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

REDACTED PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ECOLAB UA BPF 1-PROPANOL

Product type 1

Propan-1-ol

Case Number in R4BP: BC-RS050191-24

Evaluating Competent Authority: Sweden

Date: 05/04/2022

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1 CONCLUSION

[For Union Authorisation, the evaluating CA should provide a draft BPC opinion for the Union authorisation application as the conclusion.]

General

The biocidal products of the family ECOLAB UA BPF 1-PROPANOL are hand disinfectants (PT1) intended for professional use in settings like food and beverage processing areas (industry, institutional and hospital kitchen areas). The products are ready-to-use leave on disinfectants with a concentration range of 70 – 75 % w/w. pure active substance (70.35-75.38 technical).

Physico-chemical properties

All physical and chemical properties were adequately addressed.

The product family consists of clear and colourless non-viscous liquids. The ambient temperature storage stability study supports a shelf-life of 4 years in packaging type applied for (HDPE bottles). The products are to be stored at 0 °C to 25 °C

Further requirements for storage:
Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep container tightly closed. Store in suitable labelled containers.

According to the CLP criteria regarding physical hazards, the product family is classified as flammable liquids category 3 (H226: Flammable liquid and vapour). The products do not have oxidising properties and they are not explosive, self-heating, self-reactive or corrosive to metals.

A GC-FID analysis method is presented to monitor the concentration of the active substance in the products. No other methods, for relevant impurities or substances of concern, are necessary.

Efficacy

The product has been assessed using the Guidance on the Biocidal Products Regulation Efficacy - Assessment and Evaluation (Parts B+C) 2018 version 3.0. The product was shown to be bactericidal, yeasticidal, tuberculocidal, virucidal against enveloped viruses and viruses (limited spectrum virucidal activity).

The product was shown to be efficacious with a contact time of 30 seconds in all tests except limited spectrum virucidal where a contact a time of 60 seconds was needed.

Human health

General information:
The human health risk assessments were conducted with the highest concentration of this product family (75%) of the active substance propan-1-ol, listed in the Union list of approved active substances under Regulation No. 528/2012.

Propan-1-ol can cause serious eye damage, may cause drowsiness or dizziness and repeated exposure may cause skin dryness or cracking. None of the co-formulants are classified. Read-across for dermal absorption to the propan-2-ol CAR was accepted among member states during an e-consultation (SE e-consultation WG dec 2020).

The products within the biocidal product family do not contain any substances of concern and no endocrine disrupting effects were identified within the product family.
Hand disinfection products from this product family is limited to industrial and professional uses only.

Professional user/ industrial user
Primary exposure to professional use of hand disinfection occurs through dermal absorption when rubbing the substance to the skin (hand), maximum 10 times per day. Secondary exposure occurs via inhalation, since propan-1-ol is highly volatile. The exposure assessment of uptake both via skin and inhalation resulted in an exposure below the AEL (long-term) of 9.2 mg/kg bw/day.

A local qualitative risk assessment was performed due to the intrinsic properties (eye damage) of propan-1-ol. During application of the hand disinfection product no contact of the eyes is expected, however during re-filling of bottles eye protection is required. The product is not classified for skin irritation but the supplemental label phrase EUH066: Repeated exposure may cause skin dryness or cracking, has been added in line with both the CAR and the BPC opinion.

The identified risks can be handled through the following RMM:
- Avoid contact with the eyes
- If refilling is needed, gloves and eye protection should be used

In case of skin dryness, use appropriate skin care lotion

Based on the summary above, the use of the Ecolab product family, following the instructions for use and applied RMM, is considered safe.

Environment

The Ecolab biocidal product family contains propan-1-ol as the only active substance and no substances of concern have been identified. Mixture toxicity is therefore not relevant.

Based on a quantitative risk assessment the biocidal product family can be concluded to present no unacceptable risks for the sewage treatment plant, surface water, sediment, soil compartment, or the atmosphere.

Based on the guidance provided in the Technical Agreements for Biocides Environment (ENV) July 2021, ENV 188, the use pattern of the biocidal product family and the properties of propan-1-ol, it can be concluded that exposure to groundwater will be negligible.

The risks of primarily and secondary poisoning of non-targets organisms is assumed to be negligible due to the intended use as a hand disinfection product, and the low estimated BCF values in aquatic and terrestrial indicator species.

Based on the summary above, the use of the Ecolab biocidal product family, present no unacceptable risk for the environment.

Endocrine disruption

It has been concluded that neither the active substance nor any of the co-formulants in the ECOLAB UA BPF 1 are considered to be endocrine-disrupting substances, hence the products of the ECOLAB UA BPF 1-PROPANOL are not endocrine disruptors.

Overall Conclusion

The SE eCA concludes that the evaluation has shown that sufficient data have been provided to permit the authorisation of the ECOLAB UA BPF 1-PROPANOL for professional and industrial use as hand disinfection for food and beverage processing areas.

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)**
P3-Manodes LI	All EEA countries (Union Authorisation)
Manodes LI	
Epicare DES	
Skinman Sensitive	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	ECOLAB Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Pre-submission phase started on	12 March 2018	
Pre-submission phase concluded on	24 April 2018	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7, 8304 Walliselen, Switzerland
Location of manufacturing sites	All manufacturing sites listed are producing for Ecolab Europe GmbH

A.F.P. GmbH	A.F.P. GmbH Otto-Brenner-Straße 16, 21337 Lüneburg Germany
ACIDEKA	ACIDEKA S.A. Edificio Feria. Capuchinos de Basurto 6, 4a planta 48013 Bilbao. Bizkaia Spain
ADIEGO HNOS	Adiego CTRA DE VALENCIA, KM 5,900 5041 CUARTE DE HUERVA ZARAGOZA Spain
ALLIED PRODUCTS	Allied Hygiene Limited, Unit 11, Belvedere Industrial Estate Fishers Way, Belvedere Kent, DA17 6BS United Kingdom
ARKEMA GMBH	Arkema GmbH Morschheimer Strasse 19 D-67292 Krichheimbolanden Germany
AZELIS DENMARK	Lundtoftegårdsvej 95 2800 Kgs. Lyngby Denmark

BELINKA-LJUBLJANA	Belinka Zasavska Cesta 95 1001 Ljubljana Slovenija
Bentus Laboratories Lt	BENTUS LABORATORIES LTD. RUSSIA, 105005, MOSCOW, RADIO STREET, 24 BLD.1, RUSSIA
BIO_PRODUCTIONS Lt Inc STAPRO	BIO PRODUCTIONS, 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE, BURGESS HILL, WEST SUSSEX, RH15 9LH UNITED KINGDOM
BIOXAL SA	Route des Varennes - Secteur A – BP 30072 71103 Chalon sur Saône Cedex FRANCE
BORES S.R.L.	Bores Srl Via Pioppa, 179 44020 Pontegradella Italy
BRENNTAG Ardennes	BRENNTAG ARDENNES Route de Tournes C n 2 FR-08090 Cliron France
BRENNTAG CEE - GUNTRAMSDORF	Brenntag CEE GmbH Mixing / Blending Bahnstr. 13 A-2353 Guntramsdorf Austria
BRENNTAG Duisburg	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Glauchau	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Hamburg	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Heilbronn	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Kaiserslautern	Brenntag Merkurstr. 47 67663 Kaiserslautern Germany
BRENNTAG Kleinkarlbach	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Lohfelden	Brenntag GmbH Humboldtring 15 45472 Muehlheim Germany
BRENNTAG Nordic - HASLEV	Høsten Teglværksvej 47, 4690 Haslev, Denmark
BRENNTAG Nordic - VEJLE	Brenntag Nordic Vivaa Denmark
BRENNTAG Normandy	Brenntag Normandie 12 Sente des Jumelles - BP 11 76710 Montville France
BRENNTAG PL -Zgierz	ul. Kwasowa 5 95-100 Zgierz Poland
BRENNTAG Quimica - Madrid	Brenntag Quimica S.A. - Madrid Calle Gutemberg nº 22, Polig. Industrial El Lomo 28906 Getafe (Madrid), Spain

BRENNTAG Schweizerhall	Brenntag Schweizerhall AG Elsaesserstr. 23 CH-4056 Basel Switzerland
Brenntag SRL	Str. Garii nr 1 077040, Chianjna, Ilfov Romania
Budich International GmbH	Budich International GmbH Dieselstrasse 1(32120 Hiddenhause Germany
Caldic Deutschland Chemie B.V	Caldic Deutschland GmbH & Co.Kg Am Karlshof 10 D 40231 Duesseldorf GERMANY
CARBON GROUP	The Carbon Group Ringaskiddy County Cork Ireland
COLEP BAD SCHMIEDEBERG	Colep CCL Bad Schmiedeberg GmbH Kemberger Str. 3 06905 Bad Schmiedeberg Germany
COMERCIAL FARMACEUTICA CASTEL: LANA, S.A.	COMERCIAL FARMACEUTICA CASTEL: LANA S.A. "COFARCAS" Condado de Treviño, 46 P.I. Villalonquejar 09080 – BURGOS Spain
COMERCIAL GODO	COMERCIAL GODO França, 13 08700 – IGUALADA (BARCELONA) Spain
COURTOIS SARL	ZA SOUS LE BEER Route de Pacy 27730 BUEIL France
DAN MOR (DR WIPE)	DAN-MOR Natural Products and Chemicals Ltd. Or Akiva Industrial Zone 30600, Israel
Denteck BV	Heliumstraat 8, 2718 SL Zoetermeer ZOETERMEER Netherlands
DETERGENTS BURGUERA	DETERGENTS BURGUERA, S.L. Joan Ballester, 50 07630 – CAMPOS (ILLES BALEARES) Spain
Donauchem Kft Hungary	H-1225 Budapest, Bánvalég utca 37-43
Champion Technologies Aberdeen	Champion Technologies Ltd., Minto Avenue, Altens Industrial Estate, Aberdeen AB12 3JZ UK
ECL Biebesheim	NLC Biebesheim Justus-von-Liebig-Straße 11, 64584 Biebesheim am Rhein, Germany
ECL Châlons	AVENUE DU GENERAL PATTON 51000 CHALONS EN CHAMPAGNE, FRANCE
ECL Cisterna	Nalco Italiana Manufacturing Srl. Via Ninfina II Cisterna di Latina, Italy 04012
Champion Technologies Ltd - Fawley	Fawley Cadland Road, Hythe, Southampton Hampshire SO45 3NP, United Kingdom

ECL Leeds	ECOLAB Lotherton Way Garforth Leeds LS2 2JY United Kingdom
ECL Mandra	25TH KM OLD NATIONAL ROAD OF ATHENS TO THIVA, GR 19600, Greece
ECL Maribor	Vajngerlova Ulica 4, 2000 Maribor, Slovenia
ECL MICROTEK BV	MICROTEK MEDICAL B.V. GESINKKAMPSTRAAT 19, 7051 HR, VARSSEVELD, THE NETHERLANDS
ECL MICROTEK MOSTA	SORBONNE CENTRE, F20 MOSTA TECHNOPARK, MOSTA MST 3000, MALTA
ECL MICROTEK ZUTPHEN	Hekkehorst 24, 7207 BN Zutphen, Netherlands
ECL Mullingar	Ecolab Ltd (IE). Forrest Park Zone C Mullingar Industrial Estate Mullingar Co. Westmeath Ireland
ECL Mullingar	Ecolab Manufacturing IE Ltd (IE) Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar, Co. Westmeath Ireland
ECL Nieuwegein	BRUGWAL 11 A, 3432 NZ NIEUWEGEIN THE NETHERLANDS
ECL Rovigo Esoform	Esoform SRL., Laborat. Chimico Farmaceutico Viale del Lavoro 10, 45100 Rovigo (RO), Italy
ECL Rozzano	Via A. Grandi, 20089 Rozzano MI, Italy
ECL Tesjoki	NLC Tesjoki Kivikummuntie 1, Tesjoki, 07955, Finland
ECL Tessenderlo	Havenlaan 4, Ravenshout 4 210, B-3980 Tessenderlo, Belgium
ECL Weavergate	Site Nalco Manufacturing Limited, Winnington Avenue, Northwich, Cheshire CW8 3AA, UK Postal Address PO Box 11, Winnington Avenue, Northwich, Cheshire CW8 4DX
ECL Weavergate	Ecolab Ltd (UK) Winnington Avenue Northwich, Cheshire CW8 3AA
ECL Weavergate	Ecolab Manufacturing UK Ltd (UK) Winnington Avenue Northwich, Cheshire CW8 3AA

Ecolab Ltd Baglan/Swindon	Plot 7a Baglan Energy Park, Brunel way, Baglan, Port Talbot SA11 2GA, United Kingdom
Ferdinand Eimermache GmbH &Co.KG	Ferdinand Eimermacher GmbH & Co. KG Westring 24 48356 Nordwalde Germany
F.E.L.T.	BP 64 10 rue du Vertuquet 59531 NEUVILLE EN FERRAIN France
GALLOWS GREEN SERVICES LTD	Gallows Green Services Ltd. Cod Beck Mill Industrial Estate Dalton Lane Thirsk North Yorkshire YO7 3HR United Kingdom
GERDISA GERMAN RGUEZ DROGAS IND	Gerdisa Polígono Industrial Miralcampo, C. Pintura n.-4, parc.37 Azuqueca de Henares 19200, Guadalajara, Spain
GIRASOL NATURAL PRODUCTS BV	Girasol Natural Products B.V. De Veldoven 12-14 3342 GR Hendrik-Ido-Ambacht, The Netherlands
HENKEL ENGELS	Henkel Engels 413116 Engels Prospekt Str Russia
Imeco GmbH & Co. KG	Boschstraße 5 D-63768 Hösbach Germany
INCARE BV	Keizersveld 99 5803 AP Venray The Netherlands
INNOVATE GmbH	Innovate GmbH Am Hohen Stein 11 06618 Naumburg Gemany
INTERFILL LLC-TOSNO	INTERFILL LLC 187000, Moskovskoye shoss 1 Tosno - Leningradskaya Russia
JODEL - PRODUCTOS QUIMICOS	Jodel Zona Industrial 2050 Aveiras de Cima Portugal
Kleinmann GmbH	Kleinmann GmbH Am Trieb 13 72820 Sonnenbühl Sonnenbühl Germany
KOMPAK NEDERLAND BV	KOMPAK Bavel 0031-161-433651 Nederlands
La Antigua Lavandera SL	LA ANTIGUA LAVANDERA, S.L. Ctra. Antigu Sevilla-Alcalá Km.1,5 (SE-410) Apartado de Correos, 58 41500 ALCALA DE GUADAIRA SEVILLA Spain
LABORATOIRES ANIOS	Pavé du moulin 59260 Lille-Hellemmes FRANCE
LABORATOIRES ANIOS	3330 Rue de Lille 59262 Sainghin-en-Mélantois FRANCE
Laboratoires Prodene Klint	Site de Mitry-Mory 2, Rue Denis Papin ZI Mitry-Compans 7290 Mitry Mory, France
LICHTENHELDT GmbH	Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt Germany

LONZA	Lonza GmbH Morianstr.32 42103 Wupperta Germany
Multifill B.V.	Multifill BV Constructieweg 25-A 3641 SB Mijdrecht The Netherlands
Nalco Finland Manufacturing Oy (Tesjoki)	Kivikummuntie 1, Tesjoki 07955 Finland
Nalco Celra	Celra C/ Tramuntana s/n Poligona Industria Celra 17460 Girona, Spain
NOPA NORDISK PARFUMERIVARE	Nordisk Parfumerivarefabrik A/S Hvedevej 2 22 DK-8900 Randers Denmark
Nuova Farmec Srl (Verona)	Via Flemming 7, 37026 Settimo di Pescantina (VR), Italy
PAL INTERNATIONAL LTD	Pal International Ltd. Sandhurst Street, Oadby, Leicester United Kingdom
PLANOL GmbH	Planol GmbH Maybachstr. 17 63456 Hanau Germany
PLUM A/S	Plum A/S Frederik Plums Vej 2 DK 5610 Assens Denmark
PRODUCTOS LC LA CORBERANA	PRODUCTOS LA CORBERANA, S.L. Crta. Corbera – Polinyá, s/nº 46612 - CORBERA (VALENCIA) Spain
PROTON GROUP LTD	THE PROTON GROUP LTD Ripley Drive, Normanton Industrial Estate, Wakefield, WF 1QT, United Kingdom
QUIMICAS MORALES	QUIMICAS MORALES, S.L. Misiones, 11 - Urb. El Sebadal 05005 – LAS PALMAS DE GRAN CANARIA Spain
RNM PRODUCTOS QUIMICOS	RNM - Produtos Quimicos, Lda Rua da Fabrica, 123, Segade, 4765-080 Carreira Vi Nova de Famalicao Portugal
RP Adam Ltd (Arpal Group)	North Riverside Business Park, Riverside Road, Selkirk, TD7 5DU, UK
ROQUETTE & BARENTZ	Roquette Freres Route De La Gorgue F-62136 Lestrem France
RUTPEN	RUTPEN LTD MEMBURY AIRFIELD LAMBOURN BERKS RG16 7TJ UNITED KINGDOM
Simagec	Z.I. de Rousset/Peynier, 54 Avenue de la Plaine, 13790 Rousset, France
SOLIMIX	Solimix Montseny 17-19 Pol. Ind. Sant Pere Molanta 08799 Olerdola Barcelona SPAIN
STAUB & CO - SILBERMAN GMBH- Gablingen	Staub & Co. – Silbermann GmbH D-86456 Gablingen, Industriestraße 3 Germany

STOCKMEIER CHEMIE EILENBERG	Stockmeier Chemie Eilenburg GmbH & Co. KG Gustav-Adolf-Ring 5 04838 Eilenburg Germany
SYNERLOGIC BV (- IN2FOOD)	Synerlogic BV afd. L.J. Costerstraat 5 6827 ARNHEM The Netherlands
Techtex (Technical Textile Services Ltd)	Units 7 & 8, Rhodes Business Park, Silburn Way, Middleton, Manchester, M24 4NE, UK
Univar Ltd,	Argyle House, Epsom Avenue, Wilmslow. SK9 3RN United Kingdom
UNIVAR SPA	Univar SPA Via Caldera 21 20-153 Milano Italy
VAN DAM BODEGRAVE	van Dam Bodegraven B.V Postbus 48 NL 2410 AA Bodegraven The Netherlands
McBride	Calle Ramón Esteve, 0 S/N (Pol L'Illa), 08650 Botjosa (la), Barcelona, Spain
Extruplast	Avenue de la Repentie, 17000, La Rochelle, France
Brenntag Hungary Kft	Budapest, Bányalég u. 45, 1225 Hungary
DR. Becher GmbH	Vor den Specken 3, 30926 Seelze Germany
Danlind AS	Lægaardvej 90 - 94 DK-7500 Holstebro Denmark
Farmak Moravia a.s	Na Vlčinci 16, 779 00 Olomouc, Czech Republic
Hydrachem LTD	Gillmans Industrial Estate, Natts Lane Billingshurst RH14 9EZ United Kingdom
Julius Hoesch GmbH	Birkesdorfer Str. 5 52353 Düren Germany
Medentech LTD	Whitemill Industrial Estate Wexford Republic of Ireland
MKS GmbH & CO KG	Am Ockenheimer Graben 43 55411 Bingen am Rhein Germany
PDI	Aber Park, Aber Road Flint CH6 5EX United Kingdom
Peenwhite LTD	Midpoint 18 Business Park, Aston Way, Middlewich CW10 0HS United Kingdom

Jago Pro Sp.z.o.o.	Szczakowska 35 43-600 Jaworzno Poland
Wesso AG	Martin-Luther-Str.10 91217 Hersbruck Germany
CID Lines NV	Waterpoorstraat 2 8900 Ieper Belgium

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

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany
Location of manufacturing sites	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals Corporation
Address of manufacturer	2001 FM 3057, Bay City, TX 77414 USA
Location of manufacturing sites	2001 FM 3057, Bay City, TX 77414 USA

eCA comment: Note that the name of the active substance manufacturer has changed from OXEA Corporation to OQ Chemicals Corporation

2.1.2 Product (family) composition and formulation

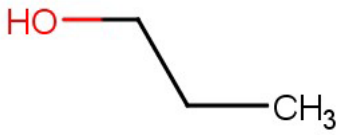
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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 ☐
No ☒ ^

^ Note that although the reference product in the CAR (Germany, 2017) was at 70 % 1-propanol (w/w), a refined concentration of 60 % was used for PT 1 hand disinfection.

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

Not applicable, the active substance is not a candidate for substitution in accordance with Article 10(1)(b) of Regulation No. 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)^	
					Min	Max
1-Propanol	Propan-1-ol	Active substance	71-23-8	200-746-9	TC 70.35 Pure 70	TC 75.38 Pure 75
(*)	(*)	Non-active substance[3]	(*)	(*)	(*)	(*)

^ All products in the product family have the same active substance content

(*) Please refer to the confidential annex for further details. In confidential annex product composition is also covered

2.1.2.4 Information on technical equivalence

Not applicable, all active substance sources have been evaluated in the Active Substance dossier, for which Ecolab is the owner (please refer to IUCLID section 13, "*1-propanol Declaration of ownership"*).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

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

Meta-SPC 1.1 – Biocidal products containing 70 % (w/w) 1-propanol

Classification	
Hazard category	Flam. Liq. 3
Hazard statement	H226
Hazard category	Eye Dam. 1
Hazard statement	H318
Hazard category	STOT SE 3
Hazard statement	H336
Labelling	
Signal words	Danger
Hazard statements	H226: Flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness EUH066: Repeated exposure may cause skin dryness or cracking
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280e Wear eye protection/face protection. P305 + P351 + P338+310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor P261 Avoid breathing vapours P312 Call a POISON CENTRE/doctor… if you feel unwell
Note	P271 Use only outdoors or in a well-ventilated area, is optional for industrial and professional users. For normal use of the product this P-phrase is not considered required. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing, is optional. For normal use of the product this is not considered required. P403+P233: Store in a well-ventilated place. Keep container tightly closed, the product is not considered highly volatile and for normal use of the product this P-phrase is not considered required. P405: Store locked up, is optional for industrial/professional users and is not considered required. P501: Dispose of contents/container to…, is recommended only if there are specific disposal requirements above the normal expectations for the disposal of chemicals. This is not the case for this product and the P-phrase is therefore not required.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1.1 – Hand Disinfection

Product Type	PT 1 – Human Hygiene
Where relevant, an exact description of the authorised use	Hygienic handrub
Target organism (including development stage)	Bacteria, tuberculosis bacilli, yeasts, enveloped viruses and viruses (limited spectrum virucidal activity)
Field of use	Indoor Hand disinfection Food processing areas (industry, institutional and hospital kitchen areas (no contact with patients)) Hygienic handrub, on visibly clean hands
Application method(s)	Manual (elbow lever or touchless) or automatic (pump)
Application rate(s) and frequency	Ready to use liquid; 3 mL per application, 10 times per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100-20000 mL HDPE bottle, jerry can.

2.1.4.2 Use-specific instructions for use

Please refer to chapter 2.1.5 General directions for use

2.1.4.3 Use-specific risk mitigation measures

Please refer to chapter 2.1.5 General directions for use

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

Please refer to chapter 2.1.5 General directions for use

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

Please refer to chapter 2.1.5 General directions for use

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

Please refer to chapter 2.1.5 General directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Use 1 – Hand Disinfection:
Hand Disinfection for food processing areas:
Apply 3 mL product on clean and dry hands for:

- 30 seconds bact/yeast/ tuberculosis bacilli /enveloped viruses
- 60 seconds viruses (limited spectrum virucidal activity)

Keep hands wet during whole contact time

2.1.5.2 Risk mitigation measures

Avoid contact with eyes.
If refilling is needed, gloves and eye protection should be used.
In case of skin dryness, use appropriate skin care lotion.

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

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: Rinse mouth.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions: Do not allow contact with soil, surface or ground water.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product and product residues: The product should not be allowed to enter drains, water courses or the soil. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.
Packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Dispose of packaging only if completely empty and closed. Do not

re-use empty containers. Dispose of in accordance with local, state, and federal regulations.

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

Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labelled containers. Storage temperature: 0 °C to 25 °C Shelf Life: 4 years

2.1.6 Other information

Not applicable

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	100 mL	HDPE	PP	Professional	Yes
Bottle	500 mL	HDPE	PP	Professional	Yes
Bottle	750 mL	HDPE	PP & POE	Professional	Yes
Bottle	1L	HDPE	PP	Professional	Yes
Jerry can	5L	HDPE	PP	Professional	Yes
Jerry can	20L	HDPE	HDPE	Professional	Yes

PP = Polypropylene
POE = Polyolefin elastomer
HDPE = High density polyethylene

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

All data submitted in support of the product dossier is referenced in the reference list of this document (attached in Annex).

2.1.8.2 Access to documentation

The applicant is the data holder of the active substance and product data.

2.1.8.3 Similar conditions of use

The biocidal product family (1-propanol BPR) is deemed to be eligible for Union Authorisation based on the pre-submission outcome.

Based on the information provided by the applicant, the application could meet the basic requirements of Article 43(1) of the Biocidal Products Regulation (528/2012).
No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards to the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product family 1-propanol BPR dossier falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union.

2.2 Assessment of the biocidal product (family)

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

Table 2. Intended use # 1.1 – Hand Disinfection[1]

Product Type(s)	PT 1 – Human Hygiene
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, tuberculosis bacilli, yeasts and virucidal (enveloped and limited spectrum)
Field of use	Indoor Hand disinfection Food processing areas (industry, institutional and hospital kitchen areas (no contact with patients))
Application method(s)	Manual or automatic (pump)
Application rate(s) and frequency	Ready to use liquid; 3 mL per application, 10 times per day
Category(ies) of user(s)	Industrial Professional
Pack sizes and packaging material	100-20000 mL HDPE bottle, jerry can.

2.2.2 Physical, chemical and technical properties

Conclusion on the physical, chemical and technical properties of the product
All the data summarised above supports a shelf life of 48 months. The physico-chemical properties of representative products in the product family have been evaluated, with the results described in the above table. The studies were conducted on products representative for the product family, and the physico-chemical properties described above are deemed acceptable and applicable for the product family. The data are considered acceptable for the appropriate use and storage of the biocidal products within the product family.

[1] Copy this section as many times as necessary (one table per use).

2.2.3 Physical hazards and respective characteristics

Conclusion on the physical hazards and respective characteristics of the product
The physical hazards of representative products of the biocidal product family (BPF) have been evaluated, with the results described in the above table. All products included in the BPF are water-based products. Their physical hazards and respective characteristics can generally be derived based on their formulation type (i.e. as a liquid) and the intrinsic properties of the individual components, unless otherwise stated. The biocidal products within the product family are classified as Category 3 flammable liquids (H226, Flammable liquid and vapour) based on a flash point of 32.3 ºC at 1013 hPa. No further classification of the BPF with regard to physical hazards are required. The products in the BPF are not explosive and the auto-ignition temperature was determined to be 420 ºC. Furthermore, the products have no oxidizing properties, and are not self-heating, self-reacting or corrosive to metals. The products will not present unacceptable risk provided that they are appropriately used, stored and transported according to precautionary use instructions.

2.2.4 Methods for detection and identification

Analytical methods for monitoring								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substance dossier for further information									

Analytical methods for soil								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substance dossier for further information									

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substance dossier for further information									

Analytical methods for water								
Analyte (type of analyte e.g. active	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other**	**Reference**
					Range	Mean	RSD		

substance)								**limits**	
Please refer to the active substance dossier for further information									

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substance dossier for further information									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not applicable.									

Conclusion on the methods for detection and identification of the product
Detection of propan-1-ol was determined using a gas chromatography (GC) system and flame ionisation detection (FID). The method was validated with regards to specificity, linearity, precision and accuracy according to SANCO/3030/99 rev. 4 (11/07/2000). For other analytical methods relating to monitoring, soil, water, and bodily fluids/tissues, please refer to the active substance dossier. Food and feedstuff residue analysis is not applicable as no food contact is intended during the biocidal product's use.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal products within the BPF are used for human hygiene – hand disinfection - under product type 1.
The function of the biocidal product is a bactericide, yeasticide, tuberculocide, virucide against enveloped viruses and virucide (limited spectrum virucidal activity).

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

The products are used to control micro-organisms including gram-positive and gram-negative bacteria (including tuberculosis bacilli) as well as yeasts and virucidal (enveloped and limited spectrum). Industrial and professional users apply the product in liquid form directly to their hands to function as a disinfectant to control the above-described micro-organisms (PT 1). The product will be stationed in food contact areas, although should only be applied to hands.

Examples of typical micro-organisms to be controlled:

Gram-negative bacteria: *Pseudomonas aeruginosa*, *Escherichia coli, Proteus mirabilis*

Gram-positive bacteria: *Enterococcus hirae*, *Staphylococcus aureus*

Tuberculocidal: *Mycobacterium terrae*

Yeasts: *Candida albicans*

Viruses: *Murine norovirus*, *Adenovirus* type 5, *modified vaccinia virus,* Ankara (MVA)

2.2.5.3 Effects on target organisms, including unacceptable suffering

Propan-1-ol is employed as a broad-spectrum microbicide for the disinfection of skin. The concentration and time period required is dependent on the organism to be controlled.

Data supporting the efficacy of the product family demonstrate that has a sufficient level of efficacy against the target organisms; bacteria (including tuberculosis bacilli but excluding bacterial spores), yeast and viruses (limited spectrum viruses and enveloped viruses). The efficacy studies are attached in the relevant records in Section 6.7 of the product IUCLID dossier.

For efficacy testing of PT 1, phase 2 tests are required as outlined in Guidance on the BPR: Volume II Parts B+C (v 3.0, April 2018)[2]. The efficacy tests performed on the product are compliant with the relevant EN guideline method, as follows:

- Bacteria: EN 13727: 2015 (Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity for instruments in the medical area - Test method and requirements (Phase 2, Step 1))

2 https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

- Bacteria: DIN EN 1500: 2017 (Hygienic handrub – test method and requirements (phase 2, step 2))
- Bacteria: DIN EN 1276: 2010 (Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics using in food, industrial, domestic and institutional areas – test method and requirements (phase 2, step 1))
- Tuberculocidal: EN 14348: 2005 (Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – test method and requirements (phase 2, step 1))
- Yeasts: EN 1650: 2013 (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 (Phase 2, Step 1))
- Yeasts: EN 13624: 2013/prA1:2018 (Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (Phase 2, step 1))
- Viruses: EN 14476:2016 + prA2:2016 (Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine – Test method and requirements (Phase 2, Step 1)
- Viruses: EN 14476:2013 + A2:2019 (Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine – Test method and requirements (Phase 2, Step 1)

Use 1: Hand Disinfection (PT 1)

Under Use 1.1, the product is used in industrial and professional settings as a hand disinfectant in food processing areas.

The following effects were observed in the efficacy tests conducted through testing of the product at various application concentrations.

Bacteria
Quantitative suspension tests were performed on bactericidal activity of the product, in line with guideline EN 13727, EN 1276 and EN 14348.

The EN 13727 study demonstrated bactericidal efficacy at 50 % application concentration of the product after 15 seconds contact time, for test strains *S. aureus, E. hirae, P. aeruginosa, E. coli* and *P. mirabilis.* The test temperature was 20 ºC ± 1 ºC and the study was conducted under clean and dirty conditions.

An EN 1276 study demonstrated bactericidal activity at 50% application concentration of the product after 15 seconds contact time, for test strains *S. aureus, E. hirae, P. aeruginosa and E. coli.* The test temperature was 20 °C ± 1 °C and the study was conducted under clean conditions.

One test was performed according to the DIN EN 1500 guideline resulted in bactericide efficacy was achieved when 3 ml of 80 % product was applied for 15 seconds using a 36 ºC ± 1 ºC incubation temperature.

Thus, 30 seconds contact time is supported for bactericidal activity.

A quantitative suspension test was also performed on the product, in line with guideline EN 14348, which demonstrated tuberculocidal activity against the strain *Mycobacterium*

terrae at an application concentration of 80 % after 15 seconds under clean conditions, thus 30 seconds contact time for tuberculocidal claim is supported.

Yeast
Quantitative suspension tests were performed on yeasticidal activity of the product, in line with guideline EN 13624 and EN 1650.

A quantitative suspension test was performed on yeasticidal efficacy of the product in line with guideline EN 1650 was performed for the *Candida albicans* test strain, but under clean conditions. Efficacy was observed at 50 % product application concentration after 15 seconds under clean conditions.

A quantitative suspension test was performed on yeasticidal activity of the product in line with guideline EN 13624 was performed for *Candida albicans* test strain, under clean and dirty conditions. Efficacy was observed at 50 % product application concentration after 15 seconds.

All tests for the yeast strain *C. albicans* under both EN 1650 and EN 13624 guidelines sufficiently demonstrated that the product is effective after the minimum contact time tested (15 seconds), at 50 % application concentration, thus 30 seconds contact time for yeast is supported.

Virucidal
Quantitative suspension tests were performed to assess the limited spectrum virucidal efficacy of the product with guideline EN 14476. The studies demonstrated that the product achieved a virucidal efficacy at an application concentration of 50% within 60 seconds contact time, at 20 °C against *Murine norovirus* and at an application concentration of 80% within 60 seconds contact time, at 20 °C against *Adenovirus type 5* under clean conditions, thus limited spectrum virucidal activety claim for 60 seconds is supported.

An additional quantitative suspension test was performed to assess the virucidal activity of the product against enveloped viruses with guideline EN 14476. The study demonstrated that the product achieved a virucidal efficacy at an application concentration of 50% within 30 seconds contract time, at 20°C against *modified vaccinia virus*, Ankara (MVA) under clean conditions, thus enveloped virucidal claim for 30 seconds is supported.

2.2.5.4 Mode of action, including time delay

Propan-1-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Gram-positive bacteria: *Enterococcus hirae; Staphylococcus aureus;* Gram-negative bacteria: *Pseudomonas aeruginosa; Escherichia coli*	EN1276 Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – test method and requirements		Efficacious bactericidal activity was achieved	
Tuberculocidal	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	*Mycobacterium terrae*	EN 14348 Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – test method and requirement (phase 2, step 1)		Efficacious tuberculoicidal activity was achieved	
Yeasticide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w	Yeast: *Candida albicans*	EN 1650 (Chemical disinfectants and antiseptics - Quantitative suspension		Efficacious yeasticidal activity was achieved	

		0.76% & 0.05% Skin care products		test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas (Phase 2, Step 1))			
Bactericide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Gram-positive bacteria: *Staphylococcus aureus, Enterococcus hirae*; Gram-negative bacteria: *Pseudomonas aeruginosa, Escherichia coli* K12, *Proteus mirabilis*	EN 13727 Draft (Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity for instruments in the medical area - Test method and requirements (Phase 2, Step 1))		Efficacious bactericidal activity was achieved	
Yeasticide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Yeast: *Candida albicans*	EN 13624 (Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity for instruments used in the medical area - Test method and		Efficacious yeasticidal activity was achieved	

				requirements)			
Bactericide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Gram-negative bacteria: *Escherichia coli* K12	DIN EN 1500: Hygienic handrub – test method and requirements (phase 2, step 2)		Efficacious bactericidal activity was achieved	
Virucide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Virucidal: *Adenovirus type 5*, strain adenoid 75	EN 14476: 2013 + A2: 2019 Chemical disinfectant and antiseptics – virucidal quantitative suspension test for chemical disinfectant and antiseptics used in human medicine – Test method and requirement (phase 2, step 1)		Efficacious limited spectrum virucidal activity was achieved	
Virucide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Virucidal: *Murine norovirus*, strain S99	EN 14476: 2013 + A2: 2019 Chemical disinfectant and antiseptics – virucidal quantitative suspension test for chemical disinfectant and antiseptics used in		Efficacious limited spectrum virucidal activity was achieved	

				human medicine – Test method and requirement (phase 2, step 1)			
Virucide	PT 1: Human hygiene (hand disinfectant)	Epicare DES. 1-propanol 70% w/w 0.76% & 0.05% Skin care products	Virucidal: *modified vaccinia virus*, Ankara (MVA)	EN 14476: 2013 + A2: 2019 Chemical disinfectant and antiseptics – virucidal quantitative suspension test for chemical disinfectant and antiseptics used in human medicine – Test method and requirement (phase 2, step 1)		Efficacious virucidal activity against the enveloped virus was achieved	

Conclusion on the efficacy of the product

The product family containing the active substance 1-propanol (70 %) are used as a hand disinfectant under PT 1. The product Epicare DES was tested in order to demonstrate the efficacy for the mentioned PT 1 family. This product contains 70% w/w 1-propanol together with two skin care products at the concentration of 0,76% and 0,05%. This is the lowest amount of 1-propanol and the highest amount of the skin care products specified for the product family. The product must be applied on visibly clean hands.

The product family was evaluated for bactericidal and yeasticidal efficacy over multiple tests, using gram-negative and gram-positive bacteria and a test yeast strain. The efficacy outcomes vary depending on the study.

Regarding bactericidal activity, an application concentration of 50 % at a contact time of 15 seconds was found to be effective in EN 13727 and EN1276 study. A DIN EN 1500 bactericidal test was performed with *Escherichia coli* K12, which demonstrated efficacy was achieved when 3 ml of 80 % product was applied and rubbed into hands for 15 seconds.

Tuberculocidal activity was achieved with an 80% product application after 15 seconds contact time in an EN 14348 study under clean conditions

Yeasticidal activity was sufficiently effective at an application concentration of 50 % after 15 seconds in all tests using the yeast strain *C. albicans* (EN 1650 and EN 13624).

Limited spectrum virucidal activity was achieved with an 80% product application after 60 seconds contact time in an EN 14476 study under clean conditions.

Virucidal activity against enveloped viruses was achieved with a 50% product application after 30 seconds contact time in an EN 14476 study under clean conditions.

Based on the above results, it is considered that the efficacy test results cover the products used in this BPF and sufficient data is available to support the product label claim of efficacy against bacteria, tuberculocidal, yeasts and viruses (limited spectrum and enveloped viruses). It can also be concluded that the biocidal products can be used under the Product Type.

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of 1-propanol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where propan-1-ol is ineffective at any concentration.

2.2.5.7 Known limitations

No undesirable or unintended side-effects are known.

Propan-1-ol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods (CAR – Germany, 2017).

2.2.5.8 Evaluation of the label claims

The label claims for this product are efficacious treatment of bacteria, tuberculosis bacilli, yeasts and enveloped viruses following 30 seconds contact time with a 3 mL volume of the product applied to hands and efficacious treatment of limited spectrum viruses following 60 seconds contact time with the same volume of product.

The bactericidal, yeasticidal, tuberculocidal and virucidal (limited spectrum virucidal activity and virucidal against enveloped viruses) label claims are satisfactorily fulfilled by the data that are available, outlined in Section 2.2.5.5. The tests performed for bactericidal efficacy were EN 13727, EN1276 and DIN EN 1500; for tuberculocidal efficacy EN 14348 was performed for yeasticidal efficacy EN 1650 and EN 13624 were performed; and for virucidal (limited spectrum and enveloped) efficacy EN 14476 was performed. These EN standards are compliant with those recommended for efficacy

testing in Appendix 2, Table 28 in the Guidance on BPR: Volume II Parts B+C (v3.0, April 2018)[3].

The results from the studies performed on the product demonstrated that the product is efficacious against yeast, bacteria and viruses, under the intended PT1 use and the use-specific instructions for use. Appropriate test organisms were used in line with organisms to be controlled, thus supporting the label claims. It was demonstrated in all studies that the product's formulation will adequately fulfil the label claims of virucidal (limited spectrum and enveloped), yeasticidal and bactericidal (including tuberculocidal) efficacy, due to the application concentrations tested in the studies. The contact times tested showed that the product is effective after the contact time dictated in the use-specific instructions for use.

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

The biocidal products are not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

As the biocidal product family contains up to 75 % propan-1-ol, it is appropriate to classify and label it in a similar manner as the active substance. The active substance, propan-1-ol (CAS-No. 71-23-8) is listed on Annex VI of Regulation (EC) No 1272/2008 and its classification and labelling for human health hazards is as follows:

- Eye Dam. 1; H318: causes serious eye damage
- STOT SE 3; H336: may cause drowsiness or dizziness

It is proposed that the above classification and labelling related to human health, which is consistent with the harmonised classification according to Annex VI of Regulation (EC) No 1272/2008, is relevant for the products in the product family. In addition, also EUH066 have been included in accordance with the Propan-1-ol CAR and BPC opinion that recommends the following supplemental hazard statement "EUH066 Repeated exposure may cause skin dryness or cracking". No additional classification and labelling requirements are considered necessary. None of the co-formulants used in the product family present additional hazard concerns.

In the propan-1-ol CAR (Germany, 2017), there were no reliable data for determining dermal absorption of the substance, therefore default values were used for tier 1 for this product. For tier 2, propan-2-ol-derived data on dermal absorption was applied for exposure of professionals to 75 % propan-1-ol. The read-across to the dermal absorption data from propan-2-ol (CAR) was discussed and agreed during an e-consultation that was sent out to all WG members in December, 2020.

According to BPR requirements applicants need to identify Substances of Concern (SoC) included in the Biocidal Product Family and take these into consideration during the risk assessment. The products within the biocidal product family do not contain any substances of concern. Please see the confidential annex for further details.

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3 https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

Additionally, an assessment of endocrine disrupting properties has been conducted for the co-formulants used in the products within the product family. No endocrine disrupting effects were identified within the product family. Please see the confidential annex for further details.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

A waiver is presented for skin corrosion and irritation. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not classified but the supplemental label phrase EUH066 will be added in line with the active substance CAR and BPC opinion.
Justification for the value/conclusion	The active substance propan-1-ol is not regarded as sufficient for classification as Skin Irrit. 2 (H315) according to Annex VI of Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	Not classified, none of the components of the product are classified for skin corrosion or irritation. However, the Propan-1-ol CAR and BPC opinion adopted for this active substance have both included the supplemental hazard statement "EUH066 Repeated exposure may cause skin dryness or cracking", which has also been included for this product.

Data waiving	
Information requirement	IUCLID Section 8.1.1, BPR Annex III 8.1
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF is not classified.

Eye irritation

A waiver is presented for eye irritation. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damage
Justification for the value/conclusion	Based on animal data and on experience relating to human occupational exposure, classification of propan-1-ol as Eye Dam. 1; H318: causes serious eye damage is regarded as appropriate, which is in line with the current classification listed in Annex VI of Regulation (EC) No 1272/2008. None of the co-formulants contribute to this hazard classification.

Classification of the product according to CLP and DSD	Eye Dam. 1; H318: Causes serious eye damage.

Data waiving	
Information requirement	IUCLID Section 8.1.2, BPR Annex III 8.2
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). Therefore, classification of the products within 1-Propanol BPF as Eye Dam. 1; H318 is required.

Respiratory tract irritation

A waiver is presented for respiratory tract irritation. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not classified
Justification for the conclusion	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF not classified.
Classification of the product according to CLP and DSD	Not classified, none of the components of the product are classified for respiratory tract irritation.

Data waiving	
Information requirement	IUCLID Section 8.3.2, BPR Annex III 8.7
Justification	A waiver is presented for respiratory tract irritation on the basis that classification of the product can be addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008 (CLP). The active substance and other co-formulants are not classified as respiratory tract irritants.

Skin sensitization

A waiver is presented for skin sensitisation. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	The active substance is not considered to be a skin sensitiser based on MEST and GPMT studies presented in the CAR.

	Additionally, none of the co-formulants are classified for skin sensitisation, classification of the products is therefore not required.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.3.1, BPR Annex III 8.4
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF is not classified.

Respiratory sensitization (ADS)

A waiver is presented for respiratory sensitisation. Classification of the product is addressed based on classification of the components according to the guidance given in Regulation (EC) No. 1272/2008 (CLP). Specific testing for respiratory sensitisation is not required and is not possible in the absence of any recognised and validated test method.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not expected to be sensitising to the respiratory tract.
Justification for the value/conclusion	The active substance propan-1-ol is not classified as a respiratory sensitiser. None of the co-formulants are classified for respiratory sensitisation. Therefore, according to the CLP Regulation, classification of the products for respiratory sensitisation is not required.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.4, BPR Annex III 8.4.
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF not classified.

Acute toxicity

Acute toxicity by oral route

A waiver is presented for acute oral toxicity. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Expected to exhibit low acute oral toxicity
Justification for the selected value	The active substance propan-1-ol is classified as STOT SE 3; H336 "may cause drowsiness or dizziness" which is in line with the current classification listed in Annex VI of Regulation (EC) No 1272/2008. None of the co-formulants contribute to this hazard classification.
Classification of the product according to CLP and DSD	STOT SE 3; H336 may cause drowsiness or dizziness

Data waiving	
Information requirement	IUCLID Section 8.5.1, BPR Annex III 8.5.1
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) - STOT SE 3, H336.

Acute toxicity by inhalation

A waiver is presented for acute inhalation toxicity. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Expected to exhibit low acute inhalation toxicity
Justification for the selected value	Neither the active substance, or the product co-formulants, are classified for acute inhalation toxicity. The products are therefore not considered to be classified for this hazard.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.2, BPR Annex III 8.5.2
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF not classified.

Acute toxicity by dermal route

A waiver is presented for acute dermal toxicity. Classification of the products is addressed based on classification of the components, according to the recommendations in Regulation (EC) No. 1272/2008.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Expected to exhibit low acute dermal toxicity
Justification for the selected value	Neither the active substance, or the product co-formulants, are classified for acute dermal toxicity. The products are therefore not considered to be classified for this hazard.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.3, BPR Annex III 8.5.3
Justification	Testing of the 1-propanol BPF has not been performed as there are valid data available on each of the components in the mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP). BPF not classified.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Propan-1-ol (75 % w/w)
Value(s)*	0.85 mg/cm^2/h
Justification for the selected value(s)	The bridging approach given in the EFSA Guidance Document on Dermal Absorption (EFSA, 2017), Chapter 6.2 Use of data on similar formulations) when considering estimation of dermal absorption for this product has been followed. The transdermal flux rate of 0.85 mg/cm^2/h determined in the propan-1-ol CAR (read-across from propan-2-ol) has been used to assess dermal absorption for this product family. Flow chart 5 (Section 8), of the EFSA guidance[4], states that dermal absorption data on another reference formulation can be used if the formulation for which dermal absorption needs to be determined is closely related. It is concluded that this product family is sufficiently similar to the representative product used in the propan-1-ol CAR and will be bridging across to this study to use the value taken from the Boatman et al, study on Propan-2-ol for transdermal flux. For the representative product used in the propan-1-ol CAR and this product family both have a minimum purity of 99.5% w/w of the active substance and the concentration of this active is in the same range 70 % (w/w) and 75% respectively, which is within the permitted variation of ±5% (section 6.2, table 3, EFSA guidance[4]. The representative product used in the propan-1-ol CAR[5], is an aqueous solution containing 70% w/w active substance. In this product, three co-formulants are added (for details, see confidential annex 3.6). The EFSA guidance on dermal absorption[4] states that the addition of substances not contained in the reference formulation is acceptable up to a concentration of ≤ 0.5 %, but only if it is shown that this minor change does not have an impact on physical-chemical or toxicological properties of the formulation. Furthermore, it is stated that in individual cases, greater variations might be acceptable. In accordance with the guidance on bridging principles for hazard assessment of mixtures provided by the Regulation (EC) No. 1272/2008[6], the co-formulants specified for this product family, are not expected to affect the hazard classification or adversely affect the

[4] EFSA Guidance on dermal absorption, adopted May 2017, EFSA Journal
[5] Propan-1-ol Assessment Report (June 2017) RMS:DE - https://echa.europa.eu/documents/10162/4048f57f-b0e2-8e88-ff04-06aa05b82810
[6] Regulation (EC) No. 1272/2008 of the European Parliament 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. OJ L 353, 31.12.2008, p. 1-1355.

	dermal absorption value chosen to represent this product. The co-formulants are either in such low concentration for even the maximum amount used in this product family that they would be below the cut off level from dermal absorption guidance[4], or the substances themselves are above 0.5% but do not affect the hazard classification and are not expected to affect dermal absorption based on their physico-chemical properties. For this product, read-across was agreed and accepted during an e-consultation sent out via WG in December 2020. For full details please refer to Confidential Annex 3.6.

** For tier 1 default values were used.*

Data waiving	
Information requirement	IUCLID Section 8.6 BPR Annex III 8.6
Justification	Testing of the 1-propanol BPF has not been performed as the dermal absorption value concluded in the CAR has been used and acceptable risk was concluded. The test item in the study used to determine the dermal absorption for propan-1-ol in the CAR has been accepted and bridged to this product family in accordance with EFSA Guidance Document on Dermal Absorption (EFSA, 2017). For full details please refer to Confidential Annex 3.6. No further testing was deemed necessary.

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

Not applicable, no substances of concern have been identified. For details please refer to Confidential Annex 3.6.

Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance(s) of concern is a component of are not required.

Endocrine Disrupting Properties of the Product

An assessment of the endocrine disrupting potential of the active substance propan-1-ol has been performed and it was concluded in the CAR (Germany, 2017) that there is no indication of endocrine disrupting properties of propan-1-ol. No further assessment of the active substance is necessary. A screening assessment of endocrine disrupting properties of the co-formulants used in the product family is also presented in the Confidential Annex 3.6. None of the co-formulants used in the biocidal product family are considered to have endocrine disrupting properties.

Other

Human exposure to the biocidal products *via* food is not considered to be relevant. Residues in food or feed from the intended use of propan-1-ol in PT 1 biocidal products are not expected, as no direct or indirect contact with food or feed is anticipated. Due to its high vapour pressure, the active substance evaporates completely within the time of

application of the biocidal product, so that no transfer from hands to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-1-ol as a biocide of PT 1 can be excluded.

2.2.6.2 Exposure assessment

The biocidal product formulations contain up to 75% active substance propan-1-ol which is considered effective in the disinfection of bacteria, tuberculosis bacilli, yeast and viruses. The products relevant for this risk assessment cover hand disinfection for industrial and professional scenarios in food preparation areas. The products are employed as ready to use disinfection solutions for disinfection of hands. The assessment is structured based on the product types covered (PT 1), exposures are assessed using the worst-case concentrations of 75% propan-1-ol (i.e. the maximum range of the active substance concentration in the product family).

The primary and secondary exposure scenarios, for product type (PT1), are described in the following sections. Primary exposure to professional use of hand disinfection occurs through rubbing of the substance to the skin (hand). Because the active substance is expected to evaporate quickly, secondary exposure of bystanders (inhalation) is also expected and assessed accordingly.

As the hand disinfection products are supplied in ready-to-use solutions, no mixing and loading is required. The product is applied with large packaging, it is applied using sprayer or automatic pump, re-filling might be needed therefore the following RMM has been added: *"If refilling is needed, gloves and eye protection should be used"*. Additionally, disposal of empty containers is not considered to result in significant exposure beyond the identified use already assessed in this Section.

The assessments used default values for dermal absorption in tier 1 and for tier 2; a transdermal flux value of 0.85 mg/cm^2/h as used in the Propan-1-ol CAR, and 100% inhalation absorption is assumed in the absence of relevant further data.

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

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

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.	PT 1 – Hand Disinfection	Primary Exposure: Exposure during use of hand rub disinfectant on skin	Industrial Professional
2.	PT 1 – Mixing and Loading (manual)	Primary Exposure: Decanting product into application equipment.	Industrial Professional
3.	PT 1 – Post Application Hand Disinfection	Secondary Exposure: Inhalation exposure for bystanders exposed to vapours following hand rub application	Industrial Bystanders Professional Bystanders

Industrial exposure

Refer to professional exposure.

Professional exposure

Scenario [1] PT 1 - Hand Disinfection

Potential primary exposures have been assessed for professional workers (also covering industrial workers) utilising the product family for hand disinfection in food preparation areas. The products are employed in ready to use disinfection solutions and applied using a manual or automatic pump dispenser.

In the risk assessment presented in the CAR (Germany, 2017), the scenario covered relates to the use of hand disinfection products in hospitals, based on Recommendation No. 1 of the BPC Ad-hoc Working Group on Human Exposure – Hand Disinfection – PT 1 Harmonisation of Exposure Determinants for Professional Users and utilising the methods for exposure assessment outlined in Recommendation No. 9 of the BPC Ad-hoc Working Group on Human Exposure – Hand Disinfection in Hospitals. This scenario is based on an assumption of healthcare practices where 25 hand disinfection procedures are conducted by nurses during each shift in a hospital. This scenario is not relevant to the target market of the applicant, which is that of food preparation areas, and as such the practices of workers in food preparation environments will differ from those in hospitals. Also note that in food preparation environments, hands are previously clean with hand soap and skin is dried before disinfectant is applied.

When considering the practices in food preparation areas, it was concluded that 10 disinfection applications per day is consistent with worker requirements in this setting and was used in the risk assessment for workers.

Additionally, the assessment in the CAR concluded that when propanol is used at 70 % (w/w) in the hospital scenario, unacceptable risks were identified. Therefore, the concentration use in the PT 1 hand disinfection scenario was reduced to 60 % (w/w). Following a tiered approach, refined exposure conditions (10 applications per day) and as per the CAR a read across to a rat transdermal flux study conducted on 2-propanol, for Tier 2, the applicant is able to conclude on safe use of the products within the family containing up to 75 % (w/w) propan-1-ol.

Description of Scenario [1]
The potential dermal worker exposure (assumed 60 kg body weight) following application of the hand disinfectant was assessed 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 (Version 3, 2017) and Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure - Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017). A 3 mL application of a product containing 75 % (w/w) propan-1-ol would result in 2.2 mg/cm^2 of the active substance to be available for dermal exposure (based on density of propan-1-ol = 0.8 g/cm^3 and skin area exposed = 820 cm^2). The number of applications per shift is 10 (as defined in the SPC and authorised use parameters). The surface area of skin exposed is 820 cm^2 (palm and back of both hands). Following the ESFA guidance on dermal absorption (2017), a tier 1 assessment of dermal exposure was conducted using default dermal absorption values and for Tier 2 an assessment was carried out using the dermal absorption value of 0.85 mg/cm^2/h derived from the transdermal flux study on rats with propan-2-ol concluded for propan-1-ol in the CAR (Germany, 2017). Estimation of the inhalation exposure was conducted in accordance with Recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure - Hand disinfection in hospitals (revision agreed at the Human Health Working Group I on 19 January 2017). The tier 1 assessment was conducted based on a worst-case approach where it is considered that all disinfectant is applied in one room successive without a break. Certain modifications were made to the tier 1 assessment described in Recommendation 9, to account for the fact that the products are used in professional food preparation areas, and not hospitals. Application frequency was 10 times per day as per the SPC and identified use parameters. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Instantaneous release". Default ConsExpo settings are as outlined in Recommendation 6, except that the room volume is reduced from 80 m^3 to 20 m^3, as the room size for the identified use in this assessment is not specified. As propan-1-ol is a volatile compound, the evaporation time from skin surface was calculated according to the EU Technical Guidance Document (TGD, 2003). For a 75 % (w/w) hand disinfectant containing propan-1-ol, evaporation of 3 mL from skin would take 106 seconds (contact time), when assuming a density of propan-1-ol = 0.8 g/cm^3, a skin temperature of 30°C (TGD 2003) and a corresponding propan-1-ol vapour pressure of 3,600 Pa (30°C). The Tier 1 assessment has been split into Tier 1 "a" and Tier 1 "b" to account for the changes made and agreed at the Human Health meeting WG-II-2019 (23rd May 2019)[7], to utilise the updated EFSA guidance on dermal absorption values. This update will harmonise the use of default dermal absorption values, and according to the EFSA guidance (2017) the default assumption for biocidal products containing an active substance which is present in a formulation at a concentration of greater than 50g/L or 5%, should be considered that of a concentrate and as such the default dermal absorption value of 25% should be used. As this guidance has been agreed but not yet updated into the Technical Agreements for Biocides (TAB), for completeness we have

7 Human Health WG-II-2019 FINAL minutes, 23rd May 2019

demonstrated a Tier 1 risk assessment showing both a 70% and 25% default dermal absorption assumption. Neither value used change the overall outcome of the assessment at a Tier 1 level, which is that both assumptions lead to an exceedance of the agreed AEL.		
	Parameters	Value
Tier 1a	Dermal absorption (%)[8]	70% (default)
	ConsExpo Input Parameters[9],[10]: **Dermal exposure (for volatile compounds)** Model Frequency (events per day) Skin Area exposed (cm^2) Loading Weight fraction substance (%) Product amount (per event) (g)[11] **Inhalatory Exposure to volatile compounds** Model Mode of Release Frequency (events per day) Exposure Duration (min)[12] Product Amount (per event) (g)[5] Weight Fraction Substance (%) Room Volume (m^3) Ventilation Rate (/h) Inhalation Rate (m^3/hr) Vapour Pressure (Pa) Application Temperature (°C)	 Direct product contact 10 820 Instant application 75 2.6 Exposure to vapour Instantaneous release 10 17.7 2.6 75 20 1.5 1.25 3,600 30
Tier 1b	Dermal absorption (%)[13]	25%
	ConsExpo Input Parameters[9,10]: **Dermal exposure (for volatile compounds)**	

8 Guidance on dermal absorption (EFSA journal, 2017)

9 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 (Version 3, 2017)

10 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure - Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

11 3 mL volume corrected for the product density = 0.8689 g/cm^3

12 Contact time of 106 seconds multiplied by application frequency (10) – Recommendation 9

13 OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 156 – Guidance Notes on Dermal Absorption (DRAFT Oct 2019) –

14 Boatman et al. 1998 – CAR (Germany, 2017)

https://www.oecd.org/chemicalsafety/testing/Guidance%20Notes%20Dermal%20Absorption%20156_Oct2019_clean.pdf

	Model Frequency (events per day) Skin Area exposed (cm^2) Loading Weight fraction substance (%) Product amount (per event) (g)[11] **Inhalatory Exposure to volatile compounds** Model Mode of Release Frequency (events per day) Exposure Duration (min)[14] Product Amount (per event) (g)[11] Room Volume (m^3) Ventilation Rate (/h) Inhalation Rate (m^3/hr) Vapour Pressure (Pa) Application Temperature (°C)	Direct product contact 10 820 Instant application 75 2.6 Exposure to vapour Instantaneous release 10 17.7 2.6 20 1.5 1.25 3,600 30
Tier 2	Propan-1-ol available for exposure (following 3 mL application of 75 % product) (mg/cm^2)	2.2
	Exposed skin area (cm^2)[9]	820
	Application Frequency (per day)	10
	Dermal Absorption ($mg/cm^2/h$)	0.85
	Evaporation Time (s)	106

ConsExpo output report is presented in Annex 3.2.

Calculations for Scenario [1]
Tier 1

Evaporation Rate Calculation (TGD, 2003) - For pure substances, the following equation is used:

$$t_{(s)} = \frac{mRT}{M\beta pA}K$$

Where:
t = time (s)
m = mass, EASE estimate (mg)
R = gas constant (8.314 $J.K^{-1}.mol^{-1}$) (TGD, 2003)
T = skin temperature (303.15 K / 30ºC) (TGD, 2003)
M = molar mass (60.09 g/mol)
β = coefficient of mass transfer in the vapour phase (8.7 $m.h^{-1}$) (TGD, 2003)
p = vapour pressure of pure substance (3,600 Pa (303.15 K))

A = area, EASE (820 cm^2)
K = conversion factor (3.6×10^4) (TGD, 2003)

m = (3000 mg x 0.8) x 0.75 = 1,800 mg (*3 mL corrected for density and then corrected for 75 % in formulation*)

t = [(1800 x 8.314 x 303.15) / (60.09 x 8.7 x 3600 x 820)] x 3.6×10^4 = **105.83 s**

Tier 1 exposure estimates were calculated using ConsExpo Web version 1.0.7 - see output in Annex 3.2.

Tier 2

Calculation of internal dermal exposure based on dermal flux:

Estimated Dermal uptake =

[(Dermal flux (mg/cm^2/hr)) X (evaporation time (hr)) X (No. of applications X total skin surface)]/Body weight (kg)

Values used:

Transdermal Flux Value taken from CAR = (0.85 mg/cm^2/hr)

Evaporation time = 106 seconds

Application Frequency = 10 times per day

Skin Surface = 820cm^2

Body weight = 60 kg

$$= \frac{(0.85 \text{ mg/cm}^2\text{/hr}) \text{ X } (106 \text{ seconds} / 60 / 60) \text{ X } (10 \times 820 \text{ cm}^2)}{60 \text{ kg}}$$

= Estimated Dermal uptake 3.42 mg/kg bw/d

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] PT 1 - Hand Disinfection	1a/-	4.80	230	n.a.	235
	1b/-	4.80	81.0	n.a.	85.8
	2/-	4.80	3.42	n.a.	7.92

Further information and considerations on scenario [1]

No further information or considerations are necessary. Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore, a qualitative risk assessment for local effects was carried out. Considering the scenario assessed, the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for a professional user. During application of the hand disinfection product no contact of the eyes is expected since only small amounts of product are used in a very controlled way (i.e. the creation of splashes is avoided during dispensation of the product). Moreover, the liquid evaporates rapidly and no residues on the skin are available for possible hand to eye exposure.
In some cases refilling might be needed and based on the classification H318, the following RMM has been added: *"If refilling is needed, gloves and eye protection should be used".*

Scenario [2] PT 1 – Mixing and Loading (manual) decanting of product into automated application equipment

In some cases refilling might be needed and potential primary exposures have been assessed for professional workers (also covering industrial workers) conducting mixing and loading activities in the chemical storage room using larger pack sizes to refill the automatic pump. Based on the classification H318, the following RMM has been added to these products *"If refilling is needed, gloves and eye protection should be used".*
Therefore for these scenarios below the operator is considered to be wearing the PPE required by the RMM phrase. Furthermore these refill procedures would not be expected to be carried out by the same workers exposed in Scenario 1a and is expected to be conducted instead by maintenance workers refilling the automated pumps with larger refill packs.

Description of Scenario [2]
Potential dermal and inhalation exposure can occur while decanting product into the automated application equipment's receiving reservoir. No dilution is envisaged under this scenario as the solution is in ready-to-use form. This scenario is relevant to uses where product may need to be manually decanted into equipment. This only occurs in occasional cases where there is a requirement to refill automated pumps using larger pack sizes and this would be done in the chemical storage room by a maintenance worker not a food worker, who would be assumed to be wearing goggles and gloves as PPE. Usually there would be no need to refill the dispensers as the product is supplied

in packaging that is to be used with specific dispensers meaning that the refilling process is usually a closed system except for in rare circumstances.

The potential dermal worker exposure (assumed 60 kg body weight) following application of the disinfectant was assessed 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 (Version 3, 2017).

As per the scenario above the Tier 1 assessment has been split into Tier 1 "a" and Tier 1 "b" to account for the changes made and agreed at the Human Health meeting WG-II-2019 (23rd May 2019)[7], to utilise the updated EFSA guidance on dermal absorption values. This update will harmonise the use of default dermal absorption values, and according to the EFSA guidance (2017) the default assumption for biocidal products containing an active substance which is present in a formulation at a concentration of greater than 50g/L or 5%, should be considered that of a concentrate and as such the default dermal absorption value of 25% should be used. As this guidance has been agreed but not yet updated into the Technical Agreements for Biocides (TAB), for completeness we have demonstrated a Tier 1 risk assessment showing both a 70% and 25% default dermal absorption assumption.

There is no proposed exposure model to estimate dermal exposure during Mixing and Loading for PT1. Mixing and Loading Model 7 is recommended for PT2 and the indicative exposure value from this has been used to demonstrate a worst-case scenario for primary exposures during mixing and loading to refill an automated pump for a PT1.

For estimation of the inhalation exposure Mixing and Loading Model 7 was also used, the indicative value is used to cover activity in PT1.

Tier 1 estimation includes a reduction factor assuming PPE as it is assumed the maintenance worker would be wearing gloves and goggles. A Tier 2 estimation using the transdermal flux calculation was not required as both results fall well under the threshold of the calculated AEL.

	Parameters	Value
Tier 1a	Dermal absorption (%)[14]	70% (default)
	Dermal Indicative exposure value[15]: Mixing and Loading Model 7 (default value)	1.01 mg/min (inside gloves)
	Exposure Duration	10 min
	Inhalation Indicative exposure value[16]: Mixing and Loading Model 7 (default value)	0.94 mg/m^3
	Exposure Duration	10 min

14 Guidance on dermal absorption (EFSA journal, 2017)

15 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 (Version 3, 2017)

Tier 1b	Dermal absorption (%)[15]	25%
	Dermal Indicative exposure value[16]: Mixing and Loading Model 7 (default value)	1.01 mg/min (inside gloves)
	Exposure Duration	10 min
	Inhalation Indicative exposure value[16]: Mixing and Loading Model 7 (default value)	0.94 mg/m^3
	Exposure Duration	10 min

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2] Mixing and Loading (manual) decanting of product into automated application equipment	1a (with PPE)	0.0024	0.0884	n.a.	0.091
Scenario [2] Mixing and Loading (manual) decanting of product into automated application equipment	1b (with PPE)	0.0024	0.0316	n.a.	0.034

Further information and considerations on scenario [2]

No further information or considerations are necessary. Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore, a qualitative risk assessment for local effects was carried out. Considering the scenario assessed, the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for

a professional user. During application of the hand disinfection product no contact of the eyes is expected since only small amounts of product are used in a very controlled way (i.e. the creation of splashes is avoided during dispensation of the product). Moreover, the liquid evaporates rapidly and no residues on the skin are available for possible hand to eye exposure. In some cases refilling might be needed and based on the classification H318, the following RMM has been added: *"If refilling is needed, gloves and eye protection should be used".*

Scenario [3] PT 1 - Post Application Hand Disinfection

Potential secondary exposures have been assessed for professional worker bystanders (also covering industrial worker bystanders) exposed to vapours following hand rub application occurring in the same room.

Description of Scenario [3]		
Dermal exposure is not considered relevant for bystanders, as any residues on co-workers hands will be negligible due to rapid evaporation. Secondary exposure estimates by inhalation should be in the same range as for primary exposure since secondarily exposed persons will be in the same room as the person that applies the biocidal product. Exposure might be acute or chronic depending on the frequency a person stays in rooms after use of the biocidal product. As the biocidal product family is not classified for acute toxicity, the long-term risk assessment is considered suitable for acute or chronic secondary exposure. Estimation of the inhalation exposure was conducted in accordance with Recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure - Hand disinfection in hospitals (revision agreed at the Human Health Working Group I on 19 January 2017). The tier 1 assessment was conducted based on a worst-case approach where it is considered that all disinfectant is applied in one room successive without a break. Certain modifications were made to the tier 1 assessment described in Recommendation 9, to account for the fact that the products are used in professional food preparation areas, and not hospitals. Application frequency was 10 times per day as per the SPC and identified use parameters. Calculation of the inhalation exposure is based on the model ConsExpo Web "Exposure to vapour: Instantaneous release". Default ConsExpo settings are as outlined in Recommendation 6, except that the room volume is reduced from 80 m^3 to 20 m^3, as the room size for the identified use in this assessment is not specified. As propan-1-ol is a volatile compound, the evaporation time from skin surface was calculated according to the EU Technical Guidance Document (TGD, 2003). For a 75 % (w/w) hand disinfectant containing propan-1-ol, evaporation of 3 mL from skin would take 106 seconds (contact time), when assuming a density of propan-1-ol = 0.8 g/cm^3, a skin temperature of 30°C (TGD 2003) and a corresponding propan-1-ol vapour pressure of 3,600 Pa (30°C).		
	Parameters	Value
Tier 1	ConsExpo Input Parameters[1, 2]: Model Mode of Release Frequency (events per day) Exposure Duration (min)[3] Product Amount (per event) (g) Weight Fraction Substance (%) Room Volume (m^3) Ventilation Rate (/h) Inhalation Rate (m^3/hr) Vapour Pressure (Pa) Application Temperature (°C)	 Exposure to vapour Instantaneous release 10 17.7 2.6 75 20 1.5 1.25 3,600 30

[1] 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 (Version 3, 2017)
[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure - Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)
[3] Below et al., 2012

ConsExpo output report is presented in Annex 3.2.

Calculations for Scenario [3]

Tier 1

Evaporation Rate Calculation (TGD, 2003) - For pure substances, the following equation is used:

$$t_{(s)} = \frac{mRT}{M\beta pA}K$$

Where:
t = time (s)
m = mass, EASE estimate (mg)
R = gas constant (8.314 $J.K^{-1}.mol^{-1}$) (TGD, 2003)
T = skin temperature (303.15 K / 30ºC) (TGD, 2003)
M = molar mass (60.09 g/mol)
β = coefficient of mass transfer in the vapour phase (8.7 $m.h^{-1}$) (TGD, 2003)
p = vapour pressure of pure substance (3,600 Pa (303.15 K))
A = area, EASE (820 cm^2)
K = conversion factor (3.6×10^4) (TGD, 2003)

m = (3000 mg x 0.8) x 0.75 = 1,800 mg (*3 mL corrected for density and then corrected for 75 % in formulation*)

t = [(1800 x 8.314 x 303.15) / (60.09 x 8.7 x 3600 x 820)] x 3.6×10^4 = **105.83 s**

Tier 1 exposure estimates were calculated using ConsExpo Web version 1.0.7 - see output in Annex 3.2.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3] PT 1 - Post Application Hand Disinfection	1/-	4.8	n.a.	n.a.	4.8

Further information and considerations on scenario [3]

No further information or considerations are necessary. Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore, a qualitative risk assessment for local effects was carried out. Considering the scenario assessed the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for a professional user. Since no contact of liquid propan-1-ol to the eyes is expected during secondary exposure, the use of eye protection is not required.

Combined scenarios

Not applicable, there are no combinations of scenarios for which industrial or professional workers may be exposed. Scenario 1 covers primary exposure of the single authorised use and scenario 3 covers secondary exposure of the single authorised use. No accumulation of primary or secondary exposures is considered relevant.

Non-professional exposure

There is no primary or secondary exposure to non-professionals as use of hand disinfection products from the product family is limited to industrial and professional uses only.

Exposure of the general public

There is no primary or secondary exposure to non-professionals as use of hand disinfection products from the product family is limited to industrial and professional uses only.

Monitoring data

Not applicable.

Dietary exposure

Residues in food or feed from the intended use of propan-1-ol in PT 1 biocidal products are not expected, as no direct or indirect contact with food or feed is intended (CAR – Germany, 2017). Due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from hands to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-1-ol as a biocide of PT 1 can be excluded.

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

The potential exposure of industrial workers during the production and formulation of the b.p. is addressed under REACH and not repeated under Regulation (EU) 528/2012 (BPR), as the manufacturing is not exclusively for biocidal purposes. The risk assessments performed have focused on the use of the product once formulated and the potential exposure to both humans and the environment.

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 (mg/kg bw/d)**

1. PT 1 - Hand Disinfection	Industrial Professional	1a/-	215
		1b	79.5
		2/-	7.92
2. PT 1 – Mixing and Loading (manual)	Industrial Professional	1a	0.091
		1b	0.034
3. PT 1 - Post Application Hand Disinfection	Industrial Bystanders Professional Bystanders	1/-	4.5

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (mg/kg bw/d)	AF[1]	Correction for oral absorption	Value (mg/kg bw/d)[1]
AELshort-term	Rat inhalation developmental toxicity study	2,760	100	No	27.6
AELmedium-term	Repeated-dose rat inhalation (13 week)	1,830	100	No	18.3
AELlong-term	Repeated-dose rat inhalation (13 week)	1,830	200	No	9.2
ARfD	Rat inhalation developmental toxicity study	2,760	100	No	27.6
ADI	Repeated-dose rat inhalation (13 week)	1,830	200	No	9.2

[1] As presented in CAR (Germany, 2017)

Local effects arising from the Eye Dam. 1 (H318) classification are considered non-threshold effects, with no relevant reference value. A qualitative risk characterisation has been conducted for this hazard.

Maximum residue limits or equivalent

Not applicable, no residues on food or animal feed are considered relevant for the PT 1 uses of the product family.

Risk for industrial users

Please refer to risk for professional users.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] PT 1 - Hand Disinfection	1a	1,830	9.2	215	2337	No
	1b			79.5	864	No
	2			7.92	86	Yes
[2] PT 1 – Mixing and Loading (manual)	1a	1,830	9.2	0.091	0.99	Yes
	1b			0.034	0.37	Yes
[3] PT 1 - Post Application Hand Disinfection	1	1,830	9.2	4.50	49	Yes

Combined scenarios

Not applicable, there are no combinations of scenarios for which industrial or professional workers may be exposed. Scenario 1 covers primary exposure of the single authorised use and scenario 3 covers secondary exposure of the single authorised use. No accumulation of primary or secondary exposures is considered relevant.

With regards to mixing and loading it is not considered that the exposed worker under scenario 1 would be the same maintenance type worker considered under scenario 2 as these roles would be separate, therefore we do not consider that a combined risk characterisation concerning all potential exposures for a single worker undertaking all duties is essential. However, the combined potential exposure for the purpose of demonstrating a worst-case scenario for both scenarios and also taking into account the assessments using both dermal absorption values for completeness of both a 70% and 25% default dermal absorption assumption is presented. Both combined scenarios result in an acceptable outcome.

Systemic effects – Propan-1-ol Combined Exposures

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)

Primary Exposures Scenarios 1 Hand Disinfection	2	1,830	9.2	7.92	8.011	87.1	Yes
Primary Exposures Scenarios 2– Mixing and Loading (manual)	1a (70% D.A with PPE)	1,830	9.2	0.091			
Primary Exposures Scenarios 1 Hand Disinfection	2	1,830	9.2	7.92	7.954	86.5	Yes
Primary Exposures Scenarios 2– Mixing and Loading (manual)	1b (25% D.A with PPE)	1,830	9.2	0.034			

Local effects

Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore, a qualitative risk assessment for local effects was carried out. Considering the scenario assessed the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for a professional user. Since no contact of liquid propan-1-ol to the eyes is expected the use of eye protection is not required, except if refilling is necessary. Then the following RMM is added: *"If refilling is needed, gloves and eye protection should be used".*

Hazard			Exposure							Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion on risk**	**Uncertainties attached to the conclusion**
High	Eye Dam. 1; H318	-	1	Industrial Professionals	Hygienic hand disinfection in food industry and institutional areas for professional users by hand washing with hand soap. Refilling in the chemical storage room where larger pack sizes are stored	Eye	10 x per day	Very low, due to professional use No splashes, no hand to eye transfer	Labelling as eye damaging PPE is not applicable for hand disinfection *"Avoid contact with the eyes"* *"If refilling is needed, gloves and eye protection should be used"*	**Acceptable:** + trained workers	Frequency of use may be higher than recommended Instructions for use adherence may vary
Low	EUH066 otherwise not classified	-	1	Industrial Professionals	Hygienic hand disinfection in food industry and institutional areas for professional users by hand	Skin	10 x per day		Labelling Instructions for use *"In case of skin dryness, use appropriate skin care lotion"*	**Acceptable** since: Reversible effect Adverse effect only after repeated	Frequency of use may be higher than recommended Instructions for use

					washing with hand soap					prolonged exposure Low frequency of use (10 use events per day is considered for the assessment) Proper instructions for use support the product	adherence may vary

Neither the active substance nor the product co-formulants are classified for acute dermal toxicity, meaning the biocidal product is not classified for this hazard, however EUH066 has been included as a supplemental label phrase based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol or to propan-1-ol dilutions. We have included this phrase as it is in line with both the CAR and BPC opinion[16] for propan-1-ol.

A local effects assessment based on this revised classification has been presented below, however, in the absence of a full local effects assessment in the propan-1-ol CAR, and the fact that active substance is not considered to be a skin sensitiser based on MEST and GPMT studies presented in the CAR, and it is also not regarded as sufficient for classification as Skin Irrit. 2 (H315) according to Annex VI of Regulation (EC) No 1272/2008, it is concluded that a quantitative local effects risk assessment is not necessary.

The Human Exposure guidance on BPR Volume III section 4.3.2 of Appendix 4 states that Risk Characterisation for local effects is not required when the active substance/and or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to CLP criteria[17]. The guidance also states that it is critical that the risk characterisation for local effects also focuses on the product, rather than the active substance only[18].

As stated above this product does not trigger any formal classification that would require a systemic or local quantitative assessment, but based on the guidance available and the revised classification to include EUH066, a qualitative risk assessment can be carried out in line with the guidance on the BPR: Volume III Parts B & C.

Table 24 of section 4.3.2.5 of this guidance, categorises the risk for this product carrying the supplemental phrase EUH066 as "low". This conclusion was made using the EU hazard classification system (both that under the DSD/DPD and that under the CLP Regulation), and this is used as a descriptor of the hazards since the classification system for these local effects tend to reflect the qualitative and semi-quantitative nature of the information that is usually available for these endpoints. This low category that has been awarded relates to moderate irritants which may cause dryness and are allocated to this category because they cause moderate, reversible effects.

This is further backed up by the adopted BPC opinion for propan-1-ol products for use in product type 1 which states that "Propan-1-ol was not irritating to the skin but may cause skin dryness and cracking".

Table 26 of the guidance on the BPR Volume III parts B&C states that relevant Risk Mitigation Measures where PPE is not relevant is labelling, and instructions for use that minimise exposure or possible health effects, such as the phrase included originally, "In case of skin dryness, use appropriate skin care lotion". The qualitative local risk assessment above also concludes that this risk is acceptable due to the reversible nature

16 BPC Opinion on the application for approval of the active substance: Propan-1-ol PT1 https://echa.europa.eu/documents/10162/24380804/8618_Propan-1-o_PT+1_BPC+opinion.pdf/e32d60c6-4061-e465-607c-cd9b64cf07a3

17 Guidance on the application of the CLP criteria, Version 5.0 July 2017 https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5

18 Guidance on the BPR: Volume III Parts B+C, Version 4.0 December 2017 https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094

of any risks, which can be done through following the instructions for use for the product and adhering to the label recommendations.

A local risk assessment was performed for eye exposure in the CAR and as stated in the BPC opinion this was based on the fact that the classification of serious eye damage was fulfilled, it was then concluded that as eye exposure is not expected, no concern was identified from the use and as such this could be avoided through risk mitigation labelling such as "avoid contact with the eyes" to minimise the possibility of exposure. We consider the supplemental hazard statement EUH066 and the labelling of the risk mitigation measure "In case of skin dryness, use appropriate skin care lotion", is acceptable in this case based on this precedent, and based of the low risk categorisation for the qualitative local risk assessment performed and the outcomes shown above.

Conclusion

All scenarios are considered acceptable without the use of personal protective equipment, as estimated exposure concentrations are below the relevant reference values. Local effects are not expected to occur (eye damage) as no contact of the products with the eyes is expected based on the conditions of the authorised use. During application of the hand disinfection product no contact of the eyes is expected since only small amounts of product are used in a very controlled way (i.e. the creation of splashes is avoided during dispensation of the product). Moreover, the liquid evaporates rapidly and no residues on the skin are available for possible hand to eye exposure. Additionally, no exposure to the eyes is relevant for secondary exposures as no direct contact with the product is foreseen. With regards to local effects seen for skin as the BPC opinion states that "Propan-1-ol was not irritating to the skin but may cause skin dryness and cracking", the supplemental label phrase "EUH066 Repeated exposure may cause skin dryness or cracking" has been included in line with both the CAR and BPC opinion[19] for propan-1-ol. Any local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol or to propan-1-ol dilutions are considered to be a low risk as they cause moderate, reversible effects, that can be countered by following the advice also given as a further risk mitigation measure "In case of skin dryness, use appropriate skin care lotion".
There is only one scenario exempting this conclusion and that is for rare cases of refilling in chemical storage rooms where larger pack sizes are stored. For this scenario the following RMM has been added: *"If refilling is needed, gloves and eye protection should be used".*

Risk for non-professional users

There is no primary or secondary exposure to non-professionals as use of hand disinfection products from the product family is limited to industrial and professional uses only.

Risk for the general public

There is no primary or secondary exposure to non-professionals as use of hand disinfection products from the product family is limited to industrial and professional uses only.

[19] BPC Opinion on the application for approval of the active substance: Propan-1-ol PT1 https://echa.europa.eu/documents/10162/24380804/8618_Propan-1-o_PT+1_BPC+opinion.pdf/e32d60c6-4061-e465-607c-cd9b64cf07a3

Risk for consumers via residues in food

Residues in food or feed from the intended use of propan-1-ol in PT 1 biocidal products are not expected, as no direct or indirect contact with food or feed is intended (CAR – Germany, 2017). Due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from hands to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-1-ol as a biocide of PT 1 can be excluded.

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

Not applicable, the products in the product family only contain one active substance (propan-1-ol).

2.2.7 Risk assessment for animal health

Food, drinking water or livestock exposure of propan-1-ol can be excluded when applied according to the recommended uses. Therefore no formal risk assessment for animal health is required.

2.2.8 Risk assessment for the environment

The Ecolab UA biocidal product family is an alcohol-based hand and skin disinfectant (PT1) used as a "leave-on" product. The biocidal product family is intended to be used by professionals and industry for hand disinfection in food and beverage processing areas. The exposure assessment has been performed using the scenario for professional use based on default values for consumption in hospitals (ESD for PT 1, EUBEES 2004). This scenario can be considered as a worst-case, since the food and beverage sector has a much lower consumption compared to hospitals (for more details see 2.2.8.2.).

2.2.8.1 Effects assessment on the environment

The table below shows a summary of the PNECs for the active substance propan-1-ol in the different environmental compartments. The information is taken from the assessment report for the active substance (CAR - Germany, 2017).

PNECs for STP, freshwater, freshwater sediment and soil		
Unit	**Unit**	**Value**
STP	[µg/L]	10,000
Freshwater	[µg/L]	2,300
Sediment	[µg/kg]	1,998
Soil	[µg/kg ww]	432
Air	[µg/m^3]	See Section 2.2.8.3 ("Atmosphere")

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

The lowest acute effect value of EC_{50} 2300 mg/L for *Nitocra spinipes* is above the trigger value >100 mg/L for environmental classification (CAR - Germany, 2017). Furthermore, propan-1-ol is considered as readily biodegradable (CAR - Germany, 2017). Referring to environmental and human health effect data, there is no indication of endocrine disrupting properties of the active substance (CAR - Germany, 2017). Consequently, no environmental classification of the active substance propan-1-ol according to Regulation (EC) 1272/1008 (CLP) is required. Similarly, none of the co-formulants used in the biocidal product family are classified for the environment according to Regulation (EC) 1272/2008.

It can therefore be concluded that the environmental classification of the products in the biocidal product family can be determined based on the environmental classification of the constituents of the products. The biocidal product family is therefore concluded to be not classified for the environment in accordance with Regulation (EC) 1272/2008.

Further Ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required.
Justification	Testing on the products does not need to be conducted as there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/ 2008 (CLP). Testing of the biocidal product family is therefore not deemed necessary. Classification may be based on read across to the active substance by means of a letter of access and reference to the components and their concentration in the mixture.

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

Data waiving	
Information requirement	No further ecotoxicological studies are required
Justification	This is not a data requirement. The products are intended for use indoors where there will be no direct exposure of the environment.

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

Data waiving	
Information requirement	No further ecotoxicological studies are required.
Justification	This is not a data requirement. The products are intended for use indoors where there will be no direct exposure of the environment.

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

Data waiving	
Information requirement	No further ecotoxicological studies are required.
Justification	This is not a data requirement. The products are intended for use indoors where there will be no direct exposure of the environment.

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

The biocidal product family is not intended for large scale treatment of habitats like water bodies, wetland, forest or fields. The products are not expected to persist in the environment or to bioaccumulate along the food chain based on the ready biodegradability and very low bioaccumulation potential of the active substance, therefore information on secondary ecological effects is not required.

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

Information on how the active substance can be released into the environment during application in PT 1 and the potential emissions have been assessed in the CAR, where sources for emissions as well as target environmental compartments have been considered and concentrations in the compartments of concern have been calculated. For detailed information, please refer the relevant sections in this document. All environmental fate and physiochemical properties data employed in the exposure calculations are taken from the CAR of propan-1-ol, PT1 (Germany, 2017).

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification	The environmental fate and behaviour properties of the product family may be derived from the properties of the active ingredient and other components of the product. Information on the fate and behaviour in the environment of propan-1-ol is presented in the Annex I dossier by means of a letter of access and with reference to the assessment reports for propan-1-ol. No further studies are required.

Leaching behaviour (ADS)

The leaching behaviour of the active substance from treated commodities is not relevant to PT 1 applications. Further studies regarding the leaching behaviour are therefore not necessary.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Further information on distribution and dissipation in soil is not required.
Justification	Based on data in the CAR (Germany, 2017), the active substance can be considered as readily biodegradable. No further testing is considered necessary to determine the distribution and degradation characteristics of the product.

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

Data waiving	
Information requirement	Further information on distribution and dissipation in water and sediment is not required.
Justification	Based on data in the CAR (Germany, 2017), the active substance can be considered as readily biodegradable. No further testing is considered necessary to determine the distribution and degradation characteristics of the product.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Further testing on distribution and dissipation in air is not required.
Justification	The product is not used as a fumigant. No further testing is considered necessary due to the intended use of the product which is limited to indoor application and on basis of the available substance information the environmental risk can be assumed as low.

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)

Data waiving	
Information requirement	Overspray study under field conditions is considered to be unnecessary.
Justification	This product is for indoor use and is not intended to be sprayed near 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 applicable, the substance is not sprayed outside, nor is there potential for large scale formation of dust.

Screening for endocrine disruption relating to non-target organisms

An assessment of the endocrine disrupting potential of the active substance propan-1-ol has been performed and it was concluded in the CAR (Germany, 2017) that there is no indication of endocrine disrupting properties of propan-1-ol. No further assessment of the active substance is necessary. A screening assessment of endocrine disrupting properties of the co-formulants used in the product family is also presented in the Confidential Annex 3.6. None of the co-formulants used in the biocidal product family are considered to have endocrine disrupting properties.

2.2.8.2 Exposure assessment

The biocidal product family is an alcohol-based hand disinfectant (PT1). The product is a ready-to-use solution that is applied onto the palm of one hand out of an automatic dispenser, and the complete surface of both hands is moistened and allowed to dry (application phase). During one hand disinfection, an amount of 3 mL biocidal product (containing 75 % 1-propanol in an aqueous solution) is used.

General information

Assessed PT	PT 1
Assessed scenarios	Hand disinfection (professional use)
ESD(s) used	Emission Scenario Document for Product Type 1: Biocides used as human hygiene biocidal products (Jan 2004)
Approach	Professional use – consumption-based assessment
Distribution in the environment	Calculated based on ECHA Guidance on BPR: Vol IV Environment Parts B+C)
Groundwater simulation	Not relevant
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No

Emission estimation

Scenarios for PT 1 Hand Disinfection

The Environmental Emission Scenario Document (ESD) for PT 1 (Royal Haskoning, 2004) presents 4 example scenarios to determine emissions for use in the environmental risk assessment:

1. Private use – tonnage-based assessment
2. Private use – consumption-based assessment
3. Professional use – tonnage-based assessment
4. Professional use – consumption-based assessment

The Ecolab UA BP family will be used as hand and skin disinfectants in areas such as restaurants and catering. Example emission scenarios 1 and 2 are therefore not relevant for this BP family as it will only be sold for professional use. Scenario 4 represents in

this case a highly worst-case scenario because of the high number of disinfections in a hospital (nursing care and surgical area) in comparison to restaurants and caterings.

Initially, the applicant also included in the PAR results for emissions based on a tonnage-based approach that were approximately 9 times lower than the emissions calculated based on a consumption-based approach. This confirms the results reported in the CAR-2017 concerning the consumption-based approach being more conservative than the tonnage-based approach. For this reason, this assessment is based only on a consumption-based approach as we consider it to be a worst-case scenario for the intended use of the product. The exposure assessment has been performed using example scenario 4; Professional use – consumption-based assessment.

Scenario: PT1 – Hand disinfection (professional use in hospital) – <u>Average consumption-based assessment</u>

The daily emission of propan-1-ol to air and wastewater have been estimated using the PT 1 emission scenario document, using the equations presented below and default inputs provided in the ESD document. Since default values are used, the outcome is the same as calculated by the eCA during the active substance assessment, for reference see CAR for propan-1-ol (Germany 2017)

$$\mathrm{Elocal_{water}} = \mathrm{Nbeds_{pres}} \times \mathrm{Qsubst_{pres\_bed}} \times 10^{-3} \times \mathrm{F_{water}}$$

$$\mathrm{Elocal_{air}} = \mathrm{Nbeds_{pres}} \times \mathrm{Qsubst_{pres\_bed}} \times 10^{-3} \times \mathrm{F_{air}}$$

Input parameters for calculating the local emission for Hand disinfection (professional use in hospital)			
Symbol	Description	**Value**	**Remarks**
Input			
$\mathrm{Nbeds_{pres}}$	Number of beds in hospital	400	D
$\mathrm{F_{water}}$	Fraction released to wastewater	0.1*	S
$\mathrm{F_{air}}$	Fraction released to air	0.9*	S
$\mathrm{Qsubst_{pres\_bed}}$	Consumption of active ingredient per bed	15 g/day	P
Output			
$\mathrm{Elocal_{water}}$	Emission rate to wastewater	0.6 kg/day	O
$\mathrm{Elocal_{air}}$	Emission rate to air	5.4 kg/day**	O

D: Default value according to ESD for PT1
O: Output value derived from ESD for PT1
S: Data set. Values presented in CAR – Germany 2017
P: Pick list. Parameter selected from pick list in ESD for PT1
** It is assumed that 90 % of the active substance is emitted to air and 10 % to wastewater (**Propan-1-ol, Document II-B, PT1, P. 30-31**)*
*** Calculated value – assuming 10 % emission to wastewater is 0.6 kg/day, as determined by ESD for PT1, emission to air will be 9 X greater (i.e. 90 % of total emission)*

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Wastewater	0.6	O
Air	5.4	Fraction (0.9) emitted to air

O: Output value derived from ESD for PT1

The biocidal product is used as hand and skin disinfectant as a "leave-on" product. The main emission path 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 may be emitted to the local outside air.

According to Technical Agreements for Biocides Environment (ENV), 2 July 2021, ENV 188, for products containing very volatile substances used in general, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air.

However, partial releases to wastewater - via leakages or rinse-off - cannot be excluded. The exact distribution between air and wastewater is not known. The emissions calculations presented in the CAR are based on the assumption that 90 % of the propan-1-ol is emitted to air and 10 % to wastewater (1-propanol, Document II-B, PT1, P. 30-31). Since propan-1-ol is readily biodegradable only small amounts will reach soil via STP and the subsequent exposure of groundwater will be negligible (see also the qualitative assessment in 2.2.8.3).

Available data on the fate and the behaviour of propan-1-ol are summarized in the following table. These data are from the CAR of propan-1-ol, PT1.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
	Freshwater	Freshwater sediment	Seawater	Seawater sediment	STP	Air	Soil	Groundwater
Scenario 1	Yes	Yes	No	No	Yes	Yes	Yes	Negligible

Available fate and distribution data for the active substance propan-1-ol			
Input	Value	Unit	Remarks
Molecular weight	60.09	g/mol	-
Melting point	-127	°C	Referenced from CAR (Germany, 2017)
Boiling point	97.2	°C	Referenced from CAR (Germany, 2017)
Vapour pressure (at 25 ºC)	2760	Pa	Referenced from CAR (Germany, 2017)
Water solubility (at 25 °C)	-	-	Dissolves indefinitely in water

Partition coefficient (log K_{OW})	0.25	-	Referenced from CAR (Germany, 2017)
Organic carbon/water partition coefficient (Koc)	3.96	L/kg	QSAR estimate for alcohols described in Guidance BPR IV ENV B (2015) – referenced from CAR (Germany, 2017)
Henry's Law Constant (at 25 ºC)	0.76	Pa*m3*mol^{-1}	Bond method. Referenced from CAR (Germany, 2017)
Biodegradability	Readily biodegradable, fulfilling 10-d window		
Rate constant for STP	1	h^{-1}	Extrapolated from the biodegradation screening test according to the Table 4, page 62 of the Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
DT_{50} for biodegradation in surface water	15	d (at 12 ºC)	Extrapolated from the biodegradation screening test according to the Table 5, page 65 of the Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
DT_{50} for hydrolysis in surface water	-	d (at 12 ºC and pH 7)	Hydrolysis under environmental conditions is not expected
DT_{50} for photolysis in surface water	-	d	Photolysis is not expected.
DT_{50} for degradation in soil	30	d (at 12 ºC)	Extrapolated from the biodegradation screening test according to the Table 6, page 67 of the Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
DT_{50} for bulk sediment	300	d (at 12 ºC)	Factor of 10 higher than soil half-life value. Page 67 of the Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
DT_{50} for degradation in air	2.8	d	Referenced from CAR (Germany, 2017)

The estimated distribution of propan-1-ol in sewage treatment plants was calculated by the eCA during the active substance assessment, using SimpleTreat 3.0. In accordance with the Technical Agreements for Biocides EnvironmentENV 9, (July, 2021) it is necessary to update these estimates using SimpleTreat 4.0. The updated values are presented below.

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0.17	Estimated using SimpleTreat 4.0
Water	7.98	
Sludge	0.037	

Degraded in STP	91.8	

Calculated PEC values

All PEC values have been estimated according to the methods detailed in the Guidance on the Biocidal Products Regulation, Volume IV (Parts B + C), October 2017, using EUSES version 2.2.0.

Sewage Treatment Plant

The predicted environmental concentration in sewage treatment plants was estimated using equation 35, 36 and 41 of the BPR guidance, Volume IV (Parts B + C) and using the distribution factors presented in the table above.

Resulting predicted environmental concentrations of propan-1-ol in the sewage treatment plant (STP)	
Scenario	**PEC_{STP} [µg/L]**
PT 1 Hand disinfection – Consumption approach	23.9

Surface Waters

The predicted environmental concentration in surface waters was estimated using equation 48 of the BPR guidance, Volume IV (Parts B + C). The PEC_{water} is equivalent to the local concentration in water ($Clocal_{water}$) as in accordance with section 2.2.1 of the BPR guidance, Volume IV (Parts B + C), regional PEC_{water} values are not required as the exposure assessment for biocides is performed only at the local scale.

Resulting predicted environmental concentrations of propan-1-ol in the surface water	
Scenario	**PEC_{water} [µg/L]**
PT 1 Hand disinfection – Consumption approach	2.39

Sediment

The predicted environmental concentration in sediment was estimated using the equilibrium partitioning method, in accordance with equation 19, 24 to 27 and equation 53 of the BPR guidance, Volume IV (Parts B + C).

Resulting predicted environmental concentrations of propan-1-ol in the sediment	
Scenario	**PEC_{sed} [µg/kg_{ww}]**
PT 1 Hand disinfection – Consumption approach	2.08

Soil

The predicted environmental concentration in soil has been estimated in accordance with the BPR guidance, Volume IV (Parts B + C). The standard calculations account for inputs to soil via 10 years of sludge application to land and 10 years of aerial deposition. However, as previously noted, according to Technical Agreements for Biocides

Environment (ENV), for very volatile substances, it is not necessary to consider any subsequent environmental compartments following release to air (ENV 188). Therefore, the determination of PEC_{soil} is only based on input via sludge application.

For comparison with ecotoxicological endpoints the concentration in soil immediately after the 10th sludge application is required and is considered the PEC_{soil} (equation 64 of BPR guidance, Volume IV (Parts B + C)). This value is not available as an output of EUSES and has been manually calculated using the appropriate equations of the BPR guidance, Volume IV (Parts B + C). For clarity, the calculations are presented below.

The concentration in soil immediately after the first sludge application is given by:

$$Csludge_{soil1}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}}$$

Input parameters for calculating PEC_{soil}			
Symbol	Description	Value	Remarks
Inputs			
C_{sludge}	Concentration in dry sludge	0.272 mg/kg	O SimpleTreat 4.0 output
$APPL_{sludge}$	Dry sludge application rate	0.5 $kg_{dwt} \cdot m^{-2} \cdot yr^{-1}$	D (BPR guidance, IV, B+C)
$DEPTH_{soil}$	Mixing depth of soil	0.2 m	D (BPR guidance, IV, B+C, Table 9)
RHO_{soil}	Bulk density of soil	1700 kg/m^3	D (BPR guidance, IV, B+C, Table 3)
Output			
$Csludge_{soil1}(0)$	Concentration in soil after first year of sludge application	4.00 x 10^{-4} mg/kg ww	O

At the end of each year, a fraction of the initial concentration may remain in the top-soil layer, this fraction (*Facc*) is estimated as follows:

$$Facc = e^{-365xk}$$

$$\mathrm{k} = \mathrm{k_{volat}} + \mathrm{k_{leach}} + \mathrm{kbio_{soil}}$$

$$\mathrm{k_{leach}} = \frac{\mathrm{Finf_{soil}} \times \mathrm{RAIN_{rate}}}{\mathrm{K_{soil-water}} \times \mathrm{DEPTH_{soil}}}$$

$$\mathrm{kbio_{soil}} = \frac{\ln(2)}{\mathrm{DT50bio_{soil}}}$$

$$\mathrm{K_{soil-water}} = \mathrm{Fair_{soil}} \times \mathrm{K_{air-water}} + \mathrm{Fwater_{soil}} + \mathrm{Fsolid_{soil}} \times \frac{\mathrm{Kp_{soil}}}{1000} \times \mathrm{RHOsolid}$$

$$\mathrm{Kp_{soil}} = \mathrm{FOC_{soil}} \times \mathrm{K_{oc}}$$

Input parameters for calculating PEC_{soil}			
Symbol	Description	Value	Remarks
Inputs			
$Finf_{soil}$	Fraction of rainwater that infiltrates soil	0.25	D (BPR guidance, IV, B+C), p. 87

$RAIN_{rate}$	Rate of wet precipitation (700 mm/yr)	1.92 x 10^{-3} m/d	D (BPR guidance, IV, B+C), p. 87
$DT50bio_{soil}$	Half-life for biodegradation in bulk soil	30 d	D (BPR guidance, IV, B+C), Table 6, p. 67
$Fair_{soil}$	Volume fraction air in soil	0.2 m^3/m^3	D (BPR guidance, IV, B+C, Table 3)
$K_{air\text{-}water}$	Air-water partition coefficient	1.54 x 10^{-4} m^3/m^3	O EUSES output
$Fwater_{soil}$	Volume fraction water in soil	0.2 m^3/m^3	D (BPR guidance, IV, B+C, Table 3)
$Fsolid_{soil}$	Volume fraction solids in soil	0.6 m^3/m^3	D (BPR guidance, IV, B+C, Table 3)
FOC_{soil}	Weight fraction organic carbon in soil solids	0.02 kg/kg	D (BPR guidance, IV, B+C, Table 3)
K_{oc}	Organic carbon normalised partition coefficient	3.96 L/kg	Presented in CAR (Germany, 2017)
RHOsolid	Density of the solid phase	2500 kg_{solid}/m_{solid}^3	D (BPR guidance, IV, B+C, Table 3)
Intermediate Values			
k	First order rate constant for removal from top soil	0.0403 /d	O
k_{leach}	Pseudo-first order rate constant for leaching from top soil	7.53 x 10^{-3} /d	O
k_{volat}	Pseudo-first order rate constant for volatilisation from soil	9.71 x 10^{-3} /d	O Calculated using the SimpleBox model incorporated into EUSES v 2.2.0
$kbio_{soil}$	Pseudo-first order rate constant for degradation in bulk soil	0.0231 /d	O
$K_{soil\text{-}water}$	Soil-water partition coefficient	0.319 m^3/m^3	O
Kp_{soil}	Partition coefficient solids-water in soil (v/w)	0.0792 L/kg	O
Output			
Facc	Fraction accumulation in one year	4.09 x 10^{-7}	O

The initial concentration after the tenth yearly application, and the values used for comparison to the soil PNEC is determined using equation 63 of the BPR guidance, Volume IV (Parts B + C).

$$Csludge_{soil10}(0) = Csludge_{soil1}(0) \times \left[1 + \sum_{n=1}^{9} Facc^n\right]$$

Input parameters for calculating PEC_{soil}			
Symbol	Description	Value	Remarks
Inputs			
$Csludge_{soil1}(0)$	Concentration in soil after first year of sludge application	4.00 x 10^{-4} mg/kg ww	0
Facc	Fraction accumulation in one year	4.09 x 10^{-7}	O

Output			
$Csludge_{soil10}(0)$	Initial concentration in soil after 10 applications of sludge	4.00×10^{-4} mg/kg ww	O

In accordance with the BPR guidance, the PEC_{soil} value has been calculated based on the concentration in soil immediately after 10 sludge applications with one-year intervals. The guidance allows for two possible approaches for the expression of the soil PEC, either the initial concentration immediately after 10 sludge applications with one-year intervals or the 30-day time-weighted average (TWA) concentration following the tenth sludge application. However, it is stipulated that the use of TWA value is only suitable when the PNEC value has been estimated from a chronic study where the results have also been expressed based on time-weighted average concentrations. This is not the case for propan-1-ol, where the soil PNEC value was derived using the equilibrium partitioning method based on the results from the acute ecotoxicity test with *Nitocra spinipes.*

The estimated concentration of propan-1-ol in soil immediately following the tenth application of sludge to land is 4.00×10^{-4} mg/kg ww. This is equivalent to the PEC_{soil} as only inputs from sludge application are considered relevant, based on the guidance on very volatile substance in the Technical Agreements for Biocides Environment (ENV).

Summary table on calculated PEC values*					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{air}**
	[µg/L]	[µg/L]	[$\mu g/kg_{ww}$]	[$\mu g/kg_{ww}$]	[mg/m^3]
Scenario 1	23.9	2.39	2.08	0.40	-

No PEC_{air} is presented in the propan-1-ol assessment report for PT1 (CAR – Germany 2017). As no ecotoxicological data is available for the air compartment only a qualitative assessment of the risk to this compartment can be performed.

Primary and secondary poisoning

Primary poisoning

Due to the intended use as a hand disinfection product, a risk assessment for non-target animals primarily exposed to propan-1-ol is not necessary.

Secondary poisoning

Propan-1-ol is unlikely to bioaccumulate in aquatic or terrestrial environment according to the Guidance on BPR IV/B (2015). It has a very low log Kow (0.25) and a low organic carbon/water partition coefficient of 3.96 L/kg. The low accumulation potential is supported by low BCF for fish and earthworms (0.33 and 0.86, respectively). These data are taken from the CAR of propan-1-ol, PT1. Further assessment of secondary exposure via the food chain is therefore not deemed reasonable, which is in accordance to the Guidance on BPR IV/B (2015).

2.2.8.3 Risk characterisation

The results of the risk characterisation for each relevant compartment are presented in the table below.

Summary of Risk Characterisation for PT 1 Hand Disinfection			
	PEC	**PNEC**	**PEC / PNEC**
STP	23.9 µg/L	10,000 µg/L	2.39×10^{-3}
Surface water	2.39 µg/L	2,300 µg/L	1.04×10^{-3}
Sediment	2.08 µg/kg ww	1,998 µg/kg ww	1.04×10^{-3}
Soil	0.40 µg/kg ww	432 µg/kg ww	9.26×10^{-4}

The estimated PEC/PNEC values for the sewage treatment plant, surface water, sediment and soil are all below the trigger value of 1. It can be concluded that the Applicant's biocidal product family poses an acceptable risk to aquatic and terrestrial compartments.

Conclusion: The risk to aquatic and terrestrial environments is acceptable.

Atmosphere

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 high vapour pressure. Therefore, most of the substance applied is released to indoor air.

As a reasonable worst-case it is assumed that 90 % of a.s. is emitted to the outdoor air (CAR - Germany, 2017). Based on data in the CAR (Germany, 2017), propan-1-ol present in the atmosphere will react with photo-chemically produced OH and NO3 radicals.

The half-life of propan-1-ol in the troposphere was estimated to be 2.8 days (CAR – Germany, 2017). Therefore, the active substance has the 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 Guidance BPR IV ENV B (2015) effects on stratospheric ozone and acidification are not expected because propan-1-ol does not contain halogens, nitrogen or sulphur substituents. The potential for global warming cannot be characterised because there is no information available in the absorption spectrum in the range from 800 to 1200 nm (CAR – Germany, 2017).

As there are no ecotoxicological data on animal species for the air compartment available, no quantitative characterisation of risk by comparison of the PEC_{AIR} to $PNEC_{AIR}$ is possible (Germany, 2017). According to Guidance BPR IV ENV B (2015, chapter 3.7) a chemical may be dangerous for the atmospheric environment at a low concentration, if it is classified as R 48 ("Danger of serious damage to health by prolonged exposure"). This classification does not apply to propan-1-ol. Furthermore, inhalation studies with mammals can be used as indicators of adverse effects of volatile compounds on animals. The comparison of effect values obtained from inhalation studies with mammals (acute and subchronic studies with rats) with predicted environmental concentration for air indicate that there is no adverse effect of the volatile compound on terrestrial animals (Germany, 2017).

On the basis of the intended use of the b.p. for PT1 which is limited to indoor application and on basis of the available substance information the environmental risk of 1-propanol for the atmosphere can be assumed to be low.

Conclusion: The risk to air is low.

Groundwater

According to the Technical Agreements for Biocides Environment (ENV), July 2021, ENV 188, for products containing very volatile substances, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air. Specifically, for the subsequent environmental compartment groundwater it should be further noted that exceedance of the groundwater trigger value is not likely. Propan-1-ol is very volatile and adsorption to soil is not expected. In addition, the substance is readily biodegradable and if anything were to reach the groundwater compartment via air-deposition to soil it will degrade rapidly.

The product is a "leave-on" product, and the use of the product does therefore not involve washing or rinsing after application. 90% of the active substance is assumed to evaporate during indoor use, and the distribution to the STP is limited. Since propan-1-ol is readily biodegradable only small amounts will then reach soil via STP. In the soil compartment propan-1-ol will be further evaporated and degraded, and the subsequent exposure of groundwater will be negligible.

Consequently, based on the guidance provided in the Technical Agreements for Biocides Environment (ENV) July 2021, ENV 188, the use pattern of the product family and the properties of propan-1-ol, it can be concluded that exposure to groundwater will be negligible.

Conclusion: Exposure is negligible

Primary and secondary poisoning

Primary poisoning

Due to the intended use as a hand disinfection product, a risk assessment for non-target animals primarily exposed to propan-1-ol is not necessary.

Secondary poisoning

Propan-1-ol is unlikely to bioaccumulate in aquatic or terrestrial environment according to the Guidance on BPR IV/B (2015). It has a very low log Kow (0.25) and a low organic carbon/water partition coefficient of 3.96 L/kg. The low accumulation potential is supported by low BCF for fish and earthworms (0.33 $L/kg_{wet\ fish}$ and 0.86 $L/kg_{wet\ earthworm}$, respectively (CAR - Germany, 2017). Further assessment of secondary exposure via the food chain is therefore not deemed reasonable, which is in accordance with the Guidance on BPR IV/B (2015).

Conclusion: With regard to the low estimated BCF values in aquatic and terrestrial indicator species, propan-1-ol is not expected to accumulate in the environment. The risk of

secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

Mixture toxicity

Conclusion: The products of the BPF only contain propan-1-ol as the active substance and no substances of concern have been identified. Mixture toxicity is therefore not relevant.

Aggregated exposure (combined for relevant emission sources)

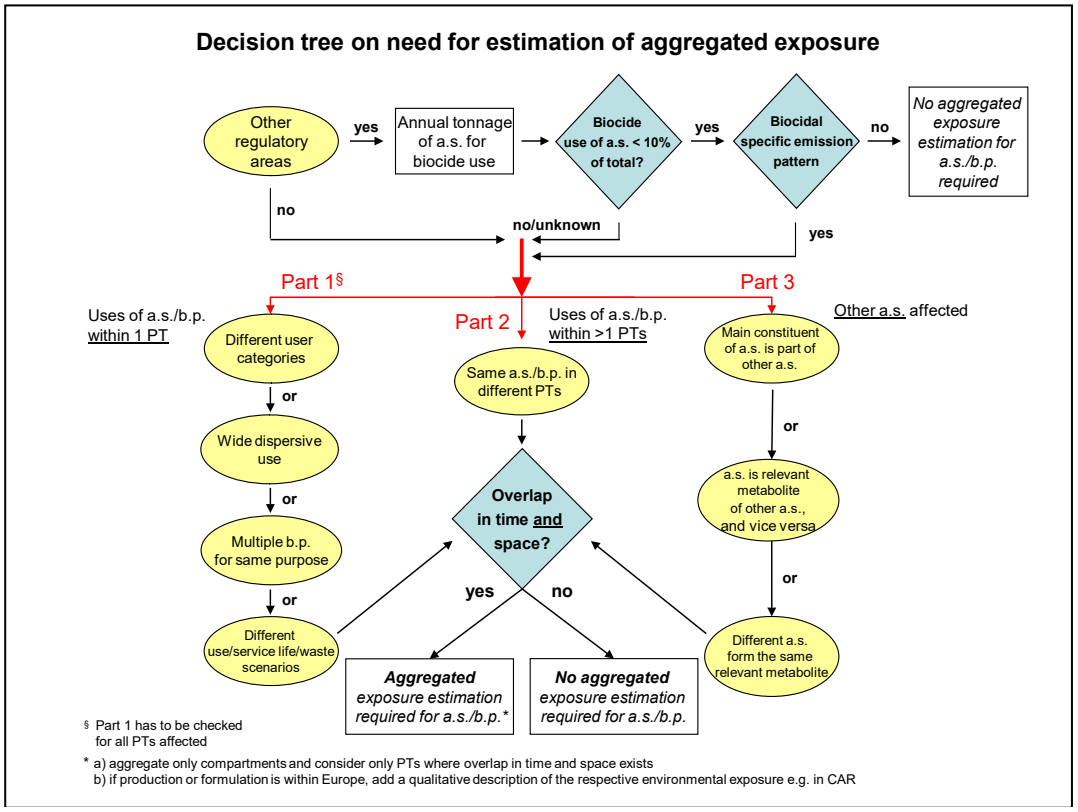

Figure 1: Decision tree on the need for estimation of aggregated exposure

Propan-1-ol is also regulated under other EU regulatory frameworks (e.g. REACH). Consequently, the annual EU tonnage of a.s. for biocidal use should be compared with the total EU production volume of propan-1-ol to be used for different applications. The total production and import volume in the EU were 30,010 t in 2007 (EU-RAR on 1-propanol, 2007). The biocidal use of propan-1-ol is < 10% of the total tonnage.

The intended use hand disinfection (leave-on-product) is widely dispersive and does not represent a specific emission pattern. Hence, according to the decision tree (Figure 8-1) it is not required to perform aggregated exposure estimation for the biocidal product family.

Overall conclusion on the risk assessment for the environment of the product
PT 1 • **STP:** PEC/PNEC values for 1-propanol < 1 have been identified for PT 1. • **Surface water:**

PEC/PNEC values for 1-propanol < 1 have been identified for PT 1.

- **Sediment:**

  PEC/PNEC values for 1-propanol < 1 have been identified for PT 1.

- **Soil:**

  PEC/PNEC values for 1-propanol < 1 have been identified for PT 1.

- **Groundwater:**

  Based on the intended use of the product and the properties of propan-1-ol the exposure is concluded to be negligible

2.2.9 Measures to protect man, animals and the environment

To protect man: The exposure of industrials / professionals to propan-1-ol in the products within the biocidal product family does not pose an unacceptable health risk when following the label instructions of the biocidal product for the respective use. Please refer to the conclusion in section 2.2.6. – "Risk characterization for human health".

To protect animals: Livestock exposure can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to animal health is expected and no measures to protect animals are required. Please refer to section 2.2.7. – "Risk assessment for animal health".

To protect the environment: Environmental exposure to the products within the biocidal product family do not pose an unacceptable risk when following the label instructions of the biocidal product for the respective use. For specific risk mitigation measures, please refer to section 2.1.5- "Directions for use".

2.2.10 Assessment of a combination of biocidal products

This assessment is not required as the biocidal product is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

A comparative assessment is not required as the biocidal product does not contain an active substance that is a candidate for substitution in accordance with Article 10(1).

3 Annexes

3.1 List of studies for the biocidal product (family)

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Below, H. et al.	2012	Dermal and Pulmonary Absorption of Propan-1-ol and Propan-2-ol from Hand Rubs	Americal Journal of Infection Control 40: 250-257	n.a.	No	Yes	No	n.a.	8.6

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published

3.2 Output tables from exposure assessment tools

ConsExpo Report – Inhalation Exposure

ConsExpo files are also available in Section 13 of IUCLID.

Report for assessment *Propan-1-ol PT1*

ConsExpo Web - Tue Feb 09 2021

Substance		
Name	Propan-1-ol	
CAS number		
Molecular weight	60.1	g/mol
Kow	0.25	10Log
Product		
Name	Product 1	
Weight fraction substance	75	%
Population		
Name	Professional	
Body weight	60	kg

Scenario *[1]* Tier 1a - 70% Default Dermal Absorption Assumption:
Scenario [3] PT 1 - Post Application Hand Disinfection (inhalation only)

Scenario PT1 *Hand Disinfection - Tier 1a*

Frequency	10	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	17.7	minute
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	2.6	g
Weight fraction substance	75	%
Room volume	20	m^3
Ventilation rate	1.5	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	30	°C
Vapour pressure	3600	Pa
Molecular weight	60.1	g/mol
Absorption model	n.a.	

Dermal

Exposure model	Direct contact - Instant application	
Exposed area	820	cm^2
Weight fraction substance	75	%
Product amount	2.6	g
Retention Factor	1	
Absorption model	Fixed fraction	
Absorption fraction	70	%

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *PT1 Hand Disinfection - Tier 1a*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.9×10^{1}	mg/m³
Peak concentration (TWA 15 min)	8.1×10^{1}	mg/m³
Mean concentration on day of exposure	9.7	mg/m³
Year average concentration	9.7	mg/m³
External event dose	4.8×10^{-1}	mg/kg bw
External dose on day of exposure	4.8	mg/kg bw

Dermal

Dermal load	2.4	mg/cm²
External event dose	3.3×10^{1}	mg/kg bw
External dose on day of exposure	3.3×10^{2}	mg/kg bw
Internal event dose	2.3×10^{1}	mg/kg bw
Internal dose on day of exposure	2.3×10^{2}	mg/kg bw/day
Internal year average dose	2.3×10^{2}	mg/kg bw/day

Integrated

Internal event dose	2.3×10^{1}	mg/kg bw
Internal dose on day of exposure	2.3×10^{2}	mg/kg bw/day
Internal year average dose	2.3×10^{2}	mg/kg bw/day

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Scenario *[1]* Tier 1b - 25% Default Dermal Absorption Assumption:

Scenario PT1 *Hand Disinfection - Tier 1b*

Frequency	10	per day
Description		

Inhalation

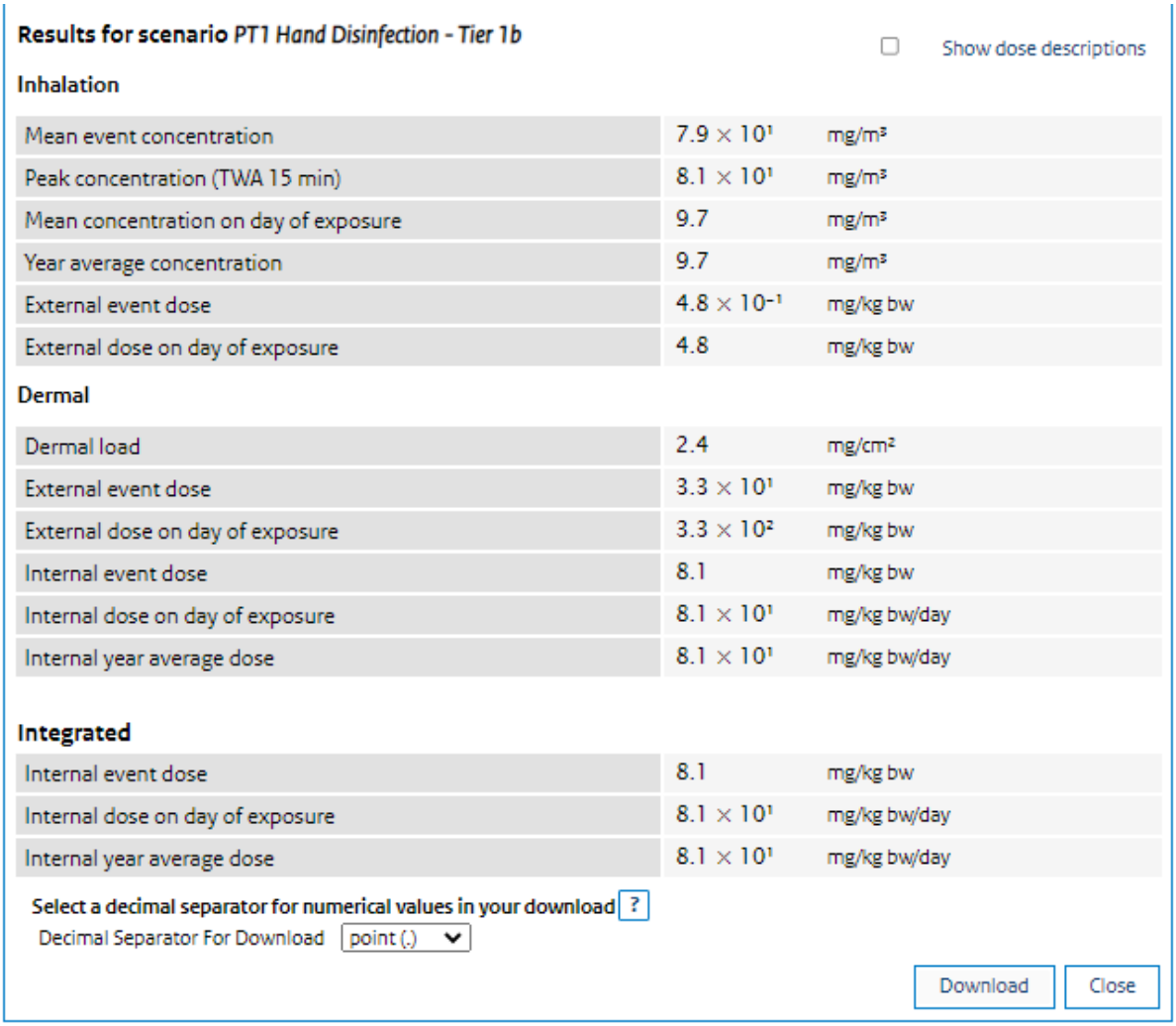
Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	17.7	minute
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	2.6	g
Weight fraction substance	75	%
Room volume	20	m^3
Ventilation rate	1.5	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	30	°C
Vapour pressure	3600	Pa
Molecular weight	60.1	g/mol
Absorption model	n.a.	

Dermal

Exposure model	Direct contact - Instant application	
Exposed area	820	cm^2
Weight fraction substance	75	%
Product amount	2.6	g
Retention Factor	1	
Absorption model	Fixed fraction	
Absorption fraction	25	%

Oral

Exposure model	n.a.
Absorption model	n.a.



Results for scenario *PT1 Hand Disinfection - Tier 1b*

Show dose descriptions

Inhalation

Mean event concentration	7.9×10^{1}	mg/m³
Peak concentration (TWA 15 min)	8.1×10^{1}	mg/m³
Mean concentration on day of exposure	9.7	mg/m³
Year average concentration	9.7	mg/m³
External event dose	4.8×10^{-1}	mg/kg bw
External dose on day of exposure	4.8	mg/kg bw

Dermal

Dermal load	2.4	mg/cm²
External event dose	3.3×10^{1}	mg/kg bw
External dose on day of exposure	3.3×10^{2}	mg/kg bw
Internal event dose	8.1	mg/kg bw
Internal dose on day of exposure	8.1×10^{1}	mg/kg bw/day
Internal year average dose	8.1×10^{1}	mg/kg bw/day

Integrated

Internal event dose	8.1	mg/kg bw
Internal dose on day of exposure	8.1×10^{1}	mg/kg bw/day
Internal year average dose	8.1×10^{1}	mg/kg bw/day

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Scenario *[1]* Tier 2 – Dermal flux value: No Consexpo calculations possible. For detailed calculations see PAR 2.2.6.2

3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

Not relevant

3.5 Summaries of the efficacy studies

Refer to accompanying IUCLID technical dossier.

3.6 Confidential annex

Refer to separate confidential annex.