be:

748 mg 2-propan-ol/day x 25% / 60 kg = 3.1 mg propan-2-ol/kg/day

Scenario 2: Professional secondary exposure

A professional secondary exposure to propan-2-ol using disinfection cannot be excluded. Inhalation exposure may occur to professional bystanders in areas where surface disinfection is performed. The inhalation exposure will be in the same order of magnitude as for the person who disinfects the surfaces. In a worst-case scenario it is assumed that the bystander stays 8 hours in the room where surface disinfection is performed. Therefore, the level of inhalation exposure of a professional bystander is estimated to be equivalent or lower compared to the operator (i.e. ≤ 9 mg/kg bw, see calculation above).

Further, it is assessed that dermal exposure of a bystander is unlikely to occur since it is directly related to the use of biocidal product. If contact with freshly disinfected surfaces occur, very short duration of dermal exposure is assumed since the active substance evaporates quickly. The secondary dermal exposure is therefore considered to be negligible.

Summary of scenario 1 and 2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg / kg / day)**	**Estimated dermal uptake (mg / kg / day)**	**Estimated oral uptake (mg / kg / day)**	**Estimated total uptake (mg / kg / day)**
Scenario 1 – primary (application)	1	9.0	3.1	n.a.	12.1
Scenario 2 – secondary (bystander)	1	≤ 9.0	n.a.	n.a.	≤ 9.0

Further information and considerations on scenario 1 and 2
The classification of the biocidal product (Eye Irrit. 2; H319 and EUH066) requires additional assessment of local risks (see chapter on Risk characterisation).

Non-professional exposure

Scenario 3 – Non-professional primary exposure
Although the biocidal product is mainly meant to be used by professionals, the product can also be used by a non-professional in a household (indoor) for disinfection of small surfaces in bathrooms.

Description of Scenario 3

The biocidal product could be used during disinfection of surfaces in the bathroom in the household. It is estimated that this usually does not occur more than 1 time per week. However, an application of 1 time/day has been assessed (in accordance with the scenario in the CAR). Furthermore, during specific conditions, such as infectious diseases of a household member, the frequency of use might increase during a short period; as worst-case 5 times/day (adapted from the CAR). The applicant suggested a worst-case assumption corresponding to a use of maximum 3 times/day. However, as 5 times/day is used in the scenario in the CAR and also in other ongoing evaluations of similar products with similar use the eCA is of the opinion that the same approach should be used.
Due to the high vapour pressure of the active substance, inhalation exposure will occur when the person stays in the room during and after application. The concentration in air will reach maximum quickly due to the high vapour pressure of the active substance, propan-2-ol. However, the grade of inhalation exposure depends on the applied amount of the biocidal product, the size of the room, temperature and the air exchange rate which affects the rate of declination of the substance in the air. The parameters of the scenario are in line with the CAR, it is assumed that the product is applied to a total surface of 1 m^2 and that the person leaves the bathroom soon after (5 minutes) application. The inhalation exposure assessment was calculated by ConsExpo Web (version 1.0.3) "Inhalation – Exposure to vapour – Evaporation".

For dermal exposure as a worst case scenario it is assumed that the product covers completely the surface of both hands (820 cm^2) with a thin liquid layer of 0.01 cm (Tier 1; according to TGD on Risk Assessment, 2003). This scenario is in accordance with the CAR however, the applicant regarded this scenario as very conservative and added two additional tiers for calculation of dermal exposure during application; 1) exposure of both hands (front and back), 2) exposure of one hand (front and back) and 3) exposure of one side of one hand. The applicant's reasoning for refinement of exposed dermal surface:
"*Simultaneous, complete exposure of both hands was considered highly unlikely. For example, in a realistic, hypothetic example where the user spills the biocidal product substantially on the back of a hand, only one side is exposed. Likewise, if the product diffused through a cleaning cloth during usage (i.e. wiping a surface), the exposure again would only be limited to one side of the hand. If a user would have both hands full exposed to the biocide, the user would have to intentionally immerse both hands into a bath of biocide or would have to immerse one hand and then wipe that hand over the other hand. In the both cases these are implausible to occur by accident; the user would actively have to attempt to achieve either scenario. Therefore, exposure of one side of the hand was anticipated as the worst-case scenario*."
Ref-MS SE agrees that it is highly conservative to assume that the palms and backs of both hands (820 cm^2) will be covered by a liquid layer during wiping of a surface. However, a value of 205 cm^2 (only the palm of one hand) is considered too low. It is likely that the cloth will be wet and contaminate the hands and it must at least be assumed that a non-professional use both hands when disinfecting surfaces, i.e. a value of 410 cm^2 can be accepted for refinement. This seems also to be an acceptable approach in the evaluations of similar products with similar use (according to notes from discussions on evaluations of union authorisations in BPC WG Health).

	Parameters[1]	Value
Tier 1	Concentration of propan-2-ol	37.6 % w/w

	Density of the solution	0.93 g/mL
	Area disinfected	1 m^2
	Application rate	50 mL/m^2
	Event exposure duration	5 minutes
	Frequency of use	1 time/day 5 times/day (worst-case)
	Product amount per application	46.5 g
	Temperature	25 °C
	Ventilation rate	2/h
	Room volume	10 m^3
	Exposed skin area	820 cm^2
	Inhalation rate (adult, light exercise)	1.25 m^3/h
	Body weight (adult)	60 kg
Tier 2	Exposed skin area	410 cm^2

[1] Default values are taken from ConsExpo General Fact Sheet, 2014 and HEAdhoc Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products"

Calculations for Scenario 3

Non-professional inhalation exposure:

The ConsExpo-reports of the calculation of inhalation exposure is included in Annex 3.2. Based on the assumptions made in the above scenario an estimated exposure is calculated to:

Normal use 1 time/day: 1.7 mg/kg bw/day
Worst case 5 times/day: 8.3 mg/kg bw/day

Due to identified risk in the worst-case scenario (see risk characterisation - 2.2.6.3), additional assessments were made for use of the product twice and three times per day.

3 times/day: 5.0 mg/kg bw/day
2 times/day: 3.3 mg/kg bw/day

Non-professional dermal exposure:

As a worst case scenario it is assumed that the product covers completely the surface of both hands (820 cm^2) with a thin liquid layer of 0.01 cm (Tier 1; according to TGD on Risk Assessment, 2003). As Tier 2 the exposure of both palms of the hands was assessed. The potential non-professional dermal exposure during application is calculated as follows:

Tier 1: (820 cm^2 x 0.01 cm) x 0.93 g/mL = 7.63 g product

As the default value of 25% is used for dermal absorption, the dermal exposure will be:

Normal use 1 time/day: 7.63 g x 37.6% x 25% / 60 kg x 1 time/day = 12.0 mg propan-2-ol/kg bw/day

Worst-case 5 times/day: 7.63 g x 37.6% x 25% / 60 kg x 5 times/day = 59.8 mg propan-2-ol/kg bw/day

Tier 2: (410 cm^2 x 0.01 cm) x 0.93 g/mL = 3.81 g product

As the default value of 25% is used for dermal absorption, the dermal exposure will be:

Normal use: 3.81 g x 37.6% x 25% / 60 kg x 1 time/day = 6.0 mg propan-2-ol/kg bw/day

Worst-case 5 times/day: 3.81 g x 37.6% x 25% / 60 kg x 5 times/day = 29.8 mg propan-2-ol/kg bw/day

Due to identified risk in the worst-case scenario (see risk characterisation - 2.2.6.3), additional assessments were made for use of the product twice and three times per day.

3 times/day: 18.0 mg/kg bw/day
2 times/day: 12.0 mg/kg bw/day

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg / kg / day)**	**Estimated dermal uptake (mg / kg / day)**	**Estimated oral uptake (mg / kg / day)**	**Estimated total uptake (mg / kg / day)**
Scenario 3; normal use (1 time/d)	1; 820 cm^2	1.7	12.0	n.a.	13.7
Scenario 3; normal use (1 time/d)	2; 410 cm^2	1.7	6.0	n.a.	7.7
Scenario 3; worst-case (5 times/d)	1; 820 cm^2	8.3	59.8	n.a.	68.1
Scenario 3; worst-case (5 times/d)	2; 410 cm^2	8.3	29.8	n.a.	38.1
Scenario 3; (3 times/d)	*2; 410 cm^2*	*5.0*	*18.0*	*n.a.*	*23.0*
Scenario 3; (2 times/d)	*2; 410 cm^2*	*3.3*	*12.0*	*n.a.*	*15.3*

Further information and considerations on scenario 3
The classification of the biocidal product (Eye Irrit. 2; H319 and EUH066) requires additional assessment of local risks (see chapter on Risk characterisation).

Exposure of the general public

Scenario 4 – Secondary exposure of non-professionals (including children/toddlers)

Description of Scenario 4		
Secondary acute (daily) exposure of the general public can occur when entering the bathroom during and/or just after disinfection (adult or children). It is estimated that this usually occurs 1 time per day. Dermal exposure will not be relevant for secondary exposure since it is only related to the use of the biocidal product. The biocidal product evaporates quickly and the concentration in air reaches the maximum quick but declines after a short time. Other factors such as the air exchange rate affects the concentration. The inhalation exposure is expected to be in the same extent, or lower, as for primary exposure. However, a worst-case scenario, including a child and toddler, needs to be considered since one cannot exclude the risk of a child or toddler standing beside or entering the bathroom during or just after application of the biocidal product. The exposure assessment was calculated by ConsExpo Web (version 1.0.3) "Inhalation – Exposure to vapour – Evaporation". The assessment is made in accordance with the CAR.		
	Parameters[1]	Value
Tier 1	Concentration of propan-2-ol	37.6 % w/w
	Density of the solution	0.93 g/mL
	Area disinfected	1 m^2
	Application rate	50 mL/m^2
	Event exposure duration	5 minutes
	Frequency of use	1 time/day
	Application duration	1 min
	Product amount per application	46.5 g
	Temperature	25 °C
	Ventilation rate	2/h
	Room volume	10 m^3
	Inhalation rate	1.32 m^3/h (child 2-6 y) 1.26 m^3/h (toddler)
	Body weight	23.9 kg (child 2-6 y) 10 kg (toddler)

[1] Default values are taken from ConsExpo General Fact Sheet, 2014 and HEAdhoc Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products"

Calculations for Scenario 4

Exposure of the general public (child and toddler) – Inhalation exposure:
The ConsExpo-reports of the calculation of inhalation exposure are included in Annex 3.2.
Based on the assumptions made in the scenarios the estimated exposure is calculated to:

Children 6-12 y (1 application): 4.4 mg/kg bw/day

Toddler (1 application): 10.0 mg/kg bw/day

Summary table: systemic exposure of the general public (children) resulting from non-professional use					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg / kg / day)**	**Estimated dermal uptake (mg / kg / day)**	**Estimated oral uptake (mg / kg / day)**	**Estimated total uptake (mg / kg / day)**
Scenario 4; Child	1	4.4	n.a.	n.a.	4.4
Scenario 4; Toddler	1	10.0	n.a.	n.a.	10.0

Further information and considerations on scenario 4

-

Dietary exposure

The product should be used by professionals on surfaces in laboratories and medical practices and by non-professionals in private bathrooms. These surfaces are not used for direct contact with food or feeding stuff. Therefore, dietary exposure due to residues in food and feed are not expected.

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

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

Aggregated exposure

N.A.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake**
1.	Professional – application; primary	1	12.1
2.	Professional – bystander; secondary	1	≤ 9.0
3.	Non-professional – application; primary Normal use 1 time/day	1 (both sides of two hands)	13.7
		2 (the palms of two hands)	7.7
	Non-professional – application; primary Worst case use 5 times/day	1 (both sides of two hands)	68.1
		2 (the palms of two hands)	38.1
	Non-professional – application; primary 3 times/day	*2 (the palms of two hands)*	*23.0*
	Non-professional – application; primary 2 times/day	*2 (the palms of two hands)*	*15.3*
4	General public – children; secondary	1	4.4
	General public – toddlers; secondary	1	10.0

2.2.6.3 Risk characterisation for human health

The risk characterisation for professional users of the biocidal product Liv DES+45 takes into account systemic and local effects of the active substance propan-2-ol.

Reference values to be used in Risk Characterisation
Reference values were derived during the assessment of the active substance propan-2-ol and are reported in the CAR. The primary toxic effect of propan-2-ol is acute CNS depression and results in the classification of the product Liv DES+45 as H336 (May cause drowsiness or dizziness).

Reference	Study	NOAEL (mg/kg bw/day)	AF[1]	Correction for oral absorption	Value (mg/kg bw/day)
AEL short, medium and long-term (General population)	Human volunteer study	68.2	6.4	100 %	10.7 (31.25 ppm for 8 h/day)
AEL short, medium and long-term (Professional and non-professional)			3.8		17.9 (52.6 ppm for 8 h/day)

[1] 6.4 for intraspecies variability within the general population (0-75 y) and 3.8 for intraspecies variability within professional workers (5-75 y); see CAR for propan-2-ol for details.

The AEL value of 17.9 mg/kg bw/day is applicable also for non-professional primary exposure during application for household use as for a non-professional user it can generally be assumed that they are adults or at least adolescents. This is in accordance with the CAR for PT2.

Maximum residue limits or equivalent
N.A.

Risk for industrial users
N.A.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1; Professional – application; primary	1	17.9	12.1	68	yes
Scenario 2; Professional – bystander; secondary	1	17.9	≤ 9.0	50	yes

Local effects
The biocidal product is classified as Eye Irrit. 2; H319 and EUH066 (repeated exposure may cause skin dryness or cracking). Therefore, a qualitative risk assessment for local effects regarding skin and eye contact has been made according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015). The hazard category was defined as “low”.

Tasks	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Small surface disinfection - professional	Eye Irrit. 2, H319 EUH066	Low	10 times per day; duration of dermal exposure: 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact with eyes" Good standard of personal hygiene	Yes

The ready to use liquid solution is poured downwards from a short distance on a cloth/paper tissue or directly from the bottle on a surface, therefore direct contact with eyes is not expected during normal use. Considering that the recommendation “Avoid contact with eyes” is followed and good standard of personal hygiene is applied the local risk is considered acceptable.

Conclusion – Professional use
In summary, the risk for professional users resulting from the intended use and from secondary exposure of a professional bystander is considered acceptable provided that the conditions in 2.1.4 and 2.1.5 are followed.

Risk for non-professional users

Systemic effects

Task / Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Scenario 3; Non-professional – application; primary *Normal use 1 time/day*	1	17.9	13.7	77	yes
	2	17.9	7.7	43	yes
Scenario 3; Non-professional – application; primary *Worst case use 5 times/day*	1	17.9	68.1	380	no
	2	17.9	38.1	213	no

No risk is identified under normal use (once/day) of the product. However, the exposure estimate after a worst case 5-fold daily application is above the systemic AEL (213 % in Tier 2; assuming a dermal exposure on both palms of the hands). Therefore, additional exposure assessments were made for inhalation and dermal exposure when using the product at a maximum of twice or three times per day (see *text in italics in the section for Exposure assessment above - 2.2.6.2*).

The results of the additional risk characterisation is shown in the table below:

Task / Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Scenario 3; Non-professional – application; primary *3 times/day*	2	17.9	23.0	128	no
Scenario 3; Non-professional – application; primary *2 times/day*	2	17.9	15.3	85	yes

The additional assessment showed that in order reduce the exposure to an acceptable level for a non-professional a maximum of two applications per day could be performed.

A human health risk was identified for the non-professional user during a reasonable worst case exposure of 5 times per day during a potential infectious disease in the private household. To ensure safe use the following risk mitigation measure must appear on the label:

“In order to avoid adverse health effect, the product must only be applied for disinfection of small surfaces (<1 m^2) and should maximum be applied twice daily”.

Local effects

The biocidal product is classified as Eye Irrit. 2; H319 and EUH066 (repeated exposure may cause skin dryness or cracking). Therefore, a qualitative risk assessment for local effects regarding skin and eye contact has been made according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015). The hazard category is defined as “low”.

Tasks	Local effects in terms of C&L	Hazard category	Frequency and duration of potential	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Small surface disinfection – non-professional	Eye Irrit. 2, H319 EUH066	Low	1 time per day (worst-case 5 times/day); duration of dermal exposure: 1 min per task	eye contact not expected (only by accidental splashes), dermal exposure expected	Labelling: "Avoid contact with eyes"	Yes

The ready to use liquid solution is poured downwards from a short distance on a cloth/paper tissue or directly from the bottle on a surface, therefore direct contact with eyes is not expected during normal use. The normal application frequency is low. Considering that the recommendation “Avoid contact with eyes” is followed the local risk will be minimized. This phrase, in addition to the precautionary statements given from the classification of the product, are considered sufficient to protect the non-professional user and the local risk is considered acceptable.

Conclusion – Non-professional use

In summary, a human health risk was identified for the non-professional user during a reasonable worst case exposure of 5 times per day during a potential infectious disease in the private household. To ensure safe use, the non-professional user must be informed on the daily maximum application frequency and therefore the following risk mitigation measure must appear on the label:

“In order to avoid adverse health effect, the product must only be applied for disinfection of small surfaces (<1 m^2) and should maximum be applied twice daily”.

“Avoid contact with eyes” should also be recommended on the label in order to minimize the local risk due to the eye irritating properties of the product,

To conclude, the risk is considered acceptable for non-professionals disinfecting small surfaces with the biocidal product in bathrooms of private households if the conditions described above and provided in 2.1.4 and 2.1.5 are followed.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4; General public – children; secondary	1	10.7	4.4	41	yes
Scenario 4; General public – toddler; secondary	1	10.7	10.0	93	yes

Local effects

The biocidal product is classified as Eye Irrit. 2 and EUH066 (repeated exposure may cause skin dryness or cracking) and may cause local effects. However, skin and eye contact is not expected for the general public entering the room during/after disinfection.

Conclusion – General public

The risk is considered acceptable for the general public (including children and toddlers) entering the bathroom during/after disinfection of small surfaces with the biocidal product, if the conditions provided in 2.1.4 and 2.1.5 are followed.

Risk for consumers via residues in food

N.A.

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

N.A.

2.2.7 Risk assessment for animal health

It is assumed that secondary exposure and risk assessment for the general public can be adopted. Hence, no risk is identified.

2.2.8 Risk assessment for the environment

The product Liv DES+45 is a ready-to-use (RTU) surface disinfectant containing 37.6% w/w propan-2-ol. The product is used for disinfection of surfaces in the medical and sanitary sector, for private and public use.

Liv DES+45 is mainly intended to be used by professionals in the medical sector for disinfection of surface. The consumer (non-professional user) is only a minimal part of the total use of Liv DES+45. Nevertheless, it is also used for disinfection of surfaces in the domestic environment. The product is covered by the product type 2 (PT2).

Environmental and ecotoxicological data specific to Liv DES+45 biocidal product are not available. Instead, information required for the environmental risk assessment is derived from data provided in the assessment of the active substance, propan-2-ol, PT2 (see CAR). This approach is justified because the type of formulation and inert substances used in the product are not expected to affect the environmental properties or ecotoxicological profile of propan-2-ol. Data generated for unformulated propan-2-ol can be extrapolated to the formulated product and environmental properties of the product do not need to be specifically tested.

2.2.8.1 Effects assessment on the environment

A summary of the available ecotoxicity data on the active substance propan-2-ol and the Predictive No Effect Concentrations (PNECs) for the different compartments are presented in the tables below. All the data are from the CAR of the active substance. Ecotoxicity data are available only for the aquatic compartment.

Available ecotoxicity data on propan-2-ol

Organism / Species	Time scale	Endpoint	Toxicity
Fish *Pimephales promelas*	96h	LC50	8692 mg a.s./L
Invertebrates *Daphnia magna*	48h	EC50	2285 mg a.s./L
Invertebrates *Daphnia magna*	16 d	NOEC (growth)	141 mg a.s./L
Algae *Pseudokirchneriella subspicata*	48h	ErC50	10 500 mg a.s./L
Microorganisms, Activated sludge	3h (static)	EC50 (respiration inhibition)	> 1000 mg a.s./L (nominal)

Summary of PNECs for propan-2-ol

Organisms (Compartment)	PNEC value
Microorganisms (STP)	10 mg/L (Assessment Factor, AF = 100)
Aquatic organism (Water)	2.82 mg/L (AF = 50)
Sediment organisms (Sediment)	2.41 mg/kg$_{wwt}$ (equilibrium partitioning method)
Terestrial organism (Soil)	0.496 mg/kg$_{wwt}$ (equilibrium partitioning method)

Direct exposure of the active substance to the soil compartment relating to the intended use does not occur and adsorption to soil is not expected. Therefore, tests on terrestrial organisms (inclusive inhibition to microbial activity) with propan-2-ol are scientifically not justified. Based on PNECwater and according to TGD on Risk Assessment (EC 2003) a PNECsoil of 0.496 mg/kg ww was derived by using equilibrium partitioning method.

For the air compartment ecotoxicological data on animal species are not available and methods for determination of effects of chemicals on species arising from atmospheric contamination have not been yet fully developed. Therefore, no quantitative estimation of PNECair for the active substance is possible.

PBT Assessment

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

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The active substance propan-2-ol is the only component of Liv DES+45 that is relevant to consider for environmental classification. Several aquatic ecotoxicological data on the active substance are available and are presented in the Table above. Based on these data, the active substance propan-2-ol is not classified for the environment according to Regulation (EC) No.1272/2008 (CLP). Therefore, the product Liv DES+45 is not classified for the environment according to CLP.

Further Ecotoxicological studies

The proposed uses of the product Liv DES+45 is only indoor use for disinfection of rooms, furniture and objects in the medical and sanitary sector including subsequent cleaning of treated areas, for private and public use.

The product is not directly applied near surface water or soil due to its proposed use pattern and usage instructions. Other than the active substance, none of the components of the biocidal product are considered relevant to the aquatic environment, and they are not expected to affect the overall fate (degradation or mobility) or toxicity profile of the active substances in the environment. Therefore, it is not considered scientifically justified to carry out additional ecotoxicity studies using the formulated product. Data on the active substance is relied upon.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data is available.

Supervised trials to assess risks to non-target organisms under field conditions
No data is available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No data is available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
Not relevant.

Foreseeable routes of entry into the environment on the basis of the use envisaged
According the CAR, 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 (log Kow =0.05, Koc=3.3 L/kg) and a very low geoaccumulation potential. Adsorption of relevant amounts of propan-2-ol on soils and sediments is not expected.

In the CAR an assumption has been done for the representative product, that 90% of a.s. is emitted to air and 10% to waste water during use of propan-2-ol in biocidal product is considered as a reasonable worst-case. The distribution of release in the sewage treatment plant using the SimpleTreat 3.0-model (a rate constant of 1 h^{-1} for STP was concluded since propan-2-ol is ready biodegradable) results in: release fractions to air 0.3%, water 12.5%, sludge 0% and degraded fraction 87.1%. For the application of the product Liv DES+45 (life cycle stages “professional or private use”), this distribution is used for environmental exposure estimation.

Further studies on fate and behaviour in the environment (ADS)
Further studies on the fate and behaviour of the biocidal product are not required. Data and information on the fate and behaviour of the active ingredient propan-2-ol are available in the CAR and are sufficient to cover the risk from the biocidal product in the event that emission to the environment was to occur. The biocidal product is used indoors only and hence there are no direct emissions to soil, water or surfaces and there is no direct release to drain. Furthermore, the only other component of the biocidal product is water and hence the product does not contain any substances of concern. There is therefore no justification to perform fate and behaviour studies on the components in the biocidal product.

Leaching behaviour (ADS)
Studies to determine the leaching behaviour of the active substance, propan-2-ol, are not required. Sufficient data are available in the CAR in order to predict the potential leaching behaviour of propan-2-ol and hence additional studies are considered scientifically unjustified.

Testing for distribution and dissipation in soil, water, sediment and air (ADS)
The fate and behaviour of the active substance is not expected to be altered by the co-formulants in the product. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. No further product specific studies are required.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

The Liv DES+45 biocidal product is not intended for spraying on a large scale near surface waters. Consequently, overspray studies are not required.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant.

2.2.8.2 Exposure assessment

The biocidal product Liv DES+45 is used as a PT2. The product Liv DES+45 is a disinfectant containing 37.6% w/w propan-2-ol. The product is a ready-to-use (RTU) solution used for disinfection of rooms, furniture and objects in the medical and sanitary sector including subsequent cleaning of treated areas, for private and public use.

If a disinfectant intended for the medical sector is also used for the disinfection of lavatories and surfaces in accommodations for humans (households, offices, public places etc.), the scenarios of the sanitary sector shall be used according ESD PT2, Chapter 3.3 (RIVM, 2001).

General information

Assessed PT	PT 2
Assessed scenarios	The scenario of the sanitary sector: Disinfection of rooms, furniture and objects.
ESD used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), (RIVM, 2001).
Approach	The biocidal product Liv DES+45 is used for disinfection of rooms, furniture, and objects in the medical sector (professional use/industrial use), in the sanitary sector of public institutions (hotels, offices, public places etc.; professional use), and of private areas (households; private use). If a disinfectant intended for the medical sector is also used for the disinfection of lavatories and surfaces in accommodations for humans (households, offices, public places etc.), the scenarios of the sanitary sector shall be used according ESD PT2, Chapter 3.3 (RIVM, 2001). The emission was calculated based on the specific consumption.
Distribution in the environment	For the applied biocidal product, an assumption that 90% is emitted to air and 10% to waste water is considered as a reasonable worst-case.

Emission estimation

The main emission path will be via air, because the substance evaporates completely within a short time due to the relatively high vapour pressure. Furthermore, the aim to disinfect surfaces is reached by leaving them dry until the product Liv DES+45 has evaporated completely. Therefore, nearly the whole amount of substance applied is released to indoor air and then, this air is emitted to the local outside air However, partial releases to waste water - via leakages or rinse-off - cannot be excluded. The exact distribution between air and waste water is not known. However, as a reasonable worst-case for propan-2-ol with regard to the described use pattern it is assumed that 90% of the a.s. is emitted to air and 10% to waste water.

No emission scenarios for the releases via the emission to wastewater and atmosphere were proposed by the applicant for of Liv DES+45. The applicant refers instead to the representative biocide “dummy product”, which is a ready to use solution containing 70% w/w of propan-2-ol and 30% water included in the CAR of propan-2-ol PT2.

Fate and distribution in exposed environmental compartments

Identification of the relevant receiving compartments based ion the exposure pathway

Scenario	Fresh-water	Freshwater sediment	Sea-water	Sea-water sediment	STP	Air	Soil	Ground-water
Indoor used	Yes	Yes	Not relevant	Not relevant	Yes	Yes (limited to local scale)	Yes	Yes

Available data on the fate and the behaviour of propan-2-ol are summarized in the following table. These data are from the CAR of propan-2-ol, PT2.

Available fate and distribution data for the active substance propan-2-ol

Input	Value	Unit	Remarks
Molecular weight	60.09	g/mol	-
Melting point	- 89.5	°C	-
Boiling point	82.5	°C	at 1013 hPa
Vapour pressure (VP) (at 25 °C)	5780	Pa	at 25°C
Water solubility (at 25°C)	1000	g/L	Propan-2-ol is indefinitely miscible with water.
Log octanol/water partition coefficient (Log Kow)	0.05	Log 10	-
Organic carbon/water partition coefficient (Koc)	3.3 (estimated)	L/kg	Adsorption of relevant amounts of propan-2-ol on soils and sediments is not expected.

Henry's Law Constant (measured at 25°C)	0.80	$Pa.m^3/mol$	Henry's law constant indicates moderate volatility from water.
Biodegradability	Readily		-
Rate constant for STP	1	h^{-1}	Extrapolated from the biodegradation screening test according to the Table 6 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015.
DT50 for biodegradation in surface water (at 12°C)	15	d	Extrapolated from the biodegradation screening test according to the Table 7 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015.
DT50 for hydrolysis in surface water	Experimentally data not available	d	Hydrolysis under Environmental conditions is not expected.
DT50 for photolysis in surface water	Experimentally data not available	d	Photolysis is not expected.
DT50 for degradation in soil (at 12°C)	30	d	Extrapolated from the biodegradation screening test according to the Table 8 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015
DT50 for degradation in air	3.1	d	Value obtained considering a global 24-hours mean and a concentration of $5*10^5$ OH radicals cm^{-3}.
BCF in fish	0.22 (estimated)	L/kg wwt	-
BCF in earthworms	0.85 (estimated)	L/kg wwt	-

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
	Scenario 1
Air	0.3%
Water	12.5%
Sludge	0%
Degraded in STP	87.1%

Aggregated Environmental Exposure Assessment (combined for relevant emission sources)

According to the CAR propan-2-ol is notified for Annex I inclusion in PT 1, 2, and 4. As biocide product containing propan-2-ol are used in a wide dispersive way an aggregated environmental exposure assessment may be reasonable. In summary, it has been concluded that no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced and no specific biocidal emission patterns are identified. On this basis, further consideration of aggregated exposure is not necessary.

Primary and secondary poisoning

Primary poisoning for the intended use-patterns is not expected. Based on the conclusion in the CAR, the low estimated BCF values in aquatic and terrestrial indicator species, propan-2-ol is not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

Mixture toxicity

As the biocidal product contains only one active substance and no substances of concern, an assessment of mixture toxicity is not required.

2.2.8.3 Risk characterisation

No environmental risk assessment have been performed for the product Liv DES+45 containing 37.6% w/w of propan-2-ol. The applicant refers instead to the representative biocide “dummy product” in the CAR of propan-2-ol PT2. The biocide “dummy product” is a ready to use solution containing 70% w/w of propan-2-ol and 30% water.

The “dummy product” is intended for disinfection of room, furniture and objects in the medical and sanitary sectors, for private and public use.
The concentration of the active substance propan-2-ol is almost half in Liv DES+45 compared to the “dummy product”:
37.6% w/w propan-2-ol in Liv DES+45 which has a product density 930 g/L and a volume propan-2-ol density 350 g/L in the product,
70% w/w propan-2-ol in the “dummy product” which has a product density 860 g/L and a volume propan-2-ol density 600 g/L in the product according the CAR of propan-2-ol PT2.

The applicant argues that these two products are similar and that it is reasonable to apply a read-across approach for the result of the environmental risk assessment on the “dummy product” to Liv DES+45. The risk assessment for the “dummy product” was performed at

the active substance authorization stage and is presented in the Assessment Report (AR) of propan-2-ol PT2 (2015, § 2.2.2.5) and DOC II of propan-2-ol the final draft AR (2014).

Ref-MS SE agrees to apply a read-across approach for the environmental risk assessment for all compartments.

Groundwater

For the "dummy product" in DOC II of the final draft CAR for propan-2-ol (2014), the EU trigger value of 0.1 µg/L (Directive 98/83/EC) is exceeded at a first tier level. The assessment was further refined using FOCUS PEARL 4.4.4 and $PEC_{groundwater}$ was estimated between 0.042 and 0.53 µg/L for some scenarios.

However, according to the conclusions of ECHA WG Environment VII meeting 2018, no FOCUS PEARL assessment of exposure of the groundwater compartment is needed based on expert judgement for alcohols used in PT2, with a release path via air. A qualitative assessment using a weight of evidence approach is described below:

• It is assumed that the distribution (90% to air, 10% to wastewater) is not necessarily unrealistic. Propan-2-ol is moderately volatile and, therefore, evaporates to the air. However, in the environmental risk assessment guidance there is no discrepancy between indoor and outdoor air. In most cases, the product containing propan-2-ol will be applied indoors, where deposition may occur as well. It would be an unrealistic worst-case approach to consider that indoor air is equal to outdoor air.

• According to the OPS model, the whole fraction released to outdoor air is emitted within 1000m vicinity of the emission source. The environmental risk assessment according to the guidance BPR IV Part B + C assumes that the active substance is emitted only to agricultural soils (FOCUS-scenarios). However, particularly for biocides/disinfection products most of the emission will take place in urban areas with sealed soil.

• An additional aspect lowering deposition to soil is the reaction of the a.s. with photo-chemically produced OH and NO_3 radicals in the atmosphere, which is currently not considered.

• FOCUS PEARL can take volatilization into account when active substance specific diffusion coefficients to air and water are available. These parameters are not part of the core data set required for active substances evaluated under the BPR.

Moreover, the atmospheric model for propan-2-ol assumes release 365 times per year and calculates deposition per day, while in the groundwater FOCUS PEARL model it is assumed that release from atmosphere accumulates during one month and the release to groundwater is then estimated as one time per month, 12 times per year, which can lead to overestimation of the concentration in groundwater.

Conclusion: Based on expert judgement in the above weight of evidence approach, the risk for the groundwater compartment can be considered as negligible when using the product Liv DES+45 according to the usage instructions.

Atmosphere

The main emission pathway during application step of the product Liv DES+45 will be via air since propan-2-ol evaporates completely within a short time due to the relatively high vapour pressure. Therefore, nearly the whole amount of substance applied is released to indoor air and then, this air is emitted to the local outside air. The exact distribution between

air and waste water is not known, but as a reasonable worst case it is assumed that 90% is emitted to air and 10% to waste water.

The half-life of propan-2-ol in the troposphere was estimated to be 3.1 days. The CAR discusses the potential for propan-2-ol to cause issues due to long-range transport since it has a half-life in air greater than 2 days. However, according to the EU TGD on Risk Assessment (EC 2003), effects on stratospheric ozone and acidification are not expected as propan-2-ol does not contain halogens, nitrogen or sulphur atoms and is not listed as a substance of concern in Regulation 1005/2009 on substances that deplete the ozone layer. The potential for global warming cannot be characterised as there is no information available in the absorption spectrum in the range 800-1200 nm.

As there are no ecotoxicological data on animal species for the air compartment available, no quantitative characterization of risk by comparison of the PECair to PNECair is possible. Only a qualitative assessment for air is feasible.

In conclusion, considering the low potential of exposition and the low toxicity of propan-2-ol, the risk for the atmospheric compartment can be considered as acceptable following the use of the product Liv DES+45 according to the usage instructions.

STP, Surface water and Sediment compartments

During the use of the product Liv DES+45 a partial insignificant release via waste water - due to leakage or rinse-off and via cleaning of treated areas - to STP and subsequent to surface water and sediment could occur. The estimated PEC/PNEC values of the representative biocide “dummy product“ for sewage treatment plant, surface water as well as for sediment are below the trigger of 1. Thus, the use of the “dummy product” indicates no unacceptable risk for the aquatic compartment.

Conclusion: Based on this assessment, the risk for the STP, surface water and sediment can be considered as acceptable when using the propan-2-ol product Liv DES+45 according to the usage instructions.

Terrestrial compartment

According to the intended use of the product Liv DES+45 direct exposure to the soil compartment does not occur. Indirect release into the terrestrial compartment as a result of deposition from the atmosphere is possible. However, the estimated $PEC_{soil}/PNEC_{soil}$ value of the “dummy product“ is below the trigger of 1. Thus, the use of the “dummy product” indicates no unacceptable risk for the soil compartment.

Conclusion: Based on this assessment, the risk for the terrestrial compartment can be considered as acceptable when using the product Liv DES+45 according to the usage instructions.

Aggregated Risk Assessment

It has been concluded in the CAR that no aggregated exposure assessment for propan-2-ol has to be performed. Therefore, no aggregated risk assessment is performed.

Overall conclusion on the risk assessment for the environment of the product
No unacceptable risk to the environmental compartments has been identified when using the product Liv DES+45 according to the usage instructions.

2.2.9 Measures to protect man, animals and the environment

The measures are summarised in section 2.1.4 and 2.1.5. Detailed information can be found in section 2.2.6 and 2.2.8.

2.2.10 Assessment of a combination of biocidal products

The product Liv DES+45 is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

A comparative assessment is not required as the active substance is not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Data protection	Owner company
1	Annex point 3	Stabilitetstest	H. Gustafsson	2018	Yes	Clemondo AB
2	Annex point 4.6	Analysis report Report no. 11601/00039807. 1/L/16	Meles A.	2016	Yes	Clemondo AB
3	Annex point 5.1	Laboratory report: Analysis of IPA in DES+45 2018/SECRC/T/L R/822	Arnsten S.	2018	Yes	Clemondo AB
4		EN 13727: Quantitative suspension test, evaluation of bactericidal activity	Woodall C.	2015	Yes	Clemondo AB
5		EN 13697: Quantitative test, evaluation of bactericidal activity	Woodall C	2015	Yes	Clemondo AB
6		EN 13624: Quantitative suspension test, evaluation of yeasticidal activity	Woodall C	2015	Yes	Clemondo AB
7		EN 14476 2013 + A1 2015: Quantitative suspension test, evaluation of virucidal activity	Woodall C	2016	Yes	Clemondo AB
8		EN 14476 2013 + A1 2015: Quantitative suspension test,	Woodall C	2016	Yes	Clemondo AB

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Data protection	Owner company
		evaluation of virucidal activity				
9		Mass change of the biocidal product after application to a non-porous surface	S. Pendergraph	2018	Yes	Clemondo AB

3.2 Output tables from exposure assessment tools

Reports from ConsExpo-Web (ver. 1.0.5; available at https://www.rivm.nl/en/consexpo).

Professional and non-professional

ConsExpo rep

Child

ConsExpo rep

Toddler

ConsExpo rep

3.3 New information on the active substance

No new information on the active substance was submitted.

3.4 Residue behaviour

N.A.

3.5 Summaries of the efficacy studies

The efficacy studies are summarised in the section on Efficacy.

3.6 Confidential annex

Please see separate document.

3.7 Other

No other information.