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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Product identifier in R4BP:
GhostMedica Hand Sanitiser

Product type 1

Active Substance: **Propan-2-ol**

Case Number in R4BP: NA-APP - **BC-BV063553-21**

Evaluating Competent Authority: Ireland

Date: **01 February 2023**

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1 CONCLUSION

GhostMedica Hand Sanitiser is an *AL - Other liquids to be applied undiluted biocidal product* containing Propan-2-ol as active substance. The product is used as a Product type 1 Human Hygiene Disinfectant by professional and non-professional users for the control of bacteria, yeast and for activity against enveloped viruses.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the uses for non-professional and professional users in the medical area and in food, industrial, domestic and institutional areas as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

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

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

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.1.3 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern.

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

The biocidal product contains the active substance *Propan-2-ol* which has been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

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

The biocidal product contains Propan-2-ol which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

Composition

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

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance propan-2-ol in Ghost Medica Hand sanitiser product are met. More information is available in sections 2.1 of the PAR. The manufacturer of the active substance is listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

An assessment of the physical, chemical and technical properties has been conducted for GhostMedica Hand Sanitiser. This product is a product type 1. The product consists of the active substance propan-2-ol. The appropriate studies for this product were submitted and when evaluated were found to be in accordance with the relevant guidance and methods. The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 2.2.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 2.2.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the active substance (propan-2-ol) content in the product is presented and this was validated in accordance with SANCO 3030/99 rev 5.
Analytical methods for soil, for water, for monitoring purposes and for animal and human body fluids and tissues were not required for the approval of propan-2-ol at EU level as no residues were expected for this active substance.

More information on the analytical methods for the active substance is available in section 2.2.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against bacteria, yeasts and for activity against enveloped viruses for all intended uses. More information is available in section 2.2.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 2.2.6 of the PAR.

Since no substance of concern has been identified above the trigger value, the human health risk assessment is based on Propan-2-ol.

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

Dietary risk assessment

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

Risk assessment for animal health

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

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 2.2.8 of the PAR.

[redacted] the risk assessment for the environment is based on Propan-2-ol.

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

Environment

An environmental risk assessment has been conducted for GhostMedica Hand Sanitiser for all intended uses. No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal product. No classification and labelling according to the CLP criteria for environmental hazards is needed.

Overall the product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

- the fate and distribution of the biocidal product in the environment,
- contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
- the impact of the biocidal product on non-target organisms,
- the impact of the biocidal product on biodiversity and the ecosystem.

Authorised uses

See section 2.1.4

Post-authorisation conditions

There are no post-authorisation conditions.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
GhostMedica Hand Sanitiser	Ireland

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Professional Hair Products Ltd
	Address	Saint Martins Road Rosslare Harbour Wexford Y35 C434 Ireland
Authorisation number	IE/BPA 70815	
Date of the authorisation	01 February 2023	
Expiry date of the authorisation	01 February 2033	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Professional Hair Products Ltd
Address of manufacturer	Saint Martins Road Rosslare Harbour Wexford Y35 C434 Ireland
Location of manufacturing sites	Saint Martins Road Rosslare Harbour Wexford Y35 C434 Ireland

2.1.1.4 Manufacturer of the active substance

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers, Germany
Location of manufacturing sites	Römerstrasse 733, 47443 Moers, Germany

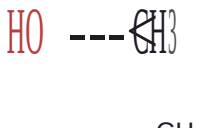
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be 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 D
No i:8J

2.1. 2.1 Identity of the active substance

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

2.1. 2.2 Candidate(s) for substitution

The active substance is not a candidate for substitution.

2.1. 2 . 3 Qualitat iv e and quant itat ive informat ion on the composit ion of the biocidal product

Common name	IUPAC name	Function	CAS number	EC num ber	Content (% w/ w)
Propan-2 -ol	Propan-2 -ol	Act ive substance	67- 63-0	200-661-7	70
-	-	Non-active substances	-	-	30

The full composition details are contained within the confidentia l annex.

2.1. 2.4 I nform ation on technical equivalence

Technical equivalence to the reference source of propan-2-o l has been verified by the manufacturer of the active substance, I NEOS Solvents Germany GmbH (ECHA decision number TAP-D-1271080-30-00 / F).

2.1. 2.5 I nform ation on the substance(s) of concern

There are no substances of concern in the product .

2.1. 2.6 Type of formulation

IAL - Other liquids to be applied undiluted

2.1.3 Hazard and precautionary statements

Classifi cation and labelling of the produ ct accor ding to Regulation (EC} 1272/2008

Classifi cation		
Hazard cateaorv	Flam. Lia. 2 Eve l rr itant 2 STOT SE 3	
Hazard statement	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritat ion. H336 May cause drowsiness or dizziness. EUH066 Repeated exposure may cause skin dryness or crackina.	
Labelling		
Sianal words	Danaer	
Pictograms	GHS02	GHS07

Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness.
Supplemental hazard statement	EUH066	Repeated exposure may cause skin dryness or cracking.
Suplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand
	P102	Keep out of reach of children.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P261	Avoid breathing mist, vapours or spray.
	P271	Use only outdoors or in a well ventilated area
	P280	Wear eye protection.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing
	P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do not induce vomiting
	P305 + P351 + P338.	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
	P312	Call a POISON CENTER/doctor if you feel unwell.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up
	P501	Dispose of contents/container in accordance with local regulations
note	-	-

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1: Hygienic handrub

Product Type	PT1 Human hygiene.
Where relevant, an exact description of the authorised use	Hygienic handrub for direct application on skin.
Target organism (including development stage)	Bacteria, yeasts and enveloped viruses.
Field of use	Indoor and outdoor.
Application method(s)	Applied directly to hands.

Application rate(s) and frequency	3 ml applied to one hand and rubbed over the complete surface of both hands for 60 seconds per application. **Professional use:** Adult: up to 25 applications per day **Non-professional use:** Adult: up to 25 applications per day Children: maximum 12 applications per day Toddler: maximum 3 applications per day
Category(ies) of users	Non-professional and professional.
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use

Comply with the instructions for use.

If the hands are visibly dirty, wash them with soap and water. Apply enough of the product to the palm of the hand to wet the hands completely. Rub the hands together, covering all surfaces, for 30 seconds or until the hands are dry.

2.1.4.3 Use-specific risk mitigation measures

Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing mist, vapours or spray.

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

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

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

Dispose of contents/container in accordance with national regulations.

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

Store in a well-ventilated place. Keep cool. Keep container tightly closed.

2.1.5 General directions for use

2.1.5.1 1 I nstructions for use

ls ee Section 2.1.4.2

2.1. 5. 2 Risk m it igat ion measur es

lsee Section 2.1.4.3

2.1. 5. 3 Part iculars of likely direct or in direct effects, first aid instructions and emergency measures to protect t he environm ent

lsee Section 2.1.4.4

2.1. 5.4 I nst ruct ions for safe disposal of the product and its packaging

ls ee Section 2.1.4.5

2.1. 5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

ls ee Section 2.1.4.6

2.1.6 Other information

None

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)
Spray pen	5 ml	PET	PET sprayer	Profession al and non-professional	Yes
Bottle	50 ml	PET	PET sprayer	Profession al and non-professional	Yes
Bottle	100 ml	PET	PET sprayer	Profession al and non-professional	Yes
Bottle	250 ml	PET	PET sprayer	Profession al	Yes
Bottle	1 L	HOPE	HOPE	Profession al	Yes

			pump		
Bottle	5 L	LDPE	LDPE pump	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance has been submitted as part of this product application.
Data on the physical-chemical properties, storage stability and efficacy of the product are included.

2.1.8.2 Access to documentation

A letter of access, allowing the applicant access to all information that was required for propan-2-ol to be included into Annex I of Directive 98/8/EC or in the Union list of approved active substances according to Regulation (EU) No 528/2012, has been obtained from the active substance data holder ASD Consortium Alcohol and is included in the IUCLID dossier.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1: Hygienic handrub

Product Type(s)	PT1 Human hygiene.
Where relevant, an exact description of the authorised use	Hygienic handrub for direct application on skin.
Target organism (including development stage)	Bacteria, yeasts and enveloped viruses.
Field of use	Indoor and outdoor.
Application method(s)	Applied directly to hands.
Application rate(s) and frequency	Applied as needed.
Category(ies) of user(s)	Nonprofessional and professional.
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA Comments 2022
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Undiluted (a.s. 70 %w/w)	Liquid	Nichett i, S. {2021a)	Final Report CH-0180/ 2021 Acceptable
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	Undiluted (a.s. 70 0/ow/w)	Colourless	Nichett i, S. {2021a)	Final Report CH-0180/ 2021 Acceotab le
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	Undiluted (a.s. 70 0/ow/w)	Characteristic odour	Nichett i, S. {2021a)	Final Report CH-0180/ 2021 Acceotab le
pH	CIPAC MT 75. 3, OECD 122	Undiluted (a.s. 70 0/ow/w)	5.8 (neat test item) 5.8 {1% aqueous dilution)	Nichett i, S. {2021a)	Final Report CH-0180/ 2021 Acceotab le
Relative density / bulk density	CIPAC MT 3.2, OECD No. 109, EC 440 / 2008 No. A.3	Undiluted (a.s. 70 %w/w)	0.8562 g/ mL at 20°c	Nichett i, S. {2021a)	Final Report CH-0180/ 2021 Acceptab le
Storage stability test – **acceler ated st ora ge**	CIPAC MT 46, GI FAP Monograph No.17, ECHA Guidance on **BPR** Vol. **1**	Undiluted (a.s. 70 %w/w)	Storage for 14 days at 54 °C PET Bott le I nitial / 14 davs Active ingredient content: 70.8 ± 0.6 %w/w / 71.1 ± 0.1 %w/w + 0.32% chanae Appearance: Colour less liqu id with cnaracterist / Colour less liqu id with cnaracterist	Nichett i, S. {202 1b)	Final Report CH-0182/2021 Acceptab le

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/wl</th><th>Result s</th><th>Reference</th><th>CA Comments 2022</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>ic odour</td><td>ic odour</td></tr>
<tr><td>oH (neat)</td><td>5.8</td><td>6.6</td></tr>
<tr><td>pH (1% dilut ion)</td><td>5.8</td><td>6.8</td></tr>
<tr><td>Compati bilit y of packaging</td><td></td><td>The container presented a deformation on the bottom with no deformation in lateral layers, or loss of sample or evident corrosion phenomena</td></tr>
<tr><td>Weight variation</td><td></td><td>Sample A: -0.53% Sample B: -0.52%</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>Storage stability test - long term storage at ambient temperatur e</td><td>GIFAP Monograph No.17, ECHA Guidance on BPR Vol. 1</td><td>Undi luted (a.s. 70 %w/w)</td><td>
Study ongoing, final report expected July 2023.

I nterim Storage for 12 months at ambient temperature PET Bott le
<table>
<tr><td></td><td>I nitial</td><td>6 months</td><td>12 months</td></tr>
<tr><td>Act ive ingredient content</td><td>70.8 ± 0.6 %w/ w</td><td>70.4 ± 0.5 % w/ w

-0.56% change from TO</td><td>69.5 ± 0.5 %w/w

-1.80% change from TO</td></tr>
<tr><td>Appearance</td><td>Colourless liquid with characterist ic odour</td><td>Colourless liquid with characterist ic odour</td><td>Colourless liquid with characterist ic odour</td></tr>
</table>
</td><td>Nichetti, S. {2021c)</td><td>I nterim Report CH-0183/2021

Acceptab le</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/wl	Results					Reference	CA Comments 2022
			oH (neat)	5.8	5.8	5.8			
			pH (1% dilution)	5.8	5.7	5.7			
			Compatibility of packaging		The container didn't presentany deformation in both bottom and lateral layers, or lossof sample or evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena			
			Weight variation		Sample C: -0.38%	Sample C: -0.54%			
Storage stabi lit y test **-low temperatur e stability test for liquids**	Test waived. This test is not required for GhostMedica Hand Sanitiser as this product is not going to be stored at temperatures below O^{0} C and will be labelled with the phrase " Protect from frost".								Final Report CH-0180/ 2021 Low t emperat ure stability test carried out according to CIPAC MT 39. 3. Results: 2 ml Solid material noted at bottom of tube after 7 davs at 0 ± 2°C.
Effects on content of the active substance and technica l characteristic s of the		Undiluted (a.s. 70 %w/w)	See long-t erm storage stabilit y study results when available.					Nichett i, S. {2021c)	Await ing final study report.

Property	Guideline and Method	Purity of the test substance (% (w/wl	Results	Reference	CA Comments 2022
biocidal product - **liaht**					
Effects on content of the active substance and technical characteristics of the biocidal product - **temperature and humidity**		Undiluted (a.s. 70 %w/w)	See long -term storage stability study results when available. Since product is water based formulation, humidity is not expected to influence content of active substance during storage.	Nichetti, S. {202 1c)	Interim Report CH-0183/ 2021 Acceptable For more on the effects of temperature, please refer to the conclusions on the accelerated storage stability data.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Test waived. The product packaging material is PET, HOPE or LOPE. In the accelerated storage stability test, the container presenteda deformation on the bottom with no deformation in lateral layers, or loss of sample or evident corrosion phenomena. Interim shelf life study update: Test item has been tested in PET bottle which is the commercial packaging for this product. No deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena was observed over 12 months storage at ambient. According to the Guidance on the BPR: Volume I Parts A+ B+ C, Version 2.0 May 2018, for water based formulations any material used in shelf life study, with the exception of metal, can be extrapolated to all packaging types, with the exception of metal. Therefore, no further testing is required for HOPE or LOPE packaging.			Interim Report CH-0183/ 2021 Acceptable
Wettability	Not applicable for this formulation type.				Acceptable
Suspensibility, spontaneity and	Not applicable for this formulation type.				Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/wl	Results	Reference	CA Comments 2022
dispersion stability					
Wet sieve analysis and dry sieve test	Not applicable for this formulat ion ty pe.				Acceptab le
Emulsifiabilit y, re-emulsifiabilit y and emulsion stability	Not applicable for this formulat ion ty pe.				Acceptab le
Disintegratio n time	Not applicable for th is formulat ion ty pe.				Acceptab le
Particle size distribution, content of dust/ fines, attr ition, friabilit y	Not applicable for this formulat ion ty pe.				Acceptab le
Persistent foamina	Not applicable for this formulat ion ty pe.				Acceptab le
Flowability / P ourability/Du stability	Not app licab le for this formulat ion ty pe.				Acceptab le
Burning rate - smoke generators	Not applicable: product is not a smoke generator.				Acceptab le
Burning completenes s - smoke aenerators	Not applicable: product is not a smoke generator.				Acceptab le

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA Comments 2022
Composition of smoke - smoke generators	Not applicable: product is not a smoke generator.				Acceptable
Spraying pattern - aerosols	Not applicable: product is not an aerosol.				Acceptable
Physical comoatibilitv	Not applicable: product will not be used in conjunction with other products.				Acceptable
Chemical compatibilit v	Not applicable: product will not be used in conjunction with other products.				Acceptable
Degree of dissolution and dilution stability	Not applicable: product is a ready-to- use liquid.				Acceptable
Surface tension	OECD No.115, EC A.S	Undiluted (a.s. 70 %w/w)	Surface-active material: Undiluted @ 20 °c = 26.3 mN/ m	Nichetti, S. {2021a)	Final Report CH-0180/ 2021 Acceptable
Viscosity	OECD No.114, CIPAC MT 22.1 or CIPAC MT 192	Undiluted (a.s. 70 %w/w)	Dynamic viscosity at 20°c: 4.29 cP (mPa* s) Kinematic viscosity at 20°c: 5.01 est (mm^2/ s) Shear-rate range: from 26.40 to 132.00 sec^{-1} (from 20 to 100 rpm, spindle SC4-18) Dynamic viscosity at 40°C: 2.45 cP (mPa* s) Kinematic viscosity at 40°C: 2.87 est (mm^2/ s) Shear-rate range: from 26.40 to 132.00 sec^{-1} (from 20 to 100 rpm, spindle SC4-18)	Nichetti, S. {2021a)	Final Report CH-0180/ 2021 Acceptable

Conclusion on thephysical, chemical and technicalproperties of the product

GhostMedica is a Hand Sanitiser product. The product analysed for the physico-chemical properties contained 70% active substance propan-2-ol. A sliaht change to a co-formulant in the product was made (:::; 1 0%) however the studies submitted are still

considered acceptable as the active substance content has not been altered.
The product is a colourless liquid with characteristic odour and a pH of 5.8 (neat and 1% aqueous dilution) . The physical properties of the product have been analysed using the appropriate guidelines and methods are acceptable.

An accelerated storage stability study was conducted for 14 days at 54 °C. No significant change was found in the active substance content for the test item stored in a PET bott le com pa red with the results obtained in the validation study. The test item showed no change in appearance, colour, odour or weight, and no significant changes in pH. I n addition, no variat ion was found in colour or in the ext ernal or internal configurat ion of the packaging aside from deformat ion on the bottom of the container, or loss of sample or evident corrosion phenomena.

A long-ter m storage stability study is currently underway. The full shelf life study report should be submitted when complete. The inter im 12-month data indicates that the product is stable and the results are within acceptable range for the shelf life in the commercial packaging.

It can be accpeted that GhostMedica Hand Sanitiser is stable in its commercial packaging under the tested storage conditions based on the accelerated study and the int erim long term study results presented.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA Comm ent s 2022
Explosives	Justification		There are no chemical groups present in the molecule which are associated with explosive orooerties & there fore a studv is not necessarv.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Flammable gases	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Flammable aerosols	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Oxidising qases	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	CA Comm ent s 2022
Gases under pressure	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Flammable liquids	Justification		Under the harmonised classification of the CLP Regulation, the active substance propan-2-o l is classified as Flam. Liq. 2, and this classification is also determined for the product by the calculation method.	CLP Regulat ion {EC) No.1272/ 2008	Acceptable
Flammable solids	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Self-reactive substances and mixtures	Justification		According to the experience of use, the product is stable to water and atmospheric moisture. The product is stable under accelerated conditions of S4° C for 14 davs.	CLP Regulat ion {EC) No.1272/ 2008	Acceptable
Pyrophoric liquids	Justification		According to the experience of use, the product is stable at room temperature and is not pyrophoric in contact with water and atmospheric moisture.	CLP Regulat ion {EC) No.1272/ 2008	Acceptable
Pyrophoric solids	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Self-heating substances and mixtures	Justification		According to the experience of use, the product is stable and neither it nor its components underao self- ianit ion durina storaae and use.	CLP Regulat ion {EC) No.1272/ 2008	Acceptable
Substances and mixtures which in contact with water emit flammable gases	Justification		According to the experience of use, the product is stable to water and atmospheric moisture. The product and its components are miscible with water.	CLP Regulat ion {EC) No.1272/ 2008	Acceptable
Oxidising liauids	Justification		The product and its components do not generate oxvaen.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Oxidising solids	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable

Property	Guid elin e and Method	Purity of the test substance (% (w/w)	Results	Reference	CA Comm ent s 2022
Organic peroxides	Justification		None of the components of the product has peroxide functional aroup properties.	CLP Regulation (EC) No.1272/ 2008	Acceptable
Corrosive to metals	Justification		Not relevant. pH of the formulation is in the neutral area of the pH scale (5.8) and neither the product nor its components are classified as corrosive to metals.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Auto- ignition temperatures of products (liquids and gases)	Justification		According to the experience of use, the product is stable and does not suffer self-ignition process during storage and use. The product consists primarily of propan-2-o l, with much of the rest of the prod uct being wat er, therefore the reasonable auto-ignition t emperature for the product would be expected to be around 425 °C, which is the report ed auto-ignit ion temperat ure for propan-2-ol.	CLP Regulation (EC) No.1272/ 2008	Acceptable
Relative self-ignition temperature for solids	Justification		Not applicable: product is a liquid.	CLP Regulat ion (EC) No.1272/ 2008	Acceptable
Dust explosion hazard	Justification		Not applicable: product is a liquid.	CLP Regulation (EC) No.1272/ 2008	Acceptable

Conclusion on the ohvsical hazard s and re soective cha ract eristics of the orodu ct
The active substance in Ghost Medica Hand Sanitiser is propan-2-o l. This substance, which according to the harmonised classification of the CLP Regu lat ion, is classified as Highly flammable liquid and vapour (Flam. Liq. 2). Propan -2-ol is not regarded as an explosive substance, self-reactive, self-heating, pyrophoric, or oxidising. The product contains no organic peroxides , and the auto-ignition temperature is expected to be approximately that of propan-2-ol (425 °C), which does not represent a physical hazard.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate** (0/o)			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Propan-2-ol	Gas chromatography wit h flame ionisation detector (GC/FI D)	5 working standard solut ions. Injected range 54.00-270.00 µg/ ml Linearit y Range (27-125% w/w)	r> 0.99	Active ingredient peak was well separated and interferences were not found	99 . 16-99 . 34	99 . 3	Not stated	-	Nichett i, S. (2021d) Final Report CH-018 1/ 202 1

Analyt ical methods for soil, for wat er, for monitoring purposes and for animal and human body fluids and tissues were not required for the approval of propan-2-ol at EU level as no residues were expected for this act ive substance.

The analyt ical methods for air are reported in the assessment report for propan-2-ol (CAR, January 2015).

Conclusion on the methods for detection and identificationof the product
A GC/FID met hod for determining the content of the active substance propan-2-ol in the Ghost Medica product was presented . A validation in accordance with SANCO/3030/ 99 rev. 5 was carried out and found to be acceptable. The method presented a mean recovery rate of propan-2- ol of 99.3%, and Repeatability (n = 5) Mean = 70.8% w/w, RSD 0.84% Horwitz 1.41 Horrat Value = 0.59 therefo re < 1 the refore acceptable.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

GhostMedica Hand Sanitiser is a ready-to-use hygienic handrub (PT1) disinfectant with active substance propan-2-ol. The product is intended to be used as a hygienic handrub for nonprofessional and professional users in the medical area and in food, industrial, domestic and institutional areas.

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

The product is intended to have bactericidal and yeasticidal activity with additional efficacy for activity against enveloped viruses.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Application of the product leads to the irreversible inactivation of bacteria, yeasts and enveloped viruses. The suffering of target organisms is not required for consideration.

2.2.5.4 Mode of action, including time delay

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

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

After thorough contact of the active substance with the target organisms, prolonged contact of the active substance with the target cells is not required since the initial contact already results in non-reversible damage of the cells, that triggers biological processes which ultimately kill the target organism.

2.2.5.5 Efficacy data

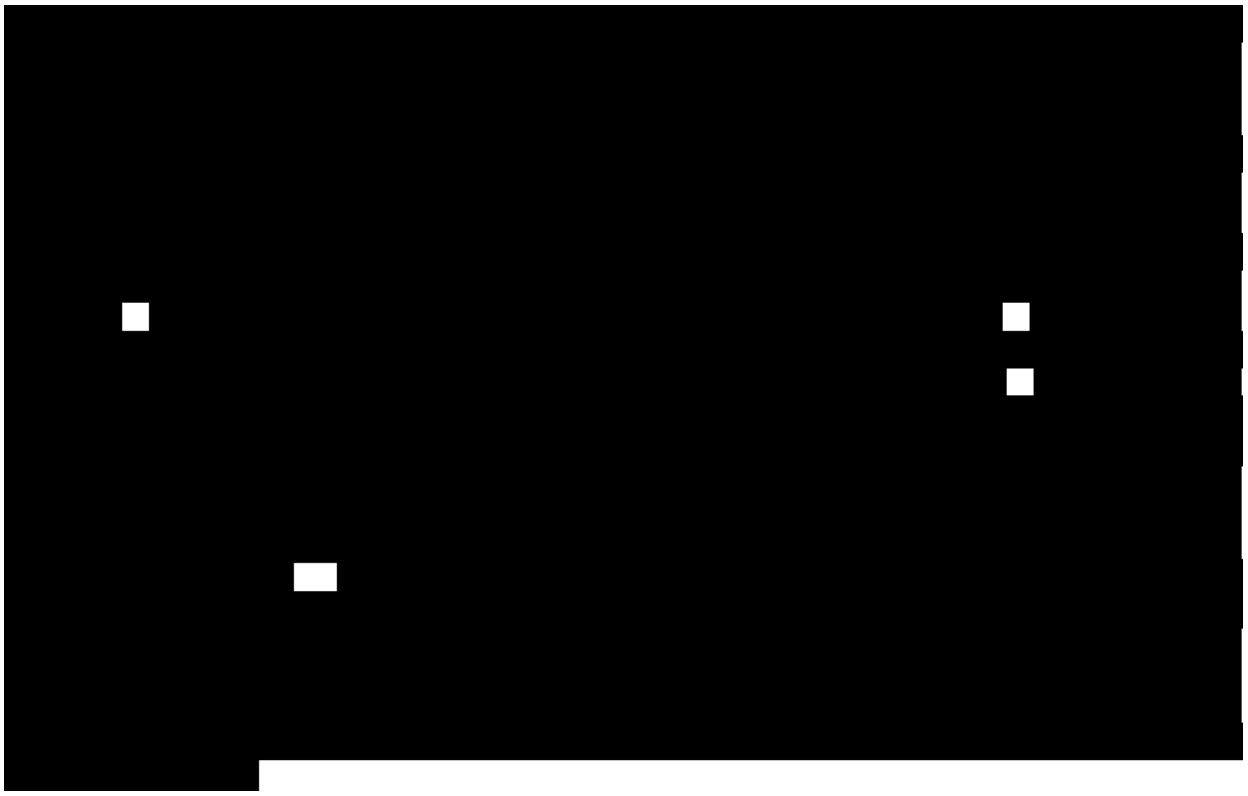
The products bactericidal, yeasticidal and efficacy for activity against enveloped viruses was tested according to current ly available efficacy guidelines (EN standards). As the biocida l product is intended to be applied for disinfection, the product was tested in a tiered approach with quantitat ive suspension tests (phase 2, step **1** tests) and by simulating practical conditions (phase 2, step 2 tests).

Experiment al data on the effi cacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test met hod**	**Test system / concentration s applied / exp o sure tim e**	**Test results: effect s**	**Reference**
PTl	Hygienic handrub	GhostMedica Hand Sanitiser	Modified vaccinia virus Ankara (MVA), ATCC VR-1508	EN 14476:2013 + A2:2019 Phase 2, step 1	Suspension test Clean conditions (0.3 g/l bovine albumin) 20 °C Test solutions: Neat (80%), mid-range (50%), non-active (0.1%) Contact time: 30 ± 5 s	80% and 50% test solutions: Pass (>4 log reduction).	Barrett (2021a)
			S. aureus, P. aeruginosa, E. hirae, E. coli	EN 1276 :2019 Phase 2, step 1	Suspension test Clean conditions (0.3 g/ l bo vine albumin) 20 °C Test solutions: Neat (80%), mid-range (50%), non-active (0.1%) Contact time: 30 ± 5 s	80% and 50% test solutions: Pass for all organisms (> 5 log reduction).	Barrett (2021b)

			C. albicans	EN 1650:2019 Phase 2, step 1	Suspension test Clean conditions (0.3 g/l bovine albumin) 20 °C Test solutions: Neat (80%), mid-range (50%), non-active (0.1%) Contact time: 30 ± 5 s	80% and 50% test solutions: Pass (>4 log reduction). The IE CA noted that on page 3 of 5 of the test report, the '*temperature of incubation'* references 'fungi'. This would implicate that the yeast *C. albicans* was incubated at the wrong temperature. However, the IE CA accepts this as a typographical error and that *C. albicans* has been incubated at the correct temperature based on the requirements of EN 1650.	Barrett (2021c)
			E. coli K12	EN 1500:2013 Phase 2, step 2	Hygienic handrub test 20 volunteers Test volume 2 x 3 ml Contact time: 1 min ± 5 s	Pass: test product is not inferior to reference product (difference in lg R is <0.6)	Barrett (2021d)
			S. aureus, P. aeruginosa, E. hirae, E. coli K12	EN 13727:2012 +A2:2015 Phase 2, step 1 medical area	Suspension test Clean conditions (0.3 g/l bovine albumin) 20 °C Test solutions: Neat (80%), mid-range (50%), non-active (0.1%) Contact time: 30 ± 5 s	80% and 50% test solutions: Pass for all organisms (>5 log reduction).	Barrett (2021e)

			C.albicans	EN 13624:2013 Phase 2, step 1 medical area	Suspension test Clean conditions (0.3 g/l bovine albumin) 20 °C Test solutions: Neat (80%), mid-range (50%), non-active (0.1%) Contact time: 30 ± 5 s	80% and 50% test solutions: Pass (>4 log reduction). The IE CA noted that on page 3 of 5 of the test report, the '*temperature of incubation'* references 'fungi'. This would implicate that the yeast *C. albicans* was incubated at the wrong temperature. Additionally on page 4 of 5, the header states '*Fungal Test Results*'. The IE CA accepts these as typographical errors and that *C. albicans* has been tested and incubated at the correct parameters based on the requirements of EN 13624.	Barrett (2021f)

Change s to the formulation



Conclusion on the effi cacv of the oroduct
Efficacy t ests were conducted on the product GhostMedica. GhostMedica hand sanitiser is a hygienic handrub applied directly to the skin for the purpose of having bactericidal, yeasticidal and efficacy for activit y against enveloped viruses when used under clean condit ions. For bactericidal activ ity, the test requirements for a phase 2, step 1 quantitative suspension test were conducted per EN 1276 (food, industrial, domestic and institut ional areas) and EN 13727 (medical areas). A 5-log reduction was achieved against all required test organisms under the test conditions per the test results. Add itiona lly, the test requirements for phase 2 step 2 testing simulating practical conditions was conducted per EN 1500. The product was concluded as non inferior to the reference product. Based on these results meeting EN and BPR acceptance criter ia's, the product demonstrated sufficient efficacy against bacteria. For yeasticidal activity, the test requirements for a phase 2, step 1 quantitat ive suspension test were conducted per EN 1650 (food, industrial, domestic and institut ional areas) and EN 13624 (medical areas). A 4- log reduction was achieved against all required test organisms under the test conditions per the test results. Based on results meeting EN and BPR acceptance criter ia, the product demonstrated sufficient efficacy against yeast. For activity against enveloped viruses, the test requirements for phase 2, step 1 quantitat ive suspension test was conducted per EN 14476 (medical areas). A 4- log reduction was achieved against the required test organism under the test conditions per

the test results. Based on the results meeting EN and BPR acceptance criteria, the product demonstrated sufficient efficacy for activity against enveloped viruses.

It is concluded that the product is efficacious when used in accordance with the use instructions proposed in the SPC. All tests were conducted on the required target organisms in accordance with the relevant EN standards within a quality assured laboratory. All controls were valid.

2.2.5.6 Occurrence of resistance and resistance management

The development of resistance is not expected for propan-2-ol because of its non-specific mode of action. A natural resistance is reported for sporulated bacteria. Propan-2-ol is also more effective against enveloped viruses compared with non-enveloped viruses.

2.2.5.7 Known limitations

No undesirable or unintended side effects were observed during the efficacy studies of GhostMedica Hand Sanitiser, which included a study with human volunteers. The handrub's effect is instant, with rapid evaporation and no residual activity.

2.2.5.8 Evaluation of the label claims

The label claims reflect the use conditions as specified in the SPC.

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

GhostMedica Hand Sanitiser is not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Please see the Confidential Annex for details of the calculation method used to determine classifications.

Skin corrosion and irritation

Conclusion used in Risk Assessment - Skin corrosion and irritation	
Value/ conclusion	Not irritating or corrosive
Justification for the value/conclusion	Two of the ingredients in the product are classified for skin irritation (according to CLP inventory), at a total concentration of 0.1%. For classification according to the summation method as outlined in Regulation (EC) 1272/2008 (CLP) the generic concentration limit (10%) has not been met . While the product does not contain any components classified for skin corrosion. Therefore classification for Skin Irritation and corrosion is not required. However the product contains the active substance Propanol which may contribute to cracking and dryness of the skin and therefore warrants the EUH066 phrase.
Classification of the product according to CLP and DSD	Not classified for this hazard. Supplemental hazard statement : EUH066 Repeated exposure may cause skin drvness or crackinq.

No new data is available or required.

Data waivina	
Information requirement	Not relevant
Justification	Not scientifically justified. Annex III part 1 of Regulation 528/ 2012 and chapter III , section 3.1. 1 " Skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume Il l, Human Health (version 1.2, 2018), states that : 'Testing on the product / mixture does not need to be conducted if, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/ 45/ EC and Regulation (EC) No 1272/ 2008 (CLP), and synergistic effects between any of the components are not expected'. The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. Classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/ 2008 and testing of the components and/or of the biocidal product is not required.

Eye irritation

Conclusion used in Risk Assessme nt - Eve irritation	
Value/ conclusion	I rritat ing to eyes
Justificat ion for the value/conclusion	Classification of the product is based on the classification of the active subatance according to regulation (EC) No 1272/ 2008 and its concentration in the biocidal product. The product contains the active substance Propan - 2-o l (70%, w/w), which is classifi ed as Eye I rr it. 2, H319; above the generic concentrat ion limit (10% w/ w). Therefore classification for category 2 eye irr it ation according to the summation method outlined in Reaulation (EC) 1272/2008 (CLP) is warranted .
Classification of the product according to CLP and DSD	Eye I rr it . 2, H319 (Causes serious eye irritat ion).

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justificat ion	Not scientifically justified . Annex II I part 1 of Regulation 528/ 2012 and chapter Il l, section 3.1.2 " Eye irr itation" of the Guidance on the Biocidal Products Regulation, Part A, Volume I II , Human Health (version 1.2, 2018) states that : Testing on the product / mixture does not need to be conducted if, there are valid data available on each of the components in the mixture to allow classifi cation of the mixture according to the rules laid down in Directive 1999/ 45/ EC and Regulation (EC) No 1272/ 2008 (CLP), and synergistic effects between any of the components are not expected. The composit ion of the biocidal product is known. Sufficient data on the intr insic properties are available through safety data sheets and other information for each of the indiv idual components in the product . Classification of the mixture was made according to the rules laid down in Regu lation (EC) No 1272/ 2008 . The product may be classified based on the classification of its components . Therefore, further testing is not required.

Respiratory tract irritation

Conclusion used in the Risk Assessment - Respiratory tract irritation	
Value/ conclusion	Not I rrit ating to the respiratory tract
Justificat ion for the conclusion	The product does not contain any components that are classified for respiratory tract irritation above the threshold for classification according to the summation method outlined in Regulat ion (EC) 1272/ 2008 (CLP).
Classification of the product according to CLP and DSD	Classification for respiratory tract irritat ion is not required.

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justificat ion	Not scientifically justi fied. There are current ly no standard tests and no OECD test guidelines available for respirat ory irritation . Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272 / 2008 . The product may be classified based on the classification of its components . Therefore, further testinq is not required.

Skin sensitisation

Conclusion used in Risk Assessme nt - Skin sensitisation	
Value/ conclusion	Not sensitising
Justificat ion for the va lue/ conclusion	Based on the calculation method and the classification of the product components in accordance with Regulation (EC) 1272/ 2008 (CLP). One of the ingredients in the product has a classification of skin Sens 1B and is present at 0.01% (according to ECHA CLP invento ry). The generic concentration limit is 1% which has not been met . Therefore classification according to CLP for skin sensitisation is not warrant ed.
Classification of the product according to CLP and DSD	Classification for Skin sensitisation is not required.

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justificat ion	Not scientifically justified . According to Annex III of Regulation (EU) 528/2012 and chapter III part A section 3.1.3 " Skin sensitisation" of the guidance on the Biocidal Products regu lations, Part A, Volume II I Human health v1.2: Testing on the product/ mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation {EC) No 1272/2008 {CLP), and synergistic effects between any of the components are not expected. The composit ion of the biocidal product is known. Sufficient data on the intr insic propert ies are available through safety data sheets and other information for each of the indiv idual components in the products. There is no informat ion on synergistic effects between any of the components . Consequent ly, classification of the mixtures was made according to the rules laid down in Regulation {EC) No 1272/ 2008 and testing of the components and/ or of the biocidal oroduct is not reauired.

Respiratory sensitization (ADS)

Conclusion used in Risk Asse ssme nt - Resoiratorv sensi tisat ion	
Value/ conclusion	Not sensitising
Justificat ion for the value/ conclusion	Based on the calculation method and the classification of the product components in accordance with Regulation {EC) 1272 / 2008 {CLP) . None of the components are sensitising . Therefore the oroduct is not exoected to be sensitisina.
Classificationof the product according to CLP and DSD	Not classified for this hazard.

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justificat ion	Not scientifically justi fied. The product may be classified based on the classification of its components. Therefore, further testing is not required.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment - Acute oral toxicity	
Value	LDso > 2000 mg/ kg bw
Justification for the selected value	The ATE calculated for the product based on the individual ATE values for the components is greater than 2000 mg/ kg bw and therefore no classification is warranted according to the summation method outlined in Regulation (EC) 1272 / 2008 (CLP) .
Classification of the product according to CLP and DSD	Not classified for this hazard.

No new data is available or required.

Data waiving	
Information requirement	Not relevant
Justification	Not scientifically justified. According to Annex III , Title 1 of the BPR (Regulation (EU) 528/ 2012) and chapter III, section 3.1.5 " Acute Toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III , Human Health (version 1.2, 2018), Testing on the product/ mixture does not need to be conducted if, There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/ 45/ EC and Regulation (EC) No 1272/ 2008 (CLP), and synergistic effects between any of the components are not expected. The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components . Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/ 2008 and testing of the components and/ or of the biocidal product is not required

Acute toxicity by inhalation

Value used in the Risk Assessment - Acute inhalation toxicity	
Value	LCso > 5 ma/l (dust / m ist)
Justificat ion for the selected value	The ATE calculated for the product based on the individual ATE values for the components is greater than 5 mg/l and therefore no classification is warranted according to the summation method outlined in Regulation (EC) 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Not classified for th is hazard. However, based on the classification of the active substance propan-2-ol the biocida l product is classified as STOT SE 3, H336 (May cause drowsiness or dizziness.)

No new data is available or required.

Data waiving	
I nformation requirement	Not relevant
Justificat ion	Not scientifically justi fied. According to Annex III, Title1 of theBPR (Regu lation (EU) 528/2012) and chapter Ill, section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulat ion, Part A, Volume II I , Human Health (version 1.2, 2018), " testing on the product/ mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regu lation (EC) No 1272/ 2008, and synergistic effects between any of the components are not expected." The composit ion of the biocidal product is known. Sufficient data on the intr insic propert ies are available through safety data sheets and other informat ion for each of the indiv idual components in the products. There is no informat ion on synergistic effects between any of the components. Consequent ly, classification of the mixtures was made according to the rules laid down in Regulat ion (EC) No 1272/ 2008 . Therefore, further testing is not required.

Acute toxicity by dermal route

Value used in the Risk Assessment - Acute dermal toxicity	
Value	LDso > 2000 mg/kg bw
Justificat ion for the selected value	The ATE calculated for the product based on the individual ATE values for the components is greater than 2000 mg/kg bw and therefore no classification is warranted according to the summation method outlined in Regulation (EC) 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Not classified for th is hazard.

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justifica tion	Not scientifically justified . According to Annex II I , Title 1 of the BPR (Regulation (EU) 528/ 2012) and chapter Ill, section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulat ion, Part A, Volume I II , Human Health (version 1.2, 2018), " testing on the product / mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regu lation (EC) No 1272/ 2008, and synergistic effects between any of the components are not expected." The composit ion of the biocidal product is known. Sufficient data on the intrinsic propert ies are available through safety data sheets and other informa tion for each of the indiv idual components in the products. There is no informa tion on synergistic effects between any of the components . Consequent ly, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/ 2008 and testing of the components and/ or of the biocidal product is not required.

Specific Target Organ Toxicity after Single Exposure (STOT SE)

Conclusion used in Risk Assessment - Specific Target Organ Toxicity after Single Exposure (STOT SE,	
Value/ conclusion	May cause drowsiness or dizziness
Justifica tion for the value/ conclusion	The product contains the active substance Propanol, which is classified for Specific Target Organ Toxicity after Single Exposure (STOT SE) above the generic concentration limi t for classifi cation for category 3 according to the sum mat ion method outlined in Regulation (EC) 1272/ 2008 (CLP).
Classification of the product according to CLP and DSD	Classification as STOT SE 3, H336 May cause drowsiness or dizziness is warranted .

No new data is available or required.

Data waiving	
I nformation reauirement	Not relevant
Justificat ion	Not scientifically justified. The product may be classified based on the classification of its components. Therefore, further testing is not required.

Information on *dermal absorption*

Value(s) used in the Risk Assessment - Dermal absorotion	
Substance	Prooan-2-o l
Value(s)	Flux rat e: 0.85 ma/ cm^2/ h
Justification for the selected value(s)	According to the 2015 assessment report for Propan-2-o l, for the calculation of the internal body burden of propan- 2-ol it is proposed to use data on dermal flux (0.85 mg/cm^2/h) instead of data on the percentage of dermal absorption. The rate and extent of dermal absorption for the active substances is stated as the following: Absorption rate (transdermalflux) in rat study: 0.85 mg/cm^2/h for aqueous solution containing 70 % propan-2-ol (by weight). *" I n a well-documented study by Boatman et al. 1998, in vivo dermal absorption rates for male and female rats were investigated under occlusive conditions, using 70 % (w/ w) propan-2-ol in aqueous solution, with 2-^{14}C-propan-2-ol as a tracer. Notably, deviations from OECD guide line conditions included shorter exposure duration (4 vs. at least 6 h) and a smaller area of application (4.3 vs. the recommended 10 cm ^{2}). Propan -2 - ol levels in blood were shown to increase linear ly with in the 4 hours of dermal exposure without reaching a plateau. Total recovery of radioactivit y within 48 h amounted to about 92 % of the applied dose. Based on recovered absorbed ^{14} C in relation to total recovery, the percutaneously absorbed port ion of applied dose was calculated as amount ing to about 7 % in 4 h for an application area of 4.3 cm ^{2}. Assuming a linear relat ionship of absorpt ion with the area of application and the durat ion of exposure, this corresponds to an absorpt ion rate of about 0.85 mg/ cm^2/ h or ca. 0.4 %/ cm ^{2}/ h. As a plat eau in propan-2 -ol blood levels had not been reached wit hin 4 h of exposure, substance uptake appeared to not vet be at equilibrium with elimination."*

No new data is available or required.

Data waivina	
I nformation requirement	Not relevant
Justification	According to the 2015 assessment report for Pro pan-2-o l, for the calculation of the intern al body burden of propan- 2-ol {ECHA, 2015) it is proposed to use data on dermal flux (0.85 mg/ cm^2/ h) instead of data on the percentage of dermal absorption.

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

Not relevant - no substance of concern is present .

Available toxicological data relating to a mixture

Not relevant - no subst ance of concern is present .

Other

According to regu lat ion (EC) No 1272/ 2008 Annex VI, Table 3.1 the active substance is classified with STOT SE 3 (H336, May cause drowsiness or dizziness). Based on the high active substance concentration in the biocidal product (> 60 %) and the recommended generic concentration limit is 20 % for substances classified as STOT SE 3. Therefore classification of STOT SE 3 H336, May cause drowsiness or dizziness is required for 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 oaths 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**
I nhalation	NA	Yes	Yes	NA	Yes	Yes	NA
Derm al	NA	Yes	Yes	NA	No	No	NA
Oral	NA	No	No	NA	No	No	NA

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non- professionals, bystanders)
1.	Hand disinfection in hospitals: adult (30-40 y).	Primary (Dermal and Inhalation)	Professionals
2.	Hand disinfection in household and public areas, adult (30-40 y).	Primary (Dermal and Inhalation)	Non-professionals
2a.	Hand disinfection in household and public areas, Children (6-12 y) and toddlers (1-2 y).	Primary (Dermal, Inhalation and HTM)	Non-professionals children and toddlers
3.	Hand disinfection in hospitals (adults: 30- 40 y)	Secondary (Inhalation)	Bystanders adults (after professional use)
4.	Hand disinfection in household and public areas adult (30-40 y).	Secondary (Inhalation)	Bystanders (after non-professional use)
4a.	Hand disinfection in household and public areas, Children (6-12 y) and toddlers (1-2 y).	Secondary (Inhalation)	Bystanders children and toddlers

Industrial exposure

No industrial exposure is foreseen. If the product is used in an industrial setting, it will be used in the same manner as for the professional use and therefore is covered by the professional exposure calculations.

Professional exposure

Scenario {11

Description of Scenario [1] - Professional		
For hand disinfection in hospitals a ready for use solution with 70 % w/ w a.s. is used. According to the information provided by the applicant, 3mls of the disinfectant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry. A total of 25 applications per day of handrub is assumed.		
	Parameters	Value
Tier 1	Mass of compound (m)	1680 mg
	Gas constant (R)	8.314 JK/ mol

	Temperature in Kelvin (T)	303.15 K, equal to 30 ºC
	Molar mass of compound (M)	60.09
	Coefficient of mass transfer in the vapour phase (ß)	8.7 m/h
	Vapour pressure of compound (p)	7649 Pa
	Applied area (A) – Adult 30-40 y (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	820 cm^2 (palm and back of both hands)
	Conversion factor (K)	3.6 x 10^4
	Product amount used	3 ml (2.4 g)
	Dermal Flux (D)	0.85 $mg/cm^2/h$
	Number of applications per shift (n)	25
	Body Weight (bw)	60 kg
	Exposure duration (t) (for ConsExpo)	1 min
	Room volume	80 m^3
	Ventilation rate (v)	1.5 per hour
	Respiratory rate (r)	1.25 m^3/hour

Calculations for Scenario [1]

For the reasonable worst case it is assumed that a total of 25 disinfections are performed per shift, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types. A vapour pressure value of 7649 at 30 ºC was considered appropriate and taken from a calculation using the Antoine equation.

Dermal exposure:

External Dermal Exposure calculation:
For volatile compounds such as propan-2-ol, the potential dermal exposure is limited to the time that the compound remains on hands. This time is calculated according to the formula presented in the TGD (EC 2003):

Evaporation time (s) = (m*T*R/M*ß*p*A)*K = 46.48 seconds
t = 46.5 seconds

According to these calculations the evaporation of 3 ml of 70 % propan-2-ol takes approx. 47 seconds. It is calculated that the applied volume of propan-2-ol (1680 mg / 820 cm²) totally evaporates within 47 seconds. It is assumed that propan-2-ol with an area dose of 2.05 mg a.s./cm² is available for dermal absorption for this short period of time respectively for one hand disinfection. A total amount of 3 ml biocidal product (2.4 g biocidal product based on the product density of 0.8 g/ml) for one hand disinfection stays

on bo th h ands. The amount of 2400 mg biocidal product (corresponding to 1680 mg active substance) is multiplied by 25 disinfections per shift . The resulting dermal exposure is estimated to be 42,000 mg a.s,/ person/ day for one working day (worst case assumption).

Calcualtion of the internal dermal exposure based on dermal flux:
The calculation of the total internal body burden significantly depends on the methodology used for the calculation of dermal absorption. For the calculation of the internal body burden of propan-2-ol data on dermal flux instead of data on the percentage of dermal absorption, as per Recommendation no. 6 of the BPC Ad hoc Wor king Grou p on Human Exposure

I nternal Dermal Exposure = (D * s * n* A)/ 3600* bw
= (0 . 8 5* 46.5* n* 820)/ 3600* 60
= 3.751 mg/ kg bw/ day (25 disinfections)

I nhalation exposure:

Due to its physico-chemical propert ies, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate . Air exchange rates in hospitals depend on the use of the room.
The propan-2-o l concentrat ions of air are calculated with ConsExpo 4.1 (Please see Annex 3.2 for the ConsExpo input and output tables). The mean event concentration (C) was 21 mg/ m^3 for one single disinfection. The internal inhalatory exposure is calculated as follows, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure:

I nternal I nhalatory exposure = (C* r * t * n) / 60* bw =
= (2 1 * 1. 2 5* 1* n)/ 60* 60
= 0 .1 82 m g/ k g b w/ day (25 disinfections)

	Summarv table: estimated ex,,osure from orofessional uses					
Exposure scenario	**Tier/PPE**	**No of uses**	**Estimated inhalation uptake** (mg/kg **bw/day)**	**Estimated dermal uptake** (mg/kg **bw/day)**	**Estimated oral uptake** (mg/kg **bw/day)**	**Estimated total uptake** (mg/kg **bw/day)**
Scenario [1]	1 (no PPE)	25	0.18	3.75	N/ A	3.93

Further information and considerations on scenario [1]

The AEL used in the risk assessment is derived from an AEC t hat is assumed to sufficiently cover local irritant effects in the eyes/ airways during exposure to vapours. As t he product is classified as irritat ing to eyes, contact with the eyes should be avoided.

Non-professional exposure

Scenario {27

De script ion of S c ena rio [2] - Non-professional {adults)		
For hand disinfection in housholds and public areas a ready for use solut ion with 70 % w/ w a.s. is used. According to th e information provided by the applicant, 3mls of the disinfectant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry . The applicant proposes 3 applications of handrub per day. However it is reasonable to assume a greater number of uses per day, therefore an assessment of a 3 and 25 applications per day was performed.		
	Parameters	Value
Tier 1	Mass of compound (m)	1680 mg
	Gas constant (R)	8. 314 JK/ mo l
	Temperature in Kelvin (T)	303.15 K, equal to 30 °C
	Molar mass of compound (M)	60.09
	Coefficient of mass trans fer in the vapour phase (13)	8.7 m/ h
	Vapour pressure of compound (p)	7649 Pa
	Applied area (A) - Adult 30-40 y (HEEG opinion No. **14** Default human fact or values for use in exposure assessments for biocidal products, 2013)	820 cm^2 (palm and back of both hands)
	Convers ion factor (K)	$\mathbf{3.6 \times 10^4}$
	Product amount used	3 ml (2.4 g)
	Dermal Flux (D)	0.85 mg/ cm^2/ h
	Number of applications (n)	3, 25
	Body Weight (bw)	60 kg
	Exposure durat ion (t) (for ConsExpo)	1 min
	Room volume	20 m^3
	Ventialtion rate (v)	0.6 per hour
	Respiratory rate (r)	1.25 m^3/ hour

Calculations for Scenario [2]

The applicant has proposed that in a reasonable worst case scenario a total of 3 disinfections would be performed, th is was not considered reasonable. I t is reasonable to assume a greater number of applications throughout the day for the non professional adult . Therefore, assessment of 3 applications (as proposed by the applicant) and 25 applications (as evaluated in German competent authority PAR for PT1 product 2021) per day were conducted for non professional. A vapour pressure value of 7649 at 30 °C was considered appropriate and taken from a calculation using the Antoine equation.

Dermal exposure:

External Dermal Exposure calculation:
For volatile compounds such as propan-2-ol, the potential dermal exposure is limited to the time that the compound remains on hands. This time is calculated according to the formula presented in the TGD (EC 2003):

Evaporation time (s) = (m*T*R/M*ß*p*A)*K = 46.5 seconds

According to these calculations the evaporation of 3 ml of 70 % propan-2-ol takes approx. 47 seconds. It is calculated that the applied volume of propan-2-ol (1680 mg / 820 cm²) totally evaporates within 47 seconds. It is assumed that propan-2-ol with an area dose of 2.05 mg a.s./cm² is available for dermal absorption for this short period of time respectively for one hand disinfection. A total amount of 3 ml biocidal product (2.4 g biocidal product based on the product density of 0.8 g/ml) for one hand disinfection stays on both hands. The amount of 2400 mg biocidal product (corresponding to 1680 mg active substance) is multiplied by 3 and 25 disinfections per day. The resulting dermal exposure is estimated to be 5,040 or 42,000 mg a.s./person/day for 3 and 25 disinfections respectively for one day (worst case assumption).

Calcualtion of the internal dermal exposure based on dermal flux:
The calculation of the total internal body burden significantly depends on the methodology used for the calculation of dermal absorption. For the calculation of the internal body burden of propan-2-ol data on dermal flux instead of data on the percentage of dermal absorption, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

Internal Dermal Exposure = (D*s*n*A)/3600*bw = (0.85*46.5*n*820)/360*60
= 0.45 mg/kg bw/day (3 disinfections)
= 3.75 mg/kg bw/day (25 disinfections)

Inhalation exposure:

Due to its physico-chemical properties, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate. The propan-2-ol concentrations of air are calculated with ConsExpo 4.1 (Please see Annex 3.2 for the ConsExpo input and output tables). The mean event concentration (C) was 84 mg/m^3 for one single disinfection. The internal inhalatory exposure is calculated as follows, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure:

Internal Inhalatory exposure = (C*r*t*n)/60*bw = (84*12.5*1*n)/60*60
= 0.0875 mg/kg bw/day (3 disinfections)
= 0.729 mg/kg bw/day (25 disinfections)

Summary table: estimated exposure from non-professional uses (Adult)						
Exposure **scenario**	**Tier/PPE**	**No of Uses**	**Estimated inhalation uptake** (mg/kg **bw/day)**	**Estimated dermal uptake** (mg/kg **bw/day)**	**Estimated oral uptake** (mg/kg **bw/day)**	**Estimated total uptake** (mg/kg **bw/day)**
Scenario [2]	1 (no PPE)	3	0.0875	0.45	N/ A	0. 538
		25	0.729	3.75	N/ A	4.48

Further information and considerations on scenario [2]

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irr itant effects in the eyes/ airways during exposure to vapours. As the product is classified as irr itat ing to eyes, contact with the eyes should be avoided.

Scenario [2a 7

Description of Scenario [2a] - Children and toddlers		
For hand disinfection of children in housholds and public areas a ready for use solution with 70 % w/ w a.s. is used. According to the informat ion provided by the applicant, 3mls of the disinfectant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solut ion and let to dry. The applicant proposes 3 applications of handrub per day, however it is reasonable to assume that a greater number of applications could be performed throughout the day. I t is recommended that adults supervise children when applying the biocidal product . Toddlers are not expected to use the product but are included here for completeness.		
	Parameters	Value
Tier 1	Mass of compound (m)	1680 mg
	Gas constant (R)	8.314 JK/ mol
	Temperature in Kelvin (T)	303.15 K, equal to 30 °C
	Molar mass of compound (M)	60. 09
	Coeff icient of mass transfer in the vapour phase (13)	8.7 m/ h
	Vapour pressure of compound (p)	7649 Pa
	Applied area (A) - Toddler 1-2 y (HEEG opinion No. **14** Default human factor values for use in exposure assessments for biocidal products, 2013)	230.4 cm^2 (palm and back of both hands)

	Applied area (A) - Children 6 - 12 y (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	427.8 cm^2 (palm and back of both hands)
	Conversion factor (K)	3.6 x 10^4
	Product amount used	3 ml (2.4 g)
	Dermal Flux (D)	0.85 $mg/cm^2/h$
	Number of applications (n) Child (6-12 y) Toddler (1-2 y)	 3, 12 & 25 3, 12 & 25
	Body Weight (bw) - Toddler 1-2 y (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Body Weight (bw) – Children 6 – 12 y (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Exposure duration (t) (for ConsExpo) Child (6-12 y) Toddler (1-2 y)	 2 mins 3 mins
	Room volume	20 m^3
	Ventilation rate (v)	0.6 per hour
	Respiratory rate (r) Child (6-12 y) Toddler (1-2 y) (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	 1.32 m^3/hour 1.26 m^3/hour

Calculations for Scenario [2a]

The applicant has proposed that in a reasonable worst case scenario a total of 3 disinfections would be performed by a toddler (presented by applicant as worst case), this was not considered reasonable. Since it is not recommended that Toddlers use the product, modelling for Children (6-12y) will be included here (also evaluated in German competent authority PAR for PT1 product 2021). It is reasonable to assume a greater number of applications for children (6-12y) and toddlers (1-6y) could be performed throughout the day. For children: assessment of 3, 12 and 25 applications (as evaluated in German competent authority PAR for PT1 product 2021) per day are presented below. For toddlers: assessment of 3 applications (as proposed by the applicant) 12 and 25 applications (25 applications as evaluated in German competent authority PAR for PT1 product 2021) per day are presented below. A vapour pressure value of 7649 at 30 ºC was considered appropriate and taken from a calculation using the Antoine equation. As a

very worst case, it is assumed that the amount of product used is 3 ml as this is the standard assumption for adults. However, for children, it is expected that a smaller amount will be used because of the smaller surface area of their hands.

Dermal exposure:

External Dermal Exposure calculation:
For volatile compounds such as propan-2-ol, the potential dermal exposure is limited to the time that the compound remains on hands. This time is calculated according to the formula presented in the TGD (EC 2003):

Evaporation time (s) = (m*T*R/M*ß*p*A)*K = 165.5 seconds
Child (6-12 y): 89.1 seconds
Toddler (1 – 2 y): 165.5 seconds

Children (6-12 y): According to these calculations the evaporation of 3 ml of 70 % propan-2-ol takes approx. 89.1 seconds. It is calculated that the applied volume of propan-2-ol (1680 mg / 427.8 cm²) totally evaporates within 89.1 seconds. It is assumed that propan-2-ol with an area dose of 3.93 mg a.s./cm² is available for dermal absorption for this short period of time respectively for one hand disinfection. As a very worst case, it is assumed that a total amount of 3 ml biocidal product (2.4 g biocidal product based on the product density of 0.8 g/ml) for one hand disinfection stays on both hands. The amount of 2400 mg biocidal product (corresponding to 1680 mg active substance) is multiplied by the number of disinfections. The resulting dermal exposure is estimated to be 5,040, 20,160 or 42,000mg a.s./person/day (for 3, 12 and 25 applications respectively) for one day.

Toddler (1-2 y): According to these calculations the evaporation of 3 ml of 70 % propan-2-ol takes approx. 166 seconds. It is calculated that the applied volume of propan-2-ol (1680 mg / 230.4 cm²) totally evaporates within 166 seconds. It is assumed that propan-2-ol with an area dose of 7.29 mg a.s./cm² is available for dermal absorption for this short period of time respectively for one hand disinfection. It is assumed that a total amount of 3 ml biocidal product (2.4 g biocidal product based on the product density of 0.8 g/ml) for one hand disinfection stays on both hands. The amount of 2400 mg biocidal product (corresponding to 1680 mg active substance) is multiplied by 3, 12 or 25 disinfections. The resulting dermal exposure is estimated to be 5,040, 20,160 or 42,000 mg a.s./person/day (for 3, 12 and 25 applications respectively) for one day (worst case assumption).

Calcualtion of the internal dermal exposure based on dermal flux:
The calculation of the total internal body burden significantly depends on the methodology used for the calculation of dermal absorption. For the calculation of the internal body burden of propan-2-ol data on dermal flux instead of data on the percentage of dermal absorption, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

Internal Dermal Exposure (Child) = (D*s*n*A)/3600*bw =
0.85*89.1*n*427.8/3600*23.9
= 1.13 mg/kg bw/day (3 disinfections)
= 4.52 mg/kg bw/day (12 disinfections)
= 9.41 mg/kg bw/day (25 disinfections)

Internal Dermal Exposure (Toddler) = (D*s*n*A)/3600*bw = 0.85*165.5*n*230.4/3600*10

= 2.7 mg/kg bw/day (3 disinfections)
= 10.80 mg/kg bw/day (12 disinfections)
= 22.5 mg/kg bw/day (25 disinfections)

Inhalation exposure:

Due to its physico-chemical properties, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate. The duration of exposure for children was considered to be 3 minutes, as a worst case, based on the calculation of the evaporation time (s) above using the worst case of 3 ml of product applied. The propan-2-ol concentrations of air are calculated with ConsExpo 4.1 (Please see Annex 3.2 for the ConsExpo input and output tables). The mean event concentration (C) was 83 mg/m^3 (for children and toddlers) for one single disinfection. The internal inhalatory exposure is calculated as follows, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure:

Internal Inhalatory exposure (Child) = (C*r*t*n)/60*bw = (83*1.32*2*n)/60*23.9

= 0.458 mg/kg bw/day (3 disinfections)
= 1.83 mg/kg bw/day (12 disinfections)
= 3.82 mg/kg bw/day (25 disinfections)

Internal Inhalatory exposure (Toddler) = (C*r*t*n)/60*bw = (83*1.26*3*n)/60*10

= 1.568 mg/kg bw/day (3 disinfections)
= 6.27 mg/kg bw/day (12 disinfections)
= 13.07 mg/kg bw/day (25 disinfections)

Hand to Mouth

Hand to mouth is considered a child specific behaviour which can lead to relevant exposure of a substance to children. The RIVM report 320005004/2007 in conjunction with Pesticides Control Products fact sheet (Bremmer et al., 2006a) is used to assess a exposure to hand to mouth (HTM) exposure of the biocidal product in children. In the case of biocidal product, its intended to be used as a hand sanitiser. Therefore hands are the main risk factor when considering hand to mouth contact with the biocidal product. 100% of the applied product to the hands will be available for hand to mouth transfer, albeit for a short period prior to evaporation. According to RIVM report , it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact.

Hand to mouth (Child) = 50% of the dermal exposure

= 1.13/100*50 = 0.56 mg/kg bw/day (3 disinfections)
= 4.52/100/50 = 2.25 mg/kg bw/day (12 disinfections)
= 9.41/100*50 = 4.70 mg/kg bw/day (25 disinfections)

Hand to mouth (Toddler) = 50% of the dermal exposure

= 2.7 /100*50 = 1.350 mg/kg bw/day (3 disinfections)
=10.80/100*50 = 5.40 mg/kg bw/day (12 disinfections)
=22.5/100*50 = 11.25 mg/kg bw/day (25 disinfections)

Summary table: estimated exposure from non-professional uses: Child						
Exposure scenario	**Tier/PPE**	**No of uses**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (HTM*) (mg/kg bw/day)**	**Estimated total uptake (incl +HTM) (mg/kg bw/day)**
Scenario [2a] - Child {6-12y)	1 (no PPE)	3	0.458	1.13	0.56	2.15
		12	1.83	4.5 2	2.25	8.61
		25	3.82	9.41	4.70	17.94

'"HTM: Hand to mouth, oral exposure via child specific activities.

Summary table: estimated exposure from non-professional uses: Toddler						
Exposure scenario	**Tier/PPE**	**No of uses**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (HTM*) (mg/kg bw/day)**	**Estimated total uptake (incl +HTM) (mg/kg bw/day)**
Scenario [2a] - Toddler {1-2y)	1 (no PPE)	3	1. 569	2.70	1.35	5.62
		12	6.27	10.804	5.40	22.48
		25	13.07	22.50	11.25	46.83

'"HTM: Hand to mouth, oral exposure via child specific activities.

Further information and considerations on scenario [2a]

TheAEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irr it ant effects in the eyes/ airways during exposure to vapours. As the product is classified as irr itat ing to eyes, contact with the eyes should be avoided.

Exposure of the general public

Scenario [3 7 after professional use

Description of Scenario [3] - Adult bystander after professional use		
For hand disinfection in hospit als a ready for use solut ion with 70 % w/ w a.s. is used. According to the info rma tion provided by the applicant, 3mls of the disinfect ant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solut ion and let to dry. Here the secondary exposure to the bystander present in the room at the time of hand disinfection is considered.		
	Parameters	Value
Tier 1	Product amount used	3 ml (2.4 g)
	Number of applications per room (n)	4, 25

	Body Weight (bw) Adu lt	60 kg
	Exposure durat ion (t) (for ConsExpo)	1 min
	Room volume	80 m^3
	Ventialtion rate (v)	1.5 per hour
	Respiratory rate (r)	1.25 m^3/ hour

Calculations for Scenario [3]

The applicant has proposed that in a reasonable worst case scenario a total of 4 disinfections would be performed per room in the presence of the adult bystander, th is was not considered reasonable. According to HEAdhoc Recommendat ion no. 9 - Hand disinfection in hospitals by professionals - I nhalation and dermal exposure during hand disinfection' where 25 disinfections are applied in one room. Therefore in a worst *case* scenario the adult bystander could be exposed to 25 disinfections. Therefore, assessment of 4 inhalation exposures (as proposed by the applicant) and 25 exposures (HEAdhoc Recommendat ion no.9) are presented below.

Dermal exposure:

Dermal exposure is not expected since propan-2 -ol evaporates with in a short time during hand disinfection and a direct contact to the hand disinfection solut ion is not conceivable.

I nhalation exposure:

Due to its physico-chemical propert ies, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-o l concentration in air depends main ly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate . Air exchange rates in hospitals depend on the use of the room.
The propan- 2-ol concentrat ions of air are calculated with ConsExpo 4 .1 (Please see Annex 3.2 for the ConsExpo input and output tables). The mean event concentration {C) was 21 mg/ m^3 for one single disinfection. The interna l inhalatory exposure is calculated as follows, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure:

I nternal I nhalatory exposure = {C* r * t * n) / 60* bw = {21* 1. 25* 1* n)* 3600
= 0 . 029 m g/ kg b w/ day (4 disinfections)
= 0 .1 82 m g/ kg b w/ day (25 disinfections)

Summary table: estimated secondary exposure from professional uses						
Expo sur e scenario	**Tier / PPE**	**No of uses**	**Estimat ed inhalation uptake (mg/ kg bw/ day)**	**Estim at ed dermal uptake (mg/ kg bw/ day)**	**Estim ated oral uptake (mg/ kg bw/ day)**	**Estim ated total uptake (mg/ kg bw/ day)**
Scenario [3] Adult	1 (no PPE)	4	0.029	N/ A	N/ A	0.029
		25	0.18 2	N/ A	N/ A	0.182

Further information and considerations on scenario [3]

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irritant effects in the eyes/ airways during exposure to vapours. As the product is classified as irritating to eyes, contact with the eyes should be avoided.

Scenario [4] after non-professional use

Description of Scenario [4] - Adult		
For hand disinfection in households and public places a ready for use solution with 70 % w/ w a.s. is used. The disinfectant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry. Here the secondary exposure to the bystander present at the time of hand disinfection is considered.		
	Parameters	Value
Tier 1	Product amount used	3 ml (2.4 g)
	Number of applications (n)	3, 25
	Body Weight (bw)	60
	Exposure duration (t) (for ConsExpo)	1 min
	Room volume	20 m^3
	Ventilation rate (v)	0.6 per hour
	Respiratory rate (r)	1.25 m^3/hour

Calculations for Scenario [4]

The applicant has proposed that in a reasonable worst case scenario a total of 3 disinfections would be performed per room in the presence of the adult bystander, this was not considered reasonable. However, it is reasonable to assume that in a realistic worst case scenario the adult non professional bystander could be exposed to 25 disinfections per day. Therefore, assessment of 3 inhalation exposures (as proposed by the applicant) and 25 exposures are presented below.

Dermal exposure:

Dermal exposure is not expected since propan-2 -ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.

Inhalation exposure:

Due to its physico-chemical properties, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate . The propan-2-ol concentrations of air are calculated with ConsExpo 4.1 (Please see Annex 3.2 for the ConsExpo input and output tables). The mean event

conc entration (C) was 84 mg/ m³ for one single disinfection. The internal inhalatory exposure is calculated as follows, as per Reco mmenda tion no. 6 of the BPC Ad hoc Wor king Group on Human Exposure:

I nternal I nhalatory exposure = (C* r * t * n) / 60* bw = (84* 1. 25* 1* n)* 3600
= 0 . 087 5 6 m g / kg b w/ day (3 disinfections)
= 0 . 729 m g/ k g b w/ day (25 disinfections)

Summarv table: estimated secondarv exoosure from non-orofessional uses						
Exposure scenario	**Tier/PPE**	**No of uses**	**Estimated inhalation uptake** (mg/kg **bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake** (mg/kg **bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario [4] - Adult :	1 (no PPE)	3	0.088	N/ A	N/ A	0.088
		25	0.729	N/ A	N/ A	0.729

Further information and considerations on scenario [4]

The AEL used in the risk assessment is derived from an AEC t hat is assumed to sufficiently cover local irritant effects in the eyes/ airways during exposure to vapours. As the product is classified as irritat ing to eyes, contact with the eyes should be avoided.

Scenario f4a7 after non-professional use Children

Description of Scenario [4a]: Child and toddler		
For hand disinfection in households and public places a ready for use solution with 70 % w/ w a.s. is used. The disinfectant is poured into the palms of one hand out of a dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry. Here the secondary exposure to the child and todd ler bystander present at the time of hand disinfection is considered.		
	Parameters	Value
Tier 1	Product amount used	3 ml (2.4 g)
	Number of applications (n)	3, 25
	Body Weight (bw) Child Toddler	 23 .9 kg 10 kg
	Exposure durat ion (t) (for ConsExpo)	1 min
	Room volume	20 m³
	Vent ialtion rate (v)	0.6 per hour

	Respiratory rate (r) Child Toddler	 1.32 m^3/hour 1.26 m^3/hour

Calculations for Scenario [4a]

The applicant has proposed that in a reasonable worst case scenario a total of 3 disinfections would be performed per room in the presence of the Child (toddler) bystander, this was not considered reasonable. However, it is reasonable to assume that in a realistic worst case scenario that children and toddlers (non professional) bystander could be exposed to 25 disinfections per day. Therefore, assessment of 3 inhalation exposures (as proposed by the applicant) and 25 exposures for both Children and toddlers are presented below.

Dermal exposure:

Dermal exposure is not expected since propan-2 -ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.

Inhalation exposure:

Due to its physico-chemical properties, propan-2-ol evaporates during the application as hand disinfectant. The propan-2-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate.The propan-2-ol concentrations of air are calculated with ConsExpo 4.1. The mean event concentration {C) was 84 mg/ m^3 (for children and toddler) for one single disinfection. The internal inhalatory exposure is calculated as follows, as per Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure:

Internal Inhalatory exposure {Child - 6-12 y) = {C* r* t * n) / 60 * bw
= {84* 1. 32* 1* n)/ 60* 23.9
= 0 . 232 mg/ kg bw/ day (3 disinfections)
= 1.933 mg/ kg bw/ day (25 disinfections)

Internal Inhalatory exposure {Toddler - 1-2 y) = {C* r* t * n) / 60* bw
= {84* 1. 32* 1* n)/ 60* 10
= 0.525 mg/ kg bw/ day (3 disinfections)
= 4 . 375 mg/ kg bw/ day (25 disinfections)

Summary table: estimated secondary exposure from non-professional uses

Exposure scenario	**Tier / PPE**	**No of uses**	**Estimated inhalation uptake** (mg/kg **bw/ day)**	**Estimated dermal uptake** (mg/ kg **bw/ day)**	**Estimated oral uptake** (mg/ kg **bw/ day)**	**Estimated total uptake** (mg/ kg **bw/ day)**
Scenario [4a]- Child	1 (no PPE)	3	0.232	N/ A	N/ A	0.232
		25	1.933	N/ A	N/ A	1.933
Scenario	1	3	0.525	N/ A	N/ A	0. 525

[4a]- Toddler	(no PPE)	25	14. 375		14. 375

Further information and considerations on scenario [4a]

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irr it ant effects in the eyes/ airways during exposure to vapours. As the product is classified as irr itat ing to eyes, contact with the eyes should be avoided.

Combined scenarios

Peop le (pro f essional and non-professional) using hand disinfection products may be exposed as users and as bystanders simult aneously, therefore, it is necessary to assess the tot al exposure that a person may receive in each of these cases.

Various scenarios have been considered for both professional and non-professional adult users as well as for children and t oddlers.

Summary table: combined systemic exposure from professional uses adult)

	Scenarios combined	**Estimated inhalation uptake** (mg/kg **bw/day)**	**Estimated dermal uptake** (mg/kg **bw/day)**	**Estimated oral uptake** (mg/kg **bw/day)**	**Estimated total uptake** (mg/kg **bw/day)**
Based on 25 professional uses and 4 bystander exposure aher professional use.	Scenarios [1]	0.182	3.75	**N/A**	3 .9 3
	Scenarios [3]	0.029	**N/A**	**N/A**	0 . 029
	Combined exposure	0.211	3.75	**N/A**	3 .9 6 3
Based on 25 professional uses and 25 exposures as bystander aher professional use	Scenarios [1]	0.182	3.751	**N/A**	3 .9 3
	Scenarios [3]	0.182	**N/A**	**N/A**	0 .1 8 2
	Combined ex p o sure	0.365	3.75	**N/A**	4 .11 6

Summary table: combined systemic exposure from non-professional uses (adults)					
	Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Based on 3 non professional uses and 3 exposures as bystander after non professional use	Scenarios [2]	0.088	0.45	N/A	0.5 38
	Scenarios [4]	0.088	N/A	N/A	0.088
	Combined exposure	0.175	0.45	N/A	0.625
Based on pot ential 25 uses and potent ial 25 exposures as bystander after non professional use *	Scenarios [2]	0.729	3.75	N/A	4.48
	Scenarios [4]	0.729	N/A	N/A	0.729
	Combined exposure	1.458	3.75	N/A	5.210

Summary table: combined systemic exposure for Children					
	Scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (HTM} (mg/kg bw/day)**	**Estimated total uptake (incl HTM} (mg/kg bw/day)**
Based on potential of 12 non professional uses and 25 exposures as non-professional bystander *	Scenarios [2a]	1.83	4.51	2.25	8.61
	Scenarios [4a]	1.93	N/A	N/A	1. 93
	Combined exposure	3.76	4.51	2.25	10.545
Based on potential of 25 non professional uses and 25 exposures as non-professional bystander *	Scenarios [2a]	3.82	9.41	4.70	17.94
	Scenarios [4a]	1.93	N/A	N/A	1.93
	Combined exposure	5.75	9.41	4.70	19.87

* note: 25 potential exposures could be foreseen in a classroom setting

Summary table: combined s ıstemic exposure for Children (Toddlers)					
	Scenario s com bin ed	**Estim at ed inh alation uptak e (mg/ kg bw/ day)**	**Estimat ed derm al uptake (mg/ kg bw/ day)**	**Estim at ed or al uptak e (HTM) (mg/ kg bw/ day)**	**Estimat ed t ot al uptak e (incl +HTM) (mg/ kg bw/ day)**
Based on 3 uses and 3 exposures as non professional bystander	Scenarios [2a]	1.5687	2.70	1.35	5.620
	Scenarios [4a]	0.525	**N/A**	**N/A**	0 . 52 5
	Comb ined exposure	2. 094	2.70	1.35	6.145
Based on 25 uses and 3 exposu res as non professional bystander	Scenarios [2a]	13.07	22.5	11.25	46.83
	Scenarios [4a]	0.525	**N/A**	**N/A**	0 . 52 5
	Com bined exposure	13.59	22.5	11.25	47.35
Based on 3 uses and 25 exposures as non professional bystander*	Scenarios [2a]	1.5687	2.70	1.30	5.620
	Scenarios [4a]	4.375	**N/A**	**N/A**	4 . 37 5
	Com bined exposure	5.94	2.70	1.35	9.995

Monitoring data

No monitoring data or information on surveys or studies with the actual product or with a surrogate are required.

Dietary exposure

The biocidal product is not intended to be applied in livestock prem ises and therefore it is not expected that livestock animals may be exposed to the product. Therefore, no dietary exposure assessment is deemed necessary.

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

Not applicable as not proposed for indust rial use.
Given that the modelling of exposures and subsequent risk characterisation during production and formulation of the product is addressed under other EU legis lation (e.g. Directive 98/ 24/ EC) and not repeated under Regu lat ion 528/ 2012 (agreed at Biocides

Technic al Meeting TMI0 6), no exposure from production of the biocidal product is considered furt her.

Aggregated exposure

Not applicable.

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 {-HTM) (mg/ kg bw/ day)**	**Estimated total uptake {+ HTM*) (mg/ kg bw/ day)**
1	**Professionals** 25 disinfections	Tier 1. No PPE	3.93	N/ A
2	**Non- prof essionals (adult)** 3 disinfections 25 disinfections	Tier 1. No PPE	0 .538 4.480	N/ A
2a	**Childr en** 3 disinfections 12 disinfections 25 disinfections **Toddlers** 3 disinfections 12 disinfections 25 disinfections	Tier 1. No PPE	1.59 6.35 13.23 4.27 17.07 35.58	2.15 8.61 17.98 5.62 22.48 46.83
3	**Bystanders (adult after professional use)** 4 secondary exposures 25 secondary exposures	Tier 1. No **PPE**	0.029 0.182	**N/A**
4	**Bystanders (adult after non-professional use)** 3 disinfect ions 25 disinfections	Tier 1. No **PPE**	0.0875 0.729	**N/A**
4a	**Bystander (aft er non-professional use)** Children 25 disinfections Toddlers 3 disinfections 25 disinfections	Tier 1. No PPE	1.933 0.525 4.375	N/ A
1 + 3	**Professionals and Bystanders** 25 direct + 4 secondary exposures 25 direct + 25 secondary exposures	Tier 1. No PPE	3.963 4.116	N/ A
2+4	**Non- prof essionals and Bystanders (adult s)** 3 direct + 3 secondary exposures 25 direct + 25 secondary exposures	Tier 1. No PPE	0.625 5.210	N/ A

2a + 4a	**Children and Bystander** <u>Children</u> 12 direct + 25 secondary exposures 25 direct + 25 secondary exposures <u>Toddler</u> 3 direct + 3 secondary exposures 3 direct + 25 secondary exposures 25 direct + 3 secondary exposures	Tier 1. No PPE	 8.285 15.16 4.79 8.64 36.10	 10.545 19.87 6.15 9.99 47.36

Risk characterisation for human health

Reference values to be used in Risk Characterisation

User	Reference	Study	NOAEC	AF	Correction for oral absorption	Value
Professional user	AELshort-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	3.8	N/A	17.9(mg / kg bw/ day) (52.6 ppm for 8 hours/ d)
	AELmedium-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	3.8	N/A	17.9(mg / kg bw/ day) (52.6 ppm for 8 hours/ d)
	AELlong-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	3.8	N/A	17.9(mg / kg bw/ day) (52.6 ppm for 8 hours/ d)
Non-Professional and general public user	AELshort-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	6.4	N/A	10.7 (mg / kg bw/ day) (31.25 ppm for 8 hours/ d)
	AELmedium-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	6.4	N/A	10.7 (mg / kg bw/ day) (31.25 ppm for 8 hours/d)
	AELlong-term	Human volunteer study (Sethre et al. 2000a)	200 ppm	6.4	N/A	10.7 (mg / kg bw/ day) (31.25 ppm for 8 hours/ d)
	ARfD	Not necessarv, no residues in food expected				
	ADI	Not necessary, no residues in food expected				

Maximum residue limits or equivalent

Not relevant

Risk for industrial users

No industrial exposure is foreseen. If the products are used in an industrial setting, they will be used in the same manner as for the professional uses and therefore are covered by the professional exposure calculations.

Risk for professional users

S,vstem1c effec ts

Task/ Scenario	Tier	No of Uses	Systemic NOAEC	AEL (mg/ kg bw / day)	Estimated uptake (mg/ kg bw / day)	Estimated uptake/ AEL (0/o)	Acceptable (yes / no)
1	1 (no PPE)	25	200ppm	17.9	3.93	21.97	Yes

Local effects

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irr it ant effects in the eyes/ airways during exposure to vapours. As the product is classified as irr itat ing to eyes, contact with the eyes should be avoided.

Conclusion

The use of the product is with in acceptable limits with regards to professional users without the use of PPE.

Risk for non-professional users

S,vstem1c effec ts - Adu,lt, To ddler an d Ch'ldren

Task/ Scenario	Tier	Noof Uses	Systemic NOAEC	AEL (mg / kg bw / day)	Estimated uptake (mg/ kg bw / day)	Estimated uptake/ AEL (0/o)	Acceptable (yes / no)
2 (non - profess iona l: Adu lt)	1 (no PPE)	3	200 ppm	10.7	0.538	5.02	Yes
		25		10 .7	4.48	41.87	Yes
2a : (non - profess iona l: Child)	1 (no PPE)	3	200 ppm	10 . 7	2 . 15	20.12	Yes
		12		10 .7	8 .61	80.48	Yes
		25		10 . 7	17.94	167.47	No
2a (non- professiona l: Toddler)	1 (no PPE)	3	200 ppm	10.7	5.62	52.52	Yes
		12		10 .7	22 .481	210.09	No
		25		10 . 7	46.83	437.70	No

Local effects

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irr it ant effects in the eyes/ airways during exposure to vapours. As the product is classified as irr itat ing to eyes, contact with the eyes should be avoided.

Conclusion

Th e use of th e product is within acceptable limits with regards to non-professional users without the use of PPE. However, A risk ex ists for children and toddlers when the product is used more then 12 times for children and 3 times for toddlers (although its not expected toddlers will use the product) per day. Product should be kept out of reach of children and toddlers.

Risk for the general public

S,vstem1c eff ec ts

Task/ Scenario	Tier	No of uses	Systemic NOAEC	AEL (mg/ kg bw / day)	Estimated uptake (mg/ kg bw /davl	Estimated uptake/ AEL (0/ol	Acceptable (yes / no)
3 (ad ult bystande r after professional use)	1 (no PPE)	4	200 ppm	10.7	0.029	0.27	Yes
		25		10.7	0.182	1.70	Yes
4 (adult bystande r after non-professional use)	1 (no PPE)	3	200 ppm	10.7	0.088	0.82	Yes
		25		10.7	0.73	6.81	Yes
4a (Toddler)	1 (no PPE)	3	200 ppm	10.7	0.525	**4 .91**	Yes
		25		10.7	4.38	40.89	Yes
4a (Chil d)	1 (no PPE)	25	200 ppm	10.7	1.93	18.06	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEC	AEL (mg/ kg bw /day)	Estimated uptake (mg/ kg bw/ day)	Estimated uptake/ AEL (0/o)	Acceptable (yes / no)	Potential Exposure Scenario
1 + 3 (adult professional)	1 (no PPE)	200 ppm	17.9	3.963	22.14	Yes	Based on 25 Prof. uses and 4 bystander exoosures
			17.9	4.12	22.9	Yes	Based on 25 Prof. uses and 25 bystander exoosures
2 + 4 (Adu lt non orofess ional)	1 (no PPE)	200 ppm	10.7	0.625	5.842	Yes	Based on 3 non -p rof uses and 3

Scenarios combined	Tier	Systemic NOAEC	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake/AEL (%)	Acceptable (yes/no)	Potential Exposure Scenario
							bystander exposures
			10.7	5.210	48.68	Yes	Based on 25 non-prof uses and 25 bystander exposures
2a + 4a Child	1 (no **PPE**)	200 ppm	10.7	10.545	98.54	Yes	Based on 12 uses and 25 bystander exposures
			10.7	19.87	185.74	No	Based on 25 uses and 25 bystander exposures
2a + 4a Toddler	1 (no **PPE**)	200ppm	10.7	6.145	57.431	Yes	Based on 3 uses and 3 bystander exposures
			10.7	9.995	93.413	Yes	Based on 3 uses and 25 bystander exposures
			10.7	47.39	442.61	No	Based on 25 uses and 3 bystander exposures

Local effects

The AEL used in the risk assessment is derived from an AEC that is assumed to sufficiently cover local irritant effects in the eyes/airways during exposure to vapours. As the product is classified as irritating to eyes, contact with the eyes should be avoided.

Conclusion

The use of the product is within acceptable limits with regards to the general population. The combined exposure to both professional and non-professional (including adults, children and toddlers) users exposed to the product from using it themselves in combination with exposure as bystanders (including child specific HTM exposure) show exposure levels below AEL, once the product is used as intended. However a risk exists for children and toddlers, it is recommended that the children and toddlers are supervised when using the biocidal product, the biodical product is not used excessively and is used in a well ventilated area. In addition, the product should be kept out of reach of children and toddlers.

Risk for consumers via residues in food

No risk to consumers via food is likely as consequence of application of the product. The product is not intended to be applied on livestock premises and therefore no contamination to housed animals is expected.

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

Not relevant. The product does not contain any substances of concern contributing the human health classification of the product.

2.2.7 Risk assessment for animal health

The product is not intended to be applied in livestock facilities and therefore no exposure during or after treatment is likely. Pets or domestic animals are not expected to be present when the product is used. However, if this is the case, risk mitigation measures resulting from the human exposure and risk assessment apply for pets (e. g. biocidal product has to be kept out of reach of pets, pets have to be kept away from rooms where disinfection is taking place and adequate ventilation before re-entering has to be ensured).

2.2.8 Risk assessment for the environment

GhostMedica Hand Sanitiser is a ready to use product to cover all surfaces of the hands for non-professional and professional users.

No new environmental data have been submitted in this dossier for GhostMedica Hand Sanitiser. The assessment for this product is based on active substance data in the CAR document for propan-2-ol (Rapporteur: Germany, 2015).

2.2.8.1 Effects assessment on the environment

All the studies supporting environmental fate and toxicity properties of GhostMedica Hand Sanitiser are based on the active substance as reported in the CAR document for propan-2-ol. [redacted] the risk assessment for the environment is based only on the properties of the active substance for propan-2-ol as reported in the CAR.

De t e rm ination of PNEC values :

Surface water:
According to the CAR, the lowest acute effect value for fish is for *Pimepha /es prome /as:* 96 h LCso = 8 , 69 2 mg a.s./ L, whereas the lowest for invert ebrates is for *Daphnia magna :* 4 8 h ECso = 2 , 2 8S mg a.s./ L. For algae, the ErCso for *Pseudokirchnerie l/a subsp icata* = 10 , SOO mg a.s./ L.
I n studies of long-term effect s, the lowest chronic effect value was det ermined for *Daphnia magna,* 16 d $NOEC_{growth}$ = 14 1 m g / L, and a PNECwater = 2 .8 2 m g/ L was derived using an assessment fact or of SO.

Conclusion used in Risk Assessment- Aquatic toxicity	
Value/ conclusion	PNECwater: 2 . 8 2 mq / L
Justification for the value/ conclusion	The lowest effect value (NOEC = 141 mg a . s./ L) for the aquatic compart ment was derived from a long-term study with *Daphnia magna.* Based on the available acute and chronic data for the aquatic compart ment an assessment factor of SO has to be used for the derivation of PNECwat,er

Sediment :
There were no studies on sediment -dwelling organisms included in the CAR, but an equ ilibr ium partitioning method was used according to the TGD on Risk Assessment (2003), result ing in an estimated PNECsediment = 2 .4 1 m g/ k g .

Conclusion used in Risk Assessment- Sediment toxicity	
Value/conclusion	PNECsediment: 2.41 ma / ka ww
Justificat ion for the value/ conclusion	Using the equilibrium partition ing method (EPM) PNECsediment was calculated based on PNECwater accord ing to equat ion 89 (Guidance on the BPR: Volume I V Part B Risk Assessment 2017).

Sewage:
I n a test of the respiration inhibition of activated sludge, an ECso > 1,000 mg a.s./ L nominal was calculated. Considering an assessment factor of 100, a PNECmicroorganisms STP = 10 m g/ L was derived in the CAR.

Conclusion used in Risk Assessment- STP	
Value/ conclusion	PNECSTP: 1 0 mq / L
Justification for the value/ conclusion	Using a respiration inhibition test (OECD 209) PNECSTP was calculated from the ECso applying an AF of 100 (Guidance on BPR Vol. IV Part B, Chapter 3.4)

Soil:
A PNECsoi1 = 0 .4 96 mg / k g ww was derived in the CAR using an equilibrium partition ing method based on the PNECwater and according to the TGD on Risk Assessment (2003).

Conclusion used in Risk Assessment -Terrestrial compartment.	
Value/conclusion	PNECsoi1: 0 .4 96 ma / kq ww
Justifica tion for the value/ conclusion	Using the equilibrium part itioning method (EPM) PNECsoil was calculated based on PNECwater according to equation 91 (Guidance on the BPR: Volume I V Part B Risk Assessment, 2017).

Air:
A PNECair cannot be derived, but available results of acute and subchronic inhalation studies with rats provide effect values that are clearly above the environmental concentration in air. Therefore, no adverse effects on terrestrial organisms (mammals) are expected. As there are no studies on honeybees or terrestrial plants available, effects on these organisms cannot be assessed.

Summary of PNEC values:
Surface water = 2.82 mg/L
Sediment = 2.41 mg/kg
Sewage = 10 mg/L
Soil = 0.496 mg/kg

Secondary poisoning

Propan-2-ol is not expected to accumulate in the environment given the low estimated BCF values in aquatic and terrestrial indicator species (BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww). The risk of secondary poisoning is, therefore, assumed to be negligible via ingestion of contaminated food by birds or mammals.

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

GhostMedica Hand Sanitiser contains 70% w/w of propan-2-ol. This active substance and none of the co-formulants of GhostMedica Hand Sanitiser trigger classification regarding environmental properties.

Further Ecotoxicological studies

No new ecotoxicological studies were submitted for GhostMedica Hand Sanitiser. Ecotoxicological data has been extrapolated from the active substance as reported in the CAR.

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

No new data are available.

Supervised trials to assess risks to non-target organisms under field conditions

No additional trials have been conducted to assess risk to non-target organisms.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant for this product type.

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

The biocidal product GhostMedica Hand Sanitiser will be predominantly applied indoors, mainly in public institutions and hospitals. Therefore, no direct emission to seawater, surface water or soil is expected. The main emission pathway to the environment is considered to be the air compartment and to a lesser extent to the STP.

Further studies on fate and behaviour in the environment (ADS)

No further studies on fate and behaviour in the environment have been performed with the active substance or product. All agreed endpoints have been taken from the final CAR document for the active substance.

Leaching behaviour (ADS)

None of the co-formulants are expected to influence fate and behaviour of the active substance. The environmental exposure and risk assessment is based on the data set of the active substance and no further studies are required.

Testing for distribution and dissipation in soil (ADS)

No further data are available and are not considered necessary. However, none of the co-formulants are expected to influence fate and behaviour of the active substance. The environmental exposure and risk assessment is based on the data set of the active substance and no further studies are required. Propan-2-ol is classified as readily biodegradable. Default half-lives of 30 days for biodegradation in surface water and 300 days in sediment are assumed based on the readily biodegradable classification. The corresponding value for the soil compartment is 30 days (based on a Koc of 3.3 L/kg).

Testing for distribution and dissipation in water and sediment (ADS)

No further data are available. However, none of the co-formulants are expected to influence fate and behaviour of the active substance. The environmental exposure and risk assessment is based on the data set of the active substance and no further studies are required. Propan-2-ol is classified as readily biodegradable. Default half-lives of 30 days for biodegradation in surface water and 300 days in sediment are assumed based on the readily biodegradable classification.

Testing for distribution and dissipation in air (ADS)

No further data are available. However, none of the co-formulants are expected to influence fate and behaviour of the active substance

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)

Not relevant. The product is not going to be sprayed near to surface waters.

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. The method of application described in the section 2.2.1 Intended use(s) as applied for by the applicant is by direct application to hands. Based on the intrinsic properties of the active substance (propan-2-ol is volatile) and the intended uses, there is no potential for dust formation.

2.2.8.2 Exposure assessment

The GhostMedica Hand Sanitiser is a ready-to-use alcoholic based disinfectant product that contains up to 70% w/ w of the active substance propan -2-ol. Em issions to the environment were calculated using the following scenarios. All calcu lations were verified by the eCA and amended where deemed appropriate.

General information

Assessed PT	PT1 Hygienic handrub
Assessed scenarios	Scenario 1: Disinfectant used for hand application for privat e use Scenario 2: Disinfectant used for hand application, professional use in hospitals
ESD{s) used	Env ironment al Em ission Scenarios for biocides used as human hygiene biocidal products (Product type 1), European Commission DG ENV/ RIVM, January 2004 ENV 42 TAB Nov 2021 (applicabilit y date for products: 29/ 08/ 2018) : Which default values should be used for private hand disinfection? ENV 43 TAB Nov 2021 (applicability date for products: 29/08/ 2018): Which default values should be used for private and professional use - average consumption (i.e. consumption per application and number of applications of b.p. per day)?
Approach	Scenario 1 and 2: Average consumpt ion
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulat ion, Volume I V Environment - Assessment and Evaluat ion, (Parts B + C), Version 2.0, October 2017
Groundwat er simulat ion	The risk to groundwater was assessed qua litat ively by the Applicant . eCA performed confirmatory calculations with FOCUS PEARL. The calculations were based on the application rate resulting from emissions via sewage sludge and the deposition after volatilisation from air was not considered in the calculation (in accordance with ENV 188 TAB 2021). Accor ding to it em ENV 188 TAB 2021 (date of applicability for products: 19/ 12/ 2019), a risk assessment for products containing very volatile substances (as defined according to the voe Directive 2004/ 42/ CE) is not required for *subsequent* environmenta l comoartments followina the release oath via air.
Confidentia l Annexes	Yes { eCATonnage data-break-even point calculat ion)
Life cycle steps assessed	Production : No, manufacture / production of active substance takes place outside of the EU so no assessment required . Formulation: No, the formulation process takes place in a closed system with appropriate control measures to exclude the release of the active substance to the envir onment . Use: Yes, fo ll ow ing the ESD Service life: Yes, following the ESD
Remarks	Remark 1: The *"Commission Implementing Regulat ion (EU) 2015/2012 approving propan-2-ol as an existing active substance for use in biocidal products*

	of PT 1, 2 and 4" states the *"product assessment shall pay particular attention to the exposures and the risks linked to any uses covered by an application for authorisation, but not addressed in the EU level risk assessment of the active substance."* <u>Remark 2:</u> The BPC opinion (ECHA/BPC/013/2014) specifies the following elements should be taken into account when authorising products: • The EU active substance environmental exposure assessment is based on the distribution of releases between air and wastewater at a ratio of 90 % and 10 % for the representative product. During product authorisation it has to be re-evaluated if this distribution still holds for other product uses. • Using FOCUS PEARL for groundwater exposure assessment four safe scenarios are identified. During product authorisation the risks for groundwater have to be re-checked based on the respective decision of each Member State regarding the relevant scenarios for their countries. The environmental risk assessment addresses these remarks. The representative use in the EU environmental exposure assessment was skin and hand disinfectant in hospitals (Jan. 2015).

The tonnage and average consumption approaches are proposed for the environmental assessment for PT1 products. The advantages and disadvantages for each approach are discussed in the Workshop on environmental risk assessment for Product types 1 to 6 (European Commission, Italy, 2008). In the submission to the eCA the Applicant stated *"For the environmental risk assessment for GhostMedica Hand Sanitiser, the average consumption approach was preferred since precise figures on tonnages for the uses proposed are not available."* The eCA notes according to the Arona Workshop (2006) a comparison of tonnage and consumption based approaches are foreseen for PT1. After the calculation of a Break-Even-Point the worst case approach should be used. In the Applicant's submission only the consumption based approach is considered and estimated. This is discussed further by the eCA in the confidential section of this report.

Values used in Applicant's Emission estimation calculations- consumption based approach

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Symbol and remarks**
Scenario 1: Disinfectants used for hand aoolication for orivate use			
Type of end-produc t	Hand cream and ot her hand disinfect ants	-	Selected from ESD Table 4 .3 eCA considers the selection of *'hand cream'* as an end product to be inappropria te for a liquid based hand sanitiser.
Number of inhabitants feeding one STP	10,000	-	Nlocal, D
Fract ion released to wastewater	1	-	eCA notes EU CAR used a value of 0.1
Fraction released to air	0	-	eCA notes EU CAR used a value of 0.9
Active substance in biocidal product	700	g/ l	The eCA no t es the act ua l concentration of a.s. in the product is 70 % w/ w and the density of the product is ~ 0.8 g/ mL. See eCA evaluation of Scenario 1 for further details.
Conusmpt ion rate -Hand cream -Other hand other hand disinfect ants	1. 7 3	ml	ESD defaults 1. 7 ml was rejected by the eCA
Number of applications	3	d-1	Value selected by Applicant for both scenarios. 2 aool/ d is the Hand cream ESD defaul t
Fraction of inhabitants using product N	0.1	-	Value selected by Applicant for both scenarios. Value rejected by eCA and adjusted to 0.5 *(fo r* other hand disnfectants)[2]
Market share of disinfectant	0.5	-	Foenetr, D
Specific density of product	1,000	kg.m-3	RHOform, D eCA notes the density of the product is <<1 g/ mL
Scenario 2: Disinfectants used for hand application for professional use in hospitals			
Active substance chemical type	Alcohols	-	From ESD Table 3.8
Number of beds in model hospital	400	-	NbedSpres, D
Occuoancv rate	0.75	-	Foccuo,D
Fract ion released to wastewater	1	-	Fwater , D eCA note EU CAR used a value of 0.1
Fract ion released to air	0	-	Fair, D

2 According to ENV 42, TAB , ENv, Nov. 2021, (Date of applicability for products:29/08/2018) there are no data to underpin thedefault for Finh for private hand disinfection. It was agreed at WG-1-2015 that for the timebeing forFinh a default value of 0.2 should be used in case of soap and liquid soap hand disinfectant. For other hand disinfectarts for private use a default value of 0.5 should be used forFinh especially for leave-on products.

Input parameters for calculating the local emission			
Inout	**Value**	**Unit**	**Svmbol and remarks**
			eCA note EU CAR us ed a value of 0.9
Consum ption of active ingredient per present bed	15	g.d-1	Qsubstpres_bed, from ESD Table 3.8
Consumpt ion of active ingredient oer occuoied bed	20 .0	g.d-1	Qsubstoccup_bed, 0

D: Default; O: Output; S: Data set

Scenario 1: Disinfectants used for hand application for private use (non-professionals)

The Applicant has estimated environmenta l emissions arising from the (private) use of the GhostMedica hand sanitiser with the ESD PT l hand cream scenario and the scenario for other hand disinfectants. No default values are specified in the ESD or in the TAB for consumer based hand rubs (alcoholic disinfect ants). According to the Applicant *"a default consumption of 1. 7 mL with 2 daily applications are proposed for the privat e use for hand cream (see figure prov ided in the above table)" .* The Applicant has not ut ilised the default value (1 ml) for the *" liquid soaps, gels (washing hands)"* scenario presumably because the product is not used during hand washing. The use instructions state *"If the hands are visibly dirt y, wash them with soap and water."* This operation is performed prior to applying the GhostMedica Hand Sanitiser product. I n addition the Env ESD Spreadsheet *"PT1 -prof use-avrg consumpt"* picklist makes a distinction between *"Hand wash with soaps and liquid soaps"* category and *"hand rubs"* (for nursing staff) products. To consider a worst-case scenario, the applicant also considered a consumption rate of 3 ml with 3 daily applications. The eCA cons iders the consumption rate of 3 ml to be reasonable and more appropriate as a a consumption rate ranging from 1.5-3 ml is mentioned in the *"Recom mendat ion no. 1 of the BPC Ad hoc Work ing Group for other hand disinfectants Human Exposure Hand disinfection - PT 1 harmon isat ion of exposure det erm inants for professional users (2014)."* The eCA also notes a consumption rate of 1-3 g/ event is specified in the TAB (ENV 43 NOV 20 21) for the use of hand rubs by nursing staff.

I n relation to the frequeny of use, a report by the Austra lian Government on *" Hand Sanit iser in Australia Market insights"* July 2020 states *"at the end of April 2020, a survey of 1,022 consumers found t hat:*

- *84 per cent increaseduse of hand sanitiser outside the house*
- *86 per cent were using publicly provided hand sanitiser*

They were using hand sanitiser 3.4 times a day on average, but planned to reduce to 2.6 times a day when restrictions were lifted."

Although , th is is Austra lian data, it supports 3 daily applications and is considered realistic. The application frequency specified for hand rubs associated with *nursing* staff is considered too conservative (Napp =25 app per d) for private (non-professional) use. Given the margin of safety reported in *1.2.8 .3 Risk charact erisat ion* for the diff erent environmental compartments, an extreme application frequency of 10 app/ d for non

professional users would also result in acceptable risk quotients (PEC/PNEC <1) and groundwater concentrations (<0.1 µg/L).[3]

The Applicant has used a concentration of 700 g a.s./L in conjunction with a consumption rate of 3 mL in the emissions calculations. However, the actual concentration is 70% w/w. This should be used in conjunction with a consumption rate of 3 g/event. Although not strictly correct the Applicants approach is considered acceptable as both approaches result in the same amount of active substance consumed.[4]

The Appplciant calculated a STP emission rate of 3.15 kg a.s./d assuming the fraction of inhabitants (Finhab) using the hand sanitiser product (3 mL of biocidal product with 3 daily applications) is 0.1 and 100% of the product is emitted to the STP (Fpenet 0.5). The eCA considers the Finhab default value of 0.5 for *"other hand disinfectants"* to be more appropriate in this case (Technical Agreements for Biocides, Version 2.0, 2018) as the product is not a hand cream product[2] and is a leave-on product. The maximum value (0.8) specified in the ESD is for antiperspirants/Deodorant - stick, roll-on and is not applicable to the GhostMedica product.

The Applicant has used the ESD defaults of 100% for the release fractions to the STP. However, during the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the active substance (a.s.) is released to air and 10% of the a.s. is released to water. In case of the ready-to-use (RTU) products containing 70% w/w propan-2-ol, the disinfection is finished when the treated surface is completely dried, and the product has evaporated completely. This is facilitated by the relatively high vapour pressure of propan-2-ol (5,780 Pa at 25°C). In addition, the palmar hand temperature is reported to be 28.9 °C which would promote volatilisation. Nearly the whole amount of substance applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to waste water – via leakages or rinse off – cannot be excluded for liquid products. Therefore, for the environmental risk assessment of the GhostMedica hand sanitiser product the distribution used during the EU assessment of the active substance is maintained by the eCA, since it is plausible that the main emission path will be via air (Fair = 0.9). This is also consistent with the methodology adopted in a recent Union authorisation of a Propan-2-ol biocidal product family which had similar uses. This issue was also discussed during the (2015) consultation on default values for professional hand disinfection. Incorporating the adjusted emission factors the STP emission rate was calculated to be 1.575 kg a.s./d by the eCA. The corresponding emission rate to the air compartment is 14.175 kg/d.

3 PECs associated with an extreme application frequency of of <u>10 app/d</u> for non professional users (3 mL/app)

PECstp (mg L^{-1})	PECwater (mg L^{-1})	PECsed (mg kg^{-1})	PECsoil (mg kg^{-1})	MaxPECgw (µg L^{-1})
2.09E-01	2.09E-02	1.79E-02	3.03E-3	0.086 (Tier 2, FOCUS PEARL)

Via 700 g/L x 3 mL x 1 L/1,000 mL x 25 app/d x 10,000 PE x 0.5 inhab x 0.5(market penet) x 1 kg/1,000 g x 0.1

4 700 g a.s/1 L x 1 L/1,000 mL x 3 mL/event = 2.1 g a.s./event
70 g a.s./100 g prod x 3 g prod /event =2.1 g a.s./event

Scenario 2: Disinfectants used for hand application for professional use in hospitals

The product is intended to be used by nursing st aff and surgical staff. Using defaults values for an alcohol disinfectant the applicant calculated an emission rate of 6 kg a.s./ d for the STP compart ment (assuming 100% emission to the STP) arising from the use of the disinfect ant in hospitals (professional). However, due to volatilisation during hand disinfection, the active substance propan-2-ol is mainly released to the air compartment. Taking this into consideration the eCA has calculated an emission rate of 0.6 kg a.s./ d to the STP (FsTP 0 .1) . The corresponding emission rate to the air compartment is 5.4 kg/d.

Emission calculations for Scenario 1 - Hygienic handrub for direct application on $_{s}k^{n}$*m-pr,vate use*

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission {Elocalcompartment) [kg/ d]**	**Remarks**
STP/ Air	3.15#/ 0	**6ggli,i1Dl:i ,ilCLlliligo** Calcul ated for worst case assumption (3 ml consumption and 3 applications) Fwater = 1 by default . Fair = 0 by default Finhab 0.1 This calcul ation was rejected by the eCA
STP/ Air	1.575 # #/ 14.175	**eCA calculation (value to be used in risk assessment)** Calcul ated for worst case assumption (3 ml consumption and 3 applications) Fwater = 0.1. Fair = 0.9 Finhab 0.5

#via 700 g/l x 3 ml x 1 l/ 1,000 ml x 3 app/d x 10,000 PE x 0.1 inhab x 0.5 x 1 kg/1,000 g x 1

700 g/ l x 3 ml x 1 l/ 1,000 ml x 3 app/d x 10,000 PE x 0.5 inhab x 0.5(market penet) x 1 kg/1,000 g x 0.1

Scenario 2: Disinfectants used for hand application for *professional* use in hosoitals

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocalcompartment) [kg/ d]**	**Remarks**
STP/ Air	**6 .0 0/ 0**	**A1212licants calculation** Calculated based on average consumption per bed and consumpt ion per application Fwater = 1 by default. Fair = 0 by default This calculation overestimates surface water exposure
STP/ Air	**0 .6 # / 5 .4**	**i:t6 Cill,ulili52D (ltih.ui: tg bi: Ll:ii:d io Ci:ils i155 55Wi:Dtl** Calculated based on average consumption per bed and consumpt ion per application Fwater = 0.1. Fair = 0.9 **(EU CAR)**

Emission scenario for calculating the release of alcohol based disinfectants used for skin and hand application in hospitals based on average consumption and ESD defau lt values

Emission rate to wast ewater (st andard STP} for an *alcohol* based active susbtance chemical ty pe

A). Based on average consumption per bed

Elocalwater= N b edSpres '" Qsubstpres_bed '" 1-0 ^{3} ™ Fwater = 4 00 x 1 5 g a .s/ d bed(d efault) x 1-0 ^{3} kg/g x 0.1 = 0.6 kg/d

B) Based on consump tion per appli cat ion

Elocalwater =Nbedspres '" Foccup '" Qsubstoccup_bed '" 10-^{3} ™ Fwater = 400 x 0.75 x 20 g a.s/d bed x 10-^{3} x 0.1 = 0.6 kg/d

The ESD spreadsheet provides the option of calculating Qsubst for substances for which no default values are provided in the pick list of the ESD. This involves the consideration of nursing staff and/or surgical staff. This approach was not utilised in the current assessment as default values are provided for the alcohol active substance category.

Fate and distribution in exposed environmental compartments

The following scenarios have been identified based on the intended application of GhostMedica Hand Sanitiser.

I dentification of relevant receiving compartm ents based on the exposure , ath wav									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	**STP**	Air	Soil	Ground-water	Other
Scenario **1** Hygienic handrub for direct application on skin- private use Scenario 2 Disinfectants used for hand application for professional use in hospitals	Yes	Yes(ID)	No	No	Yes		Yes (ID)	Yes (ID)	---

ID = indirect route of exposure.

Environmental fate and behaviour

Propan -2-ol, is a secondary alcohol. It possesses no hydrolysable functional groups and is therefore resistant to hydrolysis. Propan -2-ol is not susceptible to direct photodegradation in sunlight as it exhibits no absorption between 290 nm and 750 nm takes place.

The Henry's Law constant for propan-2-ol is 0.80 Pa m^3/ mol at 25° C. It also has a relatively high vapour pressure (5,780 Pa at 25° C). Direct evaporation is expected. Any Propan -2-ol reaching the atmosphere will undergo reaction with OH radicals. The half-life in the air compartment is 3.1 days (AOPWin)

Propan -2-ol is expected to exhibit only weak adsorption in soils and sediments. The (QSAR) Organic carbon/ water partition coefficient of 3.3 L/kg suggests it is highly mobile in soil.

Propan -2-ol is classified as readily biodegradable. Default half-lives of 15 days for biodegradation in surface water and 300 days in sediment are assumed based on the readily biodegradable classification. The corresponding value for the soil compartment is 30 days. For elimination estimations in sewage treatment plants a rate constant of 1 h^{-1} was used. Input parameters (only set values) for calculating the fate and distribution in the environment specified in the EU assessment report for propan-2-ol are summarised in the table overleaf.

The distribution in the sewage treatment plant was calculated in the EU active substance assessment using SimpleTreat 3.0-model. These were recalculated by the Applicant and verified by eCA using Simple treat 4.0.

Calculated fate and distribution in the STP (12 °C)		
Compartment	**Percentage [%]**	**eCA Remarks**
Air	~ 0.274	Calculated with SimpleTreat 4 with the settings specified in the ENV9, TAB Env v2.1, 2019
Water	7.956	
Sludge	0.031	
Dearaded in STP	91. 74	

Input parameters {only set values) for calculating the fate and distribution of Propan-2-ol in the environment				
Input	**Value**	**Unit**	**Remarks**	**eCA validation check**
Molecular weiqht	60.09	a/mol		-../
Melt ina ooint	-89.5	oc		-../
B oil i nq ooint	82.5	oc	1013 hPa	-../
Vapour pressure (at 2 5 ° C)	5, 780	Pa	25 °C / 298 K	-../
Wate r solubility	---	ma / l		Miscible with water
Log Octanol/ water partition coefficient (Lo akow)	0.05	Log 10		-../
Kow	1.12	-		-../
Organic carbon/ water pa rt ition coefficient (Koc)	3.3	l/ kg		-../ Estimated by QSAR-model for alcohols described in EU TGD (2003)
Henry ' s Law Constant	0.80	Pa/m^3/mol (at 25° C)		-../ This equates 0.383 Pa/ m^3 / mol at 12°c
Biodegradabilit y	Ready biodegrad able			-../
DTso for biodegradation in surface water	No data	d or hr (at 12° C)		-../
DTso for hyd r o lysis in surface water	No hydrolysis			-../
DTso for phot olys is in surface water	No data	d or hr	Not applicable	-../
DTso for deg r adation in soil	No data	d or hr (at 12° C)	30 d default value based on biodeg. cl assification	-../
DTso for deg r adation in air	3.1	d	Assuming reaction with OH radicals (global 24 - hou r s mean), concentration: 5 x 10^5 OH/ cm^3)	-../

V = Va lues a re consis te nt wit h the Propan-2-ol Prod uct-Type 1 EU Assess me nt re port, Jan ua ry 2015

Calculated PEC values

$PEC_{surface\ water}$

The calculation of $PEC_{surface\ water}$ was conducted in line with the ECHA Guidance on Environment Risk (Version 2.0, October 2017). The following equations and default values were used for the PEC calculations:

$$Clocal_{inf} = \frac{E_{water} \times 10^6}{EFFLUENT_{STP}}$$

$$Clocal_{eff} = Clocal_{inf} \times F_{STP,water}$$

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION}$$

Where:

$Clocal_{inf}$ = concentration in untreated water (mg/l)
$Clocal_{eff}$ = PEC_{STP} = concentration of substance in the STP effluent (mg/l)
$EFFLUENT_{stp}$ = 2 x 10^6 L/d; default value
E_{water}= total emission to wastewater during episode (kg/d).
$F_{STPwater}$ = fraction emission directed to water by SimpleTreat
$Clocal_{water}$ = $PEC_{surface\ water}$ = local concentration in surface water during emission episode (mg/l)
Kp_{susp} = solids-water partitioning coefficient of suspended matter. This value was calculated as 0.33 L/Kg.
$SUSP_{water}$ = concentration of suspended matter in the river (default value: 15 mg/l)
DILUTION = dilution factor (default value: 10)

The indoor use pattern of GhostMedica Hand Sanitiser does not allow for direct exposure to surface waters, only the potential for indirect exposure via an STP. Therefore, the local concentration arising from the indirect emission to a watercourse via the STP was calculated taking into account dilution and the removal to suspended sediments.

The concentration of propan-2-ol in bulk sediment can be derived from the corresponding water body concentration assuming thermodynamic partitioning equilibrium (EPM), as follows:

$$PEClocal_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \times PEClocal_{water} \times 1000$$

Where:
Ksusp-water = suspended matter-water partition coefficient. This parameter was calculated as 0.983 m^3/m^3 using Equation 27 of the ECHA guidance document on environment risk assessment (Version 2.0, 2017).
RHO= bulk density of (wet) suspended matter = 1,150 kg/m^3 (default value).

eCA PECs ansmg mt he STP and aquatic compartments from th e mtended uses

Scenario	Elocal water (kg/d)	Clocal;nt [mg/L]	PECsTP (Clocalett) [mg/L]	P ECsurface water (Clocalwater) [mg/L]	PECsed [mg/ kQwwt]
Scenario 1 Hygienic handrub for direct application on skin- pr ivate use	1.575	7.88 E- 1	6.27E-02	6. 27E-0 3	5.36 E-03
Scenario 2 Disinfectants used for hand application for professional use in hospitals	0 .6	3.00E-01	2.39 E-02	2.39E-0 3	2.04 E-03

N o t e - T hese PECs are conservative as they exclude volatilisation processes and air deposition flu x through D.,,. Fwater = 0.1

Applicant PECs arising in the STP and aquatic compartments from the intended uses *(for* comparison purposes onlv)

Scenario	Elocal water (ka/dl	Clocal;nt [mg/L]	PECsTP (Clocalett) [ma/LI	PEC surfacewater (Clocalwater) [ma/LI	PEC sed [mg/kQwwt]
Scenario 1	3.15	1. 58	0 .125	0.0125	0.0102
Scenario 2	6.00	3 .00	0 .239	0.0239	0.0195

Fwater = 0.9
The eCA ob tained sl ightly diff erent values for the sediment compartment: 0.0107/ 0.0204 mg/ kg wwt for scenario 1 and 2 respectively. This is because the applican t used a suspended matt er-water partitioning coefficient of 0.938 m^3/m^3 instead of 0.983 m^3/m^3

The PECs estimat ed by the Applicant for the aquatic compart ment are higher. This is because they utilised the default assumption of 100% emission to the STP. Although not *strictly* correct these PECs can be used in the aquatic risk assessment {Tier 1) as they overestimate exposure and do not tr igger risk mitigation measures.

PECsoil

The product is not applied directly to soil, but it may indirectly reach soil via application of sewage sludge in agriculture or via deposition from the atmosphere. During the WG ENV I V 20 19 it was agreed that for products containing volatile alcohols being used in small-scale applicat ions, there is no need to conduct a risk assessment of the subsequent environmental compart ments following the release path via air (te rrestr ial compart ment) (see also ENV 188, TAB Nov 2018). As the vapour pressure of propan-2-ol is very high, indicating a high rate of volatilization, no PEC needs to be calculated for soil as a subsequent environmental compartment following release via air. In addition, based on the non- adsorpt ive propert ies of propan-2-ol, the distribution in the STP resu lts in a negligible concentration of propan-2-o l in sewage sludge {0.03%, Koc is 3.3 L/kg). Propan -2-ol is also readily biodegradable. For completeness the eCA has presented the PECs arising in soil from sludge applications. No soil PECs were provided by the applicant.

eCA PECs arising in soil (via STP sludge) from the intended uses

Scenario	Elocal water (ka /d)	PECini soil (mg/ kg wwt)	TWA PEC soil (ma/ ka wwt)
Scenario 1 Hygien ic handrub for direct application on skin-private use	1.575	9.09E-04	6.56 E-04
Scenario 2 Disinfectants used for hand application for professional use in hospitals	0.6	3.46E-04	2.50 E-04

Fwater = 0.1

The soil PECs have been conservat ively calculated as volatilisation processes, leaching processes and the air deposition flux through Dair were switched off . I ncluding the deposit ion flux does not affect the soil PECs in this case.

PECgroundwater

Groundwater is a secondary compartment exposed after the active substance reaches the soil. Since no direct exposure to soil is likely due to the intended use as a hand sanitiser, exposure of groundwater via the soil is not expected. The eCA notes according ENV 188, TAB Nov 2018)

"products containing very volatile substances (according to the VOC directive) used in genera l, i.e. it is not distinguished between professionals and non-professionals, there is no need to conduct a risk assessment for subsequent environmenta l compartments following the release path via air. This conclusion concerns all relevant PTs. Specif icall y for the subsequent environmenta l compartment groundwater it should be further noted that exceedance of the groundwater trigger value is not likely."

This statement was made in reference to products that have an air release pathway (i. e. Fair 0.9, Fwater 0.1, such as propan-2-o l). This was confirmed by the eCA us ing FOCUS PEARL 4.4.4 for the realistic worst case scenario (i.e scenario 1) using the methodology described described in the TAB, (ENV 36 Technical Agreements for Biocides (TAB) - ENV Release date: 9 November 2021). [5] The 80th percentile annual average concentrat ion is predicted to be less than 0.1 µg/ L (EU tr igger value) at 1m depth for all FOCUS scenarios.

PEC Air

According to the CAR

"The main emission pathway during application step of the b.p. will be via air, because the substance 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 without deposition indoors. The exact distribut ion between air and waste water is not known, but as a reasonable worst-

5 I ,000/ 5,000 kg sludge/ha grassland (alfalfa)/ maize, 10/ 20 cm incorporation, 1st March/20 d before emergence respectively. The concentration in dry sewage sludge (Csludge)associated with scenario 1 and 2 respectively was 6.18 x 10^{-1} 2.18 x 10^{-1} mg/kg dwt respectively

Via Csludge =Elocalwater(kg/ d) x 10^{6} mg/kg x Fstpsludge/ 790 kg sludge /d)

case it is assumed that 90 % of a.s. 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. Therefore, the active substance propan-2-ol has a potential for long-range environmental transport referring to the Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): " ... a chemical that migrates significantly through the air, its half-life in air should be greater than two days ... ". On the other hand, according to the EU TGD on Risk Assessment, Part II, chapter 3. 7 .2 (2003) effects on stratospheric ozone and acidification are not expected because propan-2-ol does not contain halogens, nitrogen or sulphur substituent and propan-2-ol is not listed as a substance of concern in the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer……. No quantitative characterization of risk by comparison of the PECair to PNECair is possible. A chemical may be dangerous for the atmospheric environment at a low concentration, if it is classified as R48 ("Danger of serious damage to health by prolonged exposure"). This classification does not apply to propan-2-ol. Furthermore, inhalation studies with mammals can be used as indicators of adverse effects of volatile compounds on animals."

PECs arising in the air compartment from the intended use are summarised below

eCA PECs arising in the air compartment from the intended uses

Scenario	Etotal (kg/d)	Eair direct (kg/d)	Eair via STP (kg/d)	E(kg/d) total	Total Annual average concentration in air at 100 m from source (mg/m^3)#
Scenario 1 Hygienic handrub for direct application on skin-private use	15.75	14.175	0.043155	14.218	3.95E-03
Scenario 2 Disinfectants used for hand application for professional use in hospitals	6	5.4	0.01644	5.416	1.51E-03##

Fair 0.9 Fair STP =~0.274

Assumes STP air emission overlaps with direct emissions to air shortly after application.

Concentration in air = Eair (kg/d) x 2.78 x10^{-4} mg/m^3 /1 kg/d x 365 app yr^{-1}/365 d yr^{-1}

Standard concentration in air at 100 m from source for source strength of 1 kg/*d* = 2.78 x10^{-4} mg/m^3 (default)

Assumes 365 emission days and no degradation.

Risk assessment for metabolites

According to the CAR document for propan-2-ol (Rapporteur: Germany, 2015), no metabolites were identified in any of the relevant environmental compartments. Therefore, no further consideration is required.

SoC

Environmental substances of concern (SOCs) requiring inclusion in the risk assessment have not been identified.

Primary and secondary poisoning

Propan-2-ol is not expected to accumulate in the environment given the low estimated BCF values in aquatic and terrestrial indicator species (BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww). Therefore, the risk of primary and secondary poisoning is assumed to be negligible via ingestion of contaminated food by birds or mammals.

Aggregated environmental exposure assessment

The EU PT 1 Assessment report (Jan 2015) did not perform an aggregate exposure assessment. Instead it stated

"Propan-2-ol is notified for Annex I inclusion in PT 1, 2, and 4. For all mentioned PTs, DE is RMS. The respective CA reports consider the following uses: PT 1 - skin and hand disinfectant in hospitals; PT 2 - disinfection of rooms, furniture and objects in the sanitary sector; PT 4 - assessment of small-scale applications (spraying of surfaces) / industrial kitchens / meat processing industry. As b.p. containing propan-2-ol are used in a wide dispersive way an aggregated environmental exposure assessment may be reasonable. According to the "Decision tree on the need for estimation of aggregated exposure" (BIP6.7 Decision Tree Agg Expo), the requirement for aggregated exposure estimations was checked for propan-2-ol. 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."

This statement is equally applicable to the GhostMedica product. Hence, an aggregated environmental exposure assessment is not required.

2.2.8.3 Risk characterisation

Atmosphere

According to the CAR, *"A $PNEC_{air}$ cannot be derived, but acute and subchronic inhalation studies with rats can be used as indication of adverse effects of chemicals on species arising from atmospheric contamination. Available results of these studies reveal that effect values are clearly above the environmental concentration in air. Therefore, no adverse effects on terrestrial organisms (mammals) are expected. As there are no studies on honeybees or terrestrial plants available, effects on these organisms cannot be assessed."*

The highest PEC air **0.00395 mg/m3**, derived based on the professional use (scenario 2). Based on the available rat inhalation studies presented in the CAR document for propan-2-ol, the adverse effects of propan-2-ol are observed at concentrations equal or higher to 17100 mg/kg bw (**47.500 mg/m³ air** for 8h; whole body vapour). Based on this, no adverse effects on mammals are expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/ PNEC values	
	PEC/ PNECsTP
Scenar io 1	6.27 E-0 3
Scenar io 2	2.39 E-0 3

Conclusion: As the PEC/PNEC values are less than 1, an acceptable level of risk to STP is predicted from the two application scenarios.

Aquatic compartment

Summary table on calculated PEC/ PNEC values				
	PEC/ PNECsurtace water	**PEC/ PNECsed**	PEC / PNEC seawatre	**PEC/ PN**ECseased
Scenar io 1	2.22E-03	2.22 E-03	N/A	N/ A
Scenar io 2	8.48E-0 4	8. 46E-0 4	N/A	N/ A

Conclusion: As the PEC/ PNEC values are less than 1, an accept able level of risk to the aquatic compart ment is predict ed fr om the two application scenarios.

Soil compartment

Summary table on calculated PEC/ PNEC values	
	PEC/ PNECsoil
Scenar io 1	1.3 2E-0 3
Scenar io 2	5. 04E-0 4

Conclusion: As the PEC/ PNEC values are less than 1, an acceptable level of risk to soil compart ment is predict ed from the two application scenarios.

Primary and secondary poisoning

The risk characterisation for primary and secondary poisoning is not required given that propan-2-ol is not expected to accumulate in the environment (see above explanation for further details).

Mixture toxicity

As this product contains only one active substance, there is no need to perform a "multiple active" assessment. However, the presence of any relevant "Substances of Concern" in the formulation must be considered for any contribution they may give to overall environmental risk.

[redacted] the risk assessment for the environment is based only on the properties of the active substance for propan-2-ol as reported in the CAR. Therefore, no further consideration is required.

Aggregated exposure (combined for relevant emission sources)-risk assessment

Not required. Accord ing to the " Decision t ree on the need for estimation of aggregated exposure" (refer to Guidance BPR IV ENV Part B+C {20 17)) shown in Figure 1, an aggregated exposure assessment is not required for the biocidal product " GhostMedica" containing propan-2-ol as active substance.
Please refer to the " Aggrega ted environmental exposure assessment" section.

PST-Assessment

No new data were provided by the applicant. Thus, the conclusions for the PBT assessment are based on the results of the PBT assessment, which was performed with in the frame of the evaluation of the active substance propan-2-o l. Accordingly, propan-2-ol thus neither fulfils the PBT- nor the vP/ v B- criteria .

Endocrine disrupting properties

According to the CAR for pro pan-2-ol, there are no indications for endocrine disrupt ing properties of the active substance. However, a comprehensive ED-assessment for the active substance according to Regu lat ion 2017 / 21 00 and the EFSA/ ECHA guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the products of the BPF as well as the results of the ED-assessment of the co-formu lants are summarised in the ,,Confiden tial Annex.doc".

Overall conclusion on the risk assessment for the environment of the product
The environmental risk was determined to be acceptable for all exposure scenarios considered for the application of GhostMedica Hand Sanitiser. It *can* be concluded that the use of GhostMedica Hand Sanitiser will not pose a risk to non-target organisms. Therefore, no further consideration is required.

2.2.9 Measures to protect humans, animals and the environment

Please see Section 2.1. 4.

2.2.10 Assessment of a combination of biocidal products

Not applicable, as GhostMedica Hand Sanitiser is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

The biocidal product contains Propan -2-ol which does not meet the conditions laid down in Art icle 10(1) of Regulation (EU) No 528/ 2012 and is not considered as a candidate for substitut ion. Therefore, a comparat ive assessment of the biocidal product is not required.

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

The biocidal product does not contain any active substances having endocrine-disrupting properties. Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

2.3.1 Available toxicological data relating to endocrine disruption

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

3 ANNEXES

3.1 List of studies for the biocidal product (family)

Studies for the biocidal product are underway. The below list provides references to the study plans.

Section No/ Reference No	Author(s)	Year	Title	Data Protection (Yes/No)	Owner
2.2.2	Nichetti, S.	2021a	GHOSTMEDICA: Determination of the Physico-chemical Properties ChemService S.r.l. Report no. CH-0180/2021	Yes	Professional Hair Products Ltd.
2.2.2	Nichetti, S.	2021b	GHOSTMEDICA: Determination of the Accelerated Storage Stability and Corrosion Characteristics ChemService S.r.l. Report no. CH-0182/2021	Yes	Professional Hair Products Ltd.
2.2.2	Nichetti, S.	2021c	GHOSTMEDICA: Two-Year Storage Stability and Corrosion Characteristics [study plan] ChemService S.r.l. Study no. CH-0183/2021	Yes	Professional Hair Products Ltd.
2.2.4	Nichetti, S.	2021d	GHOSTMEDICA: Validation of the Analytical Method for the Determination of the Active Ingredient Content ChemService S.r.l. Report no. CH-0181/2021	Yes	Professional Hair Products Ltd.

Section No/ Reference No	Author(s)	Year	Title	Data Protection (Yes/No)	Owner
2.2.5	Barrett, A.	2021a	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step 1) Microbiological Solutions Ltd Test reference: J002861 (BS EN 14476:2013+A2:2019)	Y	Professional Hair Products Ltd.
2.2.5	Barrett, A.	2021b	Quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2 Step 1) Microbiological Solutions Ltd Test reference: J002861 (BS EN 1276:2019)	Y	Professional Hair Products Ltd.
2.2.5	Barrett, A.	2021c	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (Phase 2, Step 1) Microbiological Solutions Ltd Test reference: J002861 (BS EN 1650:2019)	Y	Professional Hair Products Ltd.
2.2.5	Barrett, A.	2021d	Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2) Microbiological Solutions Ltd Test reference: J002861 (BS EN 1500:2013)	Y	Professional Hair Products Ltd.

Section No/ Reference No	Author(s)	Year	Title	Data Protection (Yes/No)	Owner
2.2.5	Barrett, A.	2021e	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) Microbiological Solutions Ltd Test reference: J002861 (BS EN 13727:2012+A2:2015)	Y	Professional Hair Products Ltd.
2.2.5	Barrett, A.	2021f	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – (phase 2, step 1) Microbiological Solutions Ltd Test reference: J002861 (BS EN 13624:2013)	Y	Professional Hair Products Ltd.

3.2 Output tables from exposure assessment tools

The inputs and outputs from ConsExpo exposure assessment tool are shown in the following tables.

Scenario 1: Adult professional (30 -40 y)

Adult Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides adult	
Body weight	60	kg

Scenario [1] Adult prof direct		
Frequency	25	per day
Description		
Inhalation		
Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	1	minute
Product in pure form	No	
Molecular weight matrix		
The product is used in dilution	No	
Product amount	2.4	g
Weight fraction substance	70	%
Room volume	80	m^3
Ventilation rate	1.5	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	No	
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario [1] Adult prof direct		
Inhalation		
Mean event concentration	20.7	mg/m^3
Peak concentration (TWA 15 min)	20.7	mg/m^3
Mean concentration on day of exposure	0.36	mg/m^3
Year average concentration	0.36	mg/m^3
External event dose	0.0072	mg/kg bw
External dose on day of exposure	0.18	mg/kg bw

Scenario 2: Adult Non-professional (30 -40 y)

Scenario [2] Adult non-prof direct			
Frequency	3	25	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Instantaneous release	Exposure to vapour - Instantaneous release	
Exposure duration	1	1	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	No	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	20	20	m³
Ventilation rate	0.6	0.6	per hour
Inhalation rate	1.25	1.25	m³/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [2] Adult non-prof direct			
Inhalation			
Mean event concentration	83.6	84	mg/m³
Peak concentration (TWA 15 min)	83.6	84	mg/m³
Mean concentration on day of exposure	0.174	1.5	mg/m³
Year average concentration	0.174	1.5	mg/m³
External event dose	0.029	0.029	mg/kg bw
External dose on day of exposure	0.0871	0.73	mg/kg bw

Scenario 2a Children: 6-12 years old, bw 23.9kg.

Children (6-12 y) Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides Child (6-12 years)	
Body weight	23.9	kg

Scenario [2a] Child (6-12y)				
Frequency	3	12	25	per day
Description				
Inhalation				
Exposure model	Exposure to vapour - Instantaneous release			
Exposure duration	2	2	2	minute
Product in pure form	No	No	No	
Molecular weight matrix				
The product is used in dilution	no	no	no	
Product amount	2.4	2.4	2.4	g
Weight fraction substance	70	70	70	%
Room volume	20	20	20	m^3
Ventilation rate	0.6	0.6	0.6	per hour
Inhalation rate	1.32	1.32	1.32	m^3/hr
Limit concentration to saturated air concentration	No	No	No	
Absorption model	n.a.	n.a.	n.a.	
Dermal				
Exposure model	n.a.	n.a.	n.a.	
Absorption model	n.a.	n.a.	n.a.	
Oral				
Exposure model	n.a.	n.a.	n.a.	
Absorption model	n.a.	n.a.	n.a.	
Results for scenario [2a] Child				
Inhalation				
Mean event concentration	83	83	83	mg/m^3
Peak concentration (TWA 15 min)	83	83	83	mg/m^3
Mean concentration on day of exposure	0.35	1.4	2.9	mg/m^3
Year average concentration	0.35	1.4	2.9	mg/m^3
External event dose	0.15	0.15	0.15	mg/kg bw
External dose on day of exposure	0.46	1.8	3.8	mg/kg bw

Scenario 2a Children: Toddler 1-2 years old, BW 10Kg

Children (toddler 1-2y) Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides toddler (1-2 years)	
Body weight	10	kg

Scenario [2a] Child (toddler 1-2y) primary			
Frequency	3	25	per day
Description			
Inhalation			
Exposure model			
Exposure duration	~~1~~ 3	3	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	No	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	20	20	m³
Ventilation rate	0.6	0.6	per hour
Inhalation rate	1.26	1.26	m³/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [2a] Child (toddler 1-2y) primary			
Inhalation			
Mean event concentration	82.8	83	mg/m³
Peak concentration (TWA 15 min)	82.8	83	mg/m³
Mean concentration on day of exposure	0.517	4.3	mg/m³
Year average concentration	0.517	4.3	mg/m³
External event dose	0.521	0.52	mg/kg bw
External dose on day of exposure	1.56	4.4	mg/kg bw

Scenario 3: adult bystander after professional use

Adult Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides adult	
Body weight	60	kg

Scenario [3] Adult prof secondary			
Frequency	4	25	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Instantaneous release	Exposure to vapour - Instantaneous release	
Exposure duration	1	1	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	No	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	80	80	m^3
Ventilation rate	1.5	1.5	per hour
Inhalation rate	1.25	1.25	m^3/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [3] Adult prof secondary			
Inhalation			
Mean event concentration	20.7	21	mg/m^3
Peak concentration (TWA 15 min)	20.7	21	mg/m^3
Mean concentration on day of exposure	0.0576	0.36	mg/m^3
Year average concentration	0.0576	0.36	mg/m^3
External event dose	0.0072	0.0072	mg/kg bw
External dose on day of exposure	0.0288	0.18	mg/kg bw

Scenario 4: adult bystander after non-professional use

Adult Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides adult	
Body weight	60	kg

Scenario [4] Adult non-prof secondary			
Frequency	3	25	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Instantaneous release	Exposure to vapour - Instantaneous release	
Exposure duration	1	1	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	No	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	20	20	m³
Ventilation rate	0.6	0.6	per hour
Inhalation rate	1.25	1.25	m³/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [4] Adult non-prof secondary			
Inhalation			
Mean event concentration	83.6	84	mg/m³
Peak concentration (TWA 15 min)	83.6	84	mg/m³
Mean concentration on day of exposure	0.174	1.5	mg/m³
Year average concentration	0.174	1.5	mg/m³
External event dose	0.029	0.029	mg/kg bw
External dose on day of exposure	0.0871	0.73	mg/kg bw

Scenario 4a Children (toddler): 1-2 years old

Children (toddler 1-2y) Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides toddler (1-2 years)	
Body weight	10	kg

Scenario [4a] Child (toddler) Secondary			
Frequency	3	25	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Instantaneous release	Exposure to vapour - Instantaneous release	
Exposure duration	1	1	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	No	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	20	20	m³
Ventilation rate	0.6	0.6	per hour
Inhalation rate	1.26	1.26	m³/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [4a] Child (toddler) Secondary			
Inhalation			
Mean event concentration	84	84	mg/m³
Peak concentration (TWA 15 min)	84	84	mg/m³
Mean concentration on day of exposure	0.17	1.5	mg/m³
Year average concentration	0.18	1.5	mg/m³
External event dose	0.521	0.18	mg/kg bw

External dose on day of exposure	0.53	4.4	mg/kg bw

Scenario 4a Children: 6-12 years old.

Children (6-12 y) Exposure Scenarios		
Substance Name	Propan-2-ol	
CAS Number	67-63-0	
Molecular weight	60.1	g/mol
KOW	0.05	10Log
Product Name	GhostMedica Hand Sanitiser	
Weight fraction substance	70	%
Population Name	EU framework Biocides Child (6-12 years)	
Body weight	23.9	kg

Scenario [4a] Child (6-12y) Secondary			
Frequency	3	25	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Instantaneous release	Exposure to vapour - Instantaneous release	
Exposure duration	1	1	minute
Product in pure form	No	No	
Molecular weight matrix			
The product is used in dilution	no	No	
Product amount	2.4	2.4	g
Weight fraction substance	70	70	%
Room volume	20	20	m³
Ventilation rate	0.6	0.6	per hour
Inhalation rate	1.32	1.32	m³/hr
Limit concentration to saturated air concentration	No	No	
Absorption model	n.a.	n.a.	
Dermal			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Oral			
Exposure model	n.a.	n.a.	
Absorption model	n.a.	n.a.	
Results for scenario [4a] Child (6-12y) Secondary			
Inhalation			
Mean event concentration	84	84	mg/m³
Peak concentration (TWA 15 min)	84	84	mg/m³
Mean concentration on day of exposure	0.17	0.15	mg/m³
Year average concentration	0.17	0.15	mg/m³
External event dose	0.077	0.077	mg/kg bw

External dose on day of exposure	0.23	1.9	mg/kg bw

3.3 New information on the active substance

No new information is presented.

3.4 Residue behaviour

Not relevant. The intended uses of GhostMedica Hand Sanitiser are not expected to lead to contamination of food and feedstuff.

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

Efficacy studies are summarised in Section 2.2.5 and the IUCLID file.

3.6 Confidential annex

See below.

3.7 Other

No other information is presented

Confidential annex

[redacted]