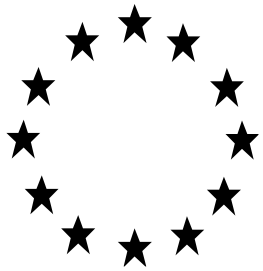
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



L+R Propanol PT1 Family

Product type **1**

Active substances: **Propan-2-ol, Propan-1-ol**

Case Number in R4BP: BC-MU051242-25

Evaluating Competent Authority: **Switzerland**

Date: October 2021

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1 ASSESSMENT REPORT

1.1 Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
L+R Propanol PT1 Family	EU

1.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Lohmann & Rauscher International GmbH & Co. KG
	Address	Westerwaldstrasse 4 57579 Rengsdorf Germany
Pre-submission phase started on	30. October 2018	
Pre-submission phase concluded on	03. December 2018	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

1.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Lohmann & Rauscher International GmbH & Co. KG
Address of manufacturer	Westerwaldstrasse 4 57579 Rengsdorf Germany
Location of manufacturing sites	A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH Otto-Brenner-Straße 16-18 21337 Lüneburg

1.1.1.4 Manufacturers of the active substances

Active substance	**Propan-1-ol**
Name of manufacturer	OQ Chemicals GmbH (formerly OXEA GmbH)
Address of manufacturer	Rheinpromenade 4a 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals Corporation (formerly Oxea Corporation) 2001 FM 3057 Bay City, TX 77414-2968, United States ***Additional Sources***
Active substance	**Propan-1-ol**

Name of manufacturer	Sasol GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations Sasol Place, 50 Katherine Street Sandton 2090 South Africa
Location of manufacturing sites	Secunda Chemical Operations PDP Kruger Street, Secunda 2302 South Africa
Active substance	**Propan-1-ol**
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Straße 38 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE Carl-Bosch-Straße 38 67056 Ludwigshafen Germany
Active substance	**Propan-2-ol**
Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH Römerstrasse 733 47443 Moers Germany

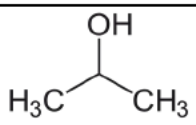
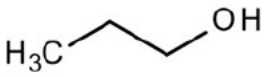
1.1.2 Product family composition and formulation

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 ☒

1.1.2.1 Identity of the active substances

Main constituents		
ISO name	Propan-2-ol	Propan-1-ol
IUPAC or EC name	Isopropanol	n-Propanol
EC number	200-661-7	200-746-9
CAS number	67-63-0	71-23-8
Index number in Annex VI of CLP	603-117-00-0	603-003-00-0
Minimum purity / content	99%	100%
Structural formula		

1.1.2.2 Candidate(s) for substitution

Propan-1-ol and Propan-2-ol are not candidates for substitution.

1.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol	n-Propanol	Active substance	71-23-8	200-746-9	30	30
Propan-2-ol	Isopropanol	Active substance[3]	67-63-0	200-661-7	45	45
Tetradecanol	Myristil alcohol		112-72-1	204-000-3	0.0	0.95

Please see the confidential Annex 3.6 for further details.

1.1.2.4 Information on technical equivalence

For **Propan-1-ol** ECHA confirmed the technical equivalence according to Article 54(4) of the European Biocidal Products Regulation (EU) 528/2012:

Decision number: [redacted]
Product type (PT): PT1 (Human hygiene); PT2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

For **Propan-2-ol** the source "Isopropylalkohol" was assessed and approved as being technically equivalent to the reference source in respect to the initial risk assessment of the active substance (supporting document "technical equivalence_Propan-2-ol_01-01"):

Decision number: [redacted]
Product type (PT): PT1 (Human hygiene); PT2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

1.1.2.5 Information on the substance(s) of concern

Please see confidential Annex 3.6 for further details.

1.1.2.6 Type of formulation

AL	Any other liquid	A liquid not yet designated by a specific code, to be applied undiluted.

1.1.3 Hazard and precautionary statements

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

Classification meta SPC 1	
Hazard category	Flam. Liq. 3 Eye Dam. 1 STOT SE 3 Aquatic chronic 3
Hazard statement	Flammable liquid and vapour Causes serious eye damage May cause drowsiness or dizziness Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H226 Flammable liquid and vapour H318 Causes serious eye damage H336 May cause drowsiness or dizziness H412 Harmful to aquatic life with long lasting effects
Supplemental Hazard Statement	EUH066: According to the BPC opinion, EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed in addition to the current classification according to table 3.1. of Annex VI of Regulation (EC) No 1272/2008 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol, propan-2-ol, or to propan-1-ol, propan-2-ol dilutions.
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapours. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/ doctor P403+P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents/container to an approved waste facility.
Note	The P phrase P280 (Wear protective gloves/protective clothing/eye protection/face protection) is highly recommended with a classification as H318 (Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008). Due to the additional risk mitigation measure "avoid contact with eyes" and the use of the product as a Hand sanitiser, the P-phrase P280 is not necessary.

Classification meta SPC 2	
Hazard category	Flam. Liq. 3 Eye Dam. 1 STOT SE 3
Hazard statement	Flammable liquid and vapour Causes serious eye damage May cause drowsiness or dizziness
Labelling	
Signal words	Danger
Hazard statements	H226 Flammable liquid and vapour H318 Causes serious eye damage H336 May cause drowsiness or dizziness
Supplemental Hazard Statement	EUH066: According to the BPC opinion, EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed in addition to the current classification according to table 3.1. of Annex VI of Regulation (EC) No 1272/2008 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol, propan-2-ol, or to propan-1-ol, propan-2-ol dilutions.
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapours. P271 Use only outdoors or in a well-ventilated area. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/ docto P403+P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents/container to an approved waste facility.
Note	The P phrase P280 (Wear protective gloves/protective clothing/eye protection/face protection) is highly recommended with a classification as H318 (Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008). Due to the additional risk mitigation measure "avoid contact with eyes" and the use of the product as a Hand sanitiser, the P-phrase P280 is not necessary.

1.1.4 Authorised use(s)

1.1.4.1 Use description Meta SPC 1

Table 1. Use # 1.1 – Hygienic handrub

Product Type	1
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria, mycobacteria, yeasts, viruses (limited spectrum virucidal activity)
Field of use	Indoor hospitals and other health care institutions such as ambulances, surgeries, nursing homes (incl. home-care of patients), hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories: hygienic handrub onto visibly clean and dry hands For professional use only
Application method(s)	rubbing
Application rate(s) and frequency	Dosage: At least 3 ml (use dispensers: e.g. set to 1.5 ml per stroke, 2 strokes per 3 ml) Minimum contact time: 30 sec There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional / Industrial user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

1.1.4.2 Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

1.1.4.3 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 2. Use # 1.2 – Surgical handrub

Product Type	1
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria, mycobacteria, yeasts, viruses (limited spectrum virucidal activity)
Field of use	Indoor hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms For professional use only
Application method(s)	rubbing
Application rate(s) and frequency	Dosage: in portions of 3 ml (use dispensers: e.g. set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum exposure time: 90 sec There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

1.1.4.7 Use-specific instructions for use

The products can be applied directly, or the products can be used in a dispenser or with a pump.For Surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

1.1.4.8 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

1.1.4.12 Use description Meta SPC 2

Table 2. Use # 2.1 – Hygienic handrub

Product Type	1
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria, mycobacteria, yeasts, viruses (limited spectrum virucidal activity)
Field of use	Indoor hospitals and other health care institutions such as ambulances, surgeries, nursing homes (incl. home-care of patients), hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories: hygienic handrub onto visibly clean and dry hands For professional use only
Application method(s)	rubbing
Application rate(s) and frequency	Dosage: in portions of 3 ml (use dispensers: e.g. set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum exposure time: 30 sec There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional / Industrial user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

1.1.4.13 Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump. For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

1.1.4.14 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 2. Use # 2.2 – Surgical handrub

Product Type	1
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	bacteria, mycobacteria, yeasts, viruses (limited spectrum virucidal activity)
Field of use	Indoor hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms For professional use only
Application method(s)	rubbing
Application rate(s) and frequency	Dosage: in portions of 3 ml (use dispensers: e.g. set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum exposure time: 90 sec There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases.

	The product may be used at any time and as often as required.
Category(ies) of users	Professional user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

1.1.4.18 Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.
For Surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

1.1.4.19 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

1.1.5 General directions for use

1.1.5.1 Instructions for use

For Professional use only

1.1.5.2 Risk mitigation measures

Avoid contact with eyes. Keep out of reach of children.

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water. for 15 minutes. Call a POISON CENTRE or a doctor. IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor. 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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid. IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. After spilling: Take up with absorbent material (e.g. Sand, kieselgur, universal binder). When picked up, treat material as prescribed under "Disposal considerations".

1.1.5.4 Instructions for safe disposal of the product and its packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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

Technical measures and storage conditions: Shelf-life: 36 months Keep container tightly closed and dry in a cool, well-ventilated place. Protect from direct sunlight. Recommended storage temperature: 0-30°C Requirements for storage rooms and vessels: Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original one. Do not store together with: oxidizing substances; spontaneously combusting substances.

1.1.6 Other information

1.1.7 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 500 ml 1000 ml	transparent HDPE	PP flip top cap	professional	Yes

1.1.8 Documentation

1.1.8.1 Data submitted in relation to product application

A reference list (references_L+R Propanol PT1 Family) and the list of attachments (list of attachments_L+R Propanol PT1 Family) from IUCLID6 are attached separately in Section 13 of the IUCLID dossier.

1.1.8.2 Access to documentation

Lohmann & Rauscher International GmbH & Co. KG is member of the ASD Consortium Alcohols. Therefore, L&R has full access to the Active Substance Dossiers for 1- and Propan-2-ol.
Please see the confidential annex and the attached LoAs for further details.

1.) LoA Propan-2-ol
2.) LoA Propan-1-ol

1.1.8.3 Similar conditions of use

No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) in regards to the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product family "L+R Propanol PT1 Family" 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 (**Decision number: UPP-D-1345042-98-00/F**).

1.2 Assessment of the biocidal product (family)

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

Use description for meta SPC 1

Table 3. Use # 1.1 – Hygienic handrub

Product Type	1
Where relevant, an exact description of the authorised use	The product is used for the control of bacteria (excluding bacterial spores), mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses for hygienic handrub
Target organism (including development stage)	Target organisms are obligatory or facultative pathogenic bacteria, mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses (adenovirus, norovirus and rotavirus).
Field of use	The product can be applied for hygienic handrub in all situations necessary, e.g. - hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients) - Hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories.
Application method(s)	It is a ready-to-use product which shall be rubbed undiluted into the hands. Contact time: 30 sec.
Application rate(s) and frequency	See use-specific instructions of meta SPC 1. There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional/Industrial user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

Table 2. Use # 1.2 – Surgical handrub

Product Type	1
Where relevant, an exact description of the authorised use	The product is used for the control of bacteria (excluding bacterial spores), mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses for surgical handrub.
Target organism (including development stage)	Target organisms are obligatory or facultative pathogenic bacteria, mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses (adenovirus, norovirus and rotavirus).
Field of use	The product is applied for surgical handrub in hospitals and other health care institutions.

Application method(s)	It is a ready-to-use product which shall be rubbed undiluted in portions into the hands and forearms. Contact time: 90 sec.
Application rate(s) and frequency	See use-specific instructions of meta SPC 1. There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

Use description for meta SPC 2

Table 4. Use # 2.1 – Hygienic handrub

Product Type	1
Where relevant, an exact description of the authorised use	The product is used for the control of bacteria (excluding bacterial spores), mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses for hygienic handrub
Target organism (including development stage)	Target organisms are obligatory or facultative pathogenic bacteria, mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses (adenovirus, norovirus and rotavirus).
Field of use	The product can be applied for hygienic handrub in all situations necessary, e.g. - hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients) - Hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories.
Application method(s)	It is a ready-to-use product which shall be rubbed undiluted into the hands. Contact time: 30 sec.
Application rate(s) and frequency	See use-specific instructions of meta SPC 2. There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional/Industrial user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

Table 2. Use # 2.2 – Surgical handrub

Product Type	1

Where relevant, an exact description of the authorised use	The product is used for the control of bacteria (excluding bacterial spores), mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses for surgical handrub
Target organism (including development stage)	Target organisms are obligatory or facultative pathogenic bacteria, mycobacteria, yeasts, enveloped viruses and a limited number of non-enveloped viruses (adenovirus, norovirus and rotavirus).
Field of use	The product is applied for surgical handrub in hospitals and other health care institutions.
Application method(s)	It is a ready-to-use product which shall be rubbed undiluted in portions into the hands and forearms. Contact time: 90 sec.
Application rate(s) and frequency	See use-specific instructions of meta SPC 2. There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional user
Pack sizes and packaging material	100, 500 and 1000 ml in transparent HDPE bottles with PP flip top cap.

1.2.2 Physical, chemical and technical properties

The physical, chemical and technical properties were shown on the reference product *L+R handdisinfect blue* (Product 1.1, meta SPC 1). Since the only difference is a change in the skin care complex (1% of the formulation), product 1.1 of meta SPC 1 is reliable also for physical chemical and technical properties of meta SPC 2.
For meta SPC 2, individual data as cornerstone testing for relative density and pH value are outlined below. In addition, an accelerated storage stability test at 40°C was carried out with both *L+R handdisinfect 03 (product 2.1) and + L+R handdisinfect 04* (product 2.2) in order to derive an initial shelf life of two years. In parallel, a long-term test at ambient temperature is ongoing. The accelerated and long-term data can be traced back to the same batch, data is generated in the worst-case commercial packaging and active substance contents are determined using validated methods of analysis.

The table below provides an overview on the products of the meta SPCs and active substance contents:

Meta SPC	Product No.	Trade name	Propan-1-ol (%)	Propan-2-ol (%)
Meta 1	Product 1.1	L+R handdisinfect blue	30	45
Range Meta 1			30-30	45-45
Meta 2	Product 2.1	L+R handdisinfect 03	30	45
	Product 2.2	L+R handdisinfect 04	30	45
Range Meta 2			30-30	45-45

Phys/chem and technical properties of meta SPC 1 and 2

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
Physical state at 20 °C and 101.3 kPa	A.F.P internal test method H20, visual inspection and olfactory test	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	Product 1.1: clear, colourless liquid with an alcoholic odour	[redacted] 2017, SR02-05-01-R;	Data acceptable.
Colour at 20 °C and 101.3 kPa					

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
Odour at 20 °C and 101.3 kPa		***Product 2.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 151018	Product 2.1: clear, colourless liquid with an alcoholic odour	[redacted] 2019, SR02-06-01;	
		Product 2.2, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 160119	Product 2.2: clear, colourless liquid with an alcoholic odour	[redacted] 2019, SR02-07-01	
Acidity / alkalinity pH value (1% in water/ undiluted)	CIPAC MT 75 at 20°C / 21.5°C	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batches 15001/17463A1406	Product 1.1: 6.22 (diluted 1% in water) / 7.0 (undiluted)	Henke, W., 2016, 16012001G907 / [redacted] 2019, Determination of the pH value of L+R handdisinfect blue	Data on pH acceptable. No data on acidity / alkalinity required because the pH is in the range [4,10].
	CIPAC MT 75 at 23°C / 21.5°C	***Product 2.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 151018	meta 2.1: 6.08 (diluted 1% in water) / 7.6 (undiluted)	[redacted] 2019, Determination of the pH value of an aqueous solution of L+R handdisinfect 03 / [redacted] 2019, Determination of the pH value of L+R handdisinfect 03	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
	CIPAC MT 75 at 23°C / 21.5°C	***Product 2.2***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 160119	meta 2.2: 8.1 (diluted 1% in water) / 7.4 (undiluted) Acidity / alkalinity: The pH of the biocidal products as formulated is inside the pH range 4-10. Therefore, further testing with regard to acidity/ alkalinity is not mandatory.	[redacted] 2019, Determination of the pH value of an aqueous solution of L+R handdisinfect 04 / [redacted] 2019, Determination of the pH value of L+R handdisinfect 04	
Relative density / bulk density g/cm^3 (20°C)	OECD 109, pycnometer determination	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	Product 1.1: 0.8497 (20°C) (relative density)	Henke, W., 2016, 16012001G912	Data acceptable.
	OECD 109, oscillating densitometer	***Product 2.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 270919	Product 2.1: 0.851 (20°C) (relative density)	[redacted] 2020, HD03/170220/RD	
	OECD 109, oscillating densitometer	***Product 2.2***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 270919	Product 2.2: 0.851 (20°C) (relative density)	[redacted] 2020, HD04/170220/RD	
Storage stability test – **accelerated storage**	CIPAC MT 46.3 at 40°C/75% RH	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45%	<u>Meta SPC 1</u> Reference product 1.1 in 100ml transparent HDPE bottle with PP flip top cap was stored at 40 ± 2 °C / 75 ± 5% RH for 12 weeks.	[redacted] 2017, SR02-05-01_R	Meta SPC 1: Data acceptable. No relevant change in active substance

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results</th><th>Reference</th><th>Evaluation by the eCA</th></tr>
<tr><td></td><td>A.S. (validated GC-FID method B46, see 2.2.4); Appearance (Inhouse methods H20, H21); Density (Ph. Eur. 2.2.5); Refractive index (Ph. Eur 2.2.6); Odour (Inhouse method H20)</td><td>w/w Propan-2-ol, Batch 15001</td><td>
<table>
<tr><th>Parameter</th><th>t=0 weeks</th><th>t= 12 weeks</th></tr>
<tr><td>Propan-1-ol content % w/w</td><td>30.05</td><td>30.08 (% change in a.s.: +0.10)</td></tr>
<tr><td>Propan-2-ol content % w/w</td><td>44.97</td><td>45.12 (% change in a.s.: +0.33)</td></tr>
<tr><td>Appearance of content</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td></tr>
<tr><td>Appearance of primary packaging</td><td>No change</td><td>No change</td></tr>
<tr><td>Density (g/ml) 20°C</td><td>0.850</td><td>0.850</td></tr>
<tr><td>Refractive index</td><td>1.3784</td><td>1.3784</td></tr>
<tr><td>Odour</td><td>alcoholic</td><td>alcoholic</td></tr>
</table>
The BP is stable 12 weeks at 40°C.</td><td></td><td>content (no decrease >10%) or technical properties of the biocidal product.
Note: The product in Meta SPC 1 contains an SOC. This component is added as co-formulant. Therefore, no increase of its concentration during storage is expected.

Product of Meta SPC 1 is stable for 12 weeks at 40 ± 2 °C / 75 ± 5% RH.</td></tr>
<tr><td></td><td></td><td>Product 2.1, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 151018</td><td><u>Meta SPC 2</u>
Product 2.1 in 100ml transparent HDPE bottle with PP flip top cap was stored at 40 ± 2 °C / 75 ± 5% RH for 12 weeks.
<table>
<tr><th>Parameter</th><th>t=0 weeks</th><th>t= 8 weeks</th><th>t= 12 weeks</th></tr>
<tr><td>Propan-1-ol content % w/w</td><td>29.83</td><td>29.95 (+0.40%)</td><td>30.03 (+0.67%)</td></tr>
<tr><td>Propan-2-ol content % w/w</td><td>44.71</td><td>44.82 (+0.25%)</td><td>44.86 (+0.34%)</td></tr>
</table></td><td>[redacted] 2019, SR02-06-01</td><td>Meta SPC 2: Data acceptable. No relevant change in active substance content (no decrease >10%) or technical properties of the biocidal products.

Stability of products of Meta SPC 2 were demonstrated at 40 ±</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results</th><th>Reference</th><th>Evaluation by the eCA</th></tr>
<tr>
<td></td>
<td></td>
<td>Product 2.2, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 160119</td>
<td>
<table>
<tr><td>Appearance of content</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td></tr>
<tr><td>Appearance of primary packaging</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Density (g/ml) 20°C</td><td>0.852</td><td>0.852</td><td>0.852</td></tr>
<tr><td>Refractive index</td><td>1.3782</td><td>1.3782</td><td>1.3782</td></tr>
<tr><td>Odour</td><td>alcoholic</td><td>alcoholic</td><td>alcoholic</td></tr>
</table>
The BP is stable 12 weeks at 40°C.

Product 2.2 in 100ml transparent HDPE bottle with PP flip top cap was stored at 40 ± 2 °C / 75 ± 5% RH for 8 weeks.
<table>
<tr><th>Parameter</th><th>t=0 weeks</th><th>t= 8 weeks</th></tr>
<tr><td>Propan-1-ol content % w/w</td><td>30.04</td><td>30.00 (% change in a.s.: -0.13)</td></tr>
<tr><td>Propan-2-ol content % w/w</td><td>45.09</td><td>45.06(% change in a.s.: -0.07)</td></tr>
<tr><td>Appearance of content</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td></tr>
<tr><td>Appearance of primary packaging</td><td>No change</td><td>No change</td></tr>
<tr><td>Density (g/ml) 20°C</td><td>0.851</td><td>0.852</td></tr>
<tr><td>Refractive index</td><td>1.3783</td><td>1.3783</td></tr>
<tr><td>Odour</td><td>alcoholic</td><td>alcoholic</td></tr>
</table>
</td>
<td>[redacted] 2019, SR02-07-01</td>
<td>2 °C / 75 ± 5% RH for 12 weeks (product 2.1) or 8 weeks (product 2.2).</td>
</tr>
</table>

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
			The BP is stable 8 weeks at 40°C.		
Storage stability test – **long term storage at ambient temperature (36 mo.)**	at 25°C/60% RH for 3, 6, 12, 24, 36 months in worst case commercial packaging Same parameters/ methods as for accelerated storage. Additionally, microbiological quality (Ph. Eur. 2.6.12, 2.6.13) A.S. (validated GC-FID method B46, see 2.2.4)	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	Meta SPC 1 Reference product 1.1 in 100ml transparent HDPE bottle with PP flip top cap was stored at 25 ± 2 °C / 60 ± 5% RH for 36 months. Data are shown in the table below. (Note: In the course of intermediate testing there was no reason to conclude the need of determining the weight change since the a.s. contents kept very stable. The pH value is not reasonable as monitoring parameter in alcohol-based solutions with low amounts of water). The BP is stable 36 months at 25°C.	[redacted] 2020, SR04-05-01	Meta SPC 1: Data acceptable. No relevant change in active substance content (no decrease >10%) or technical properties of the biocidal product. The product in Meta SPC 1 contains an SOC but no increase in concentration is expected during storage as this component is added as co-formulant. Product of Meta SPC 1 is stable for 36 months at 25 ± 2 °C / 60 ± 5% RH. The worst–case commercial packaging was tested. The shelf-life of 36 months claimed is

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
					supported by the data.

Storage data of reference product 1.1 in 100ml transparent HDPE bottle with PP flip top cap at 25 ± 2 °C / 60 ± 5% RH for 36 months.

Parameter	t=0 month	t= 3 months	t= 6 months	t= 12 month	t= 24 months	t= 36 months
Propan-1-ol content % w/w	30.1	30.1	30.1	29.8	30.0	30.0 (% change in a.s.: -0.33)
Propan-2-ol content % w/w	45.0	45.0	45.1	44.9	44.9	45.1 (% change in a.s.: +0.22)
Appearance of content	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid
Appearance of primary packaging*	inconspicuous	inconspicuous	inconspicuous	inconspicuous	inconspicuous	inconspicuous
Density (g/ml) 20°C	0.850	0.850	0.850	0.850	0.850	0.850
Refractive index	1.3784	1.3784	1.3784	1.3785	1.3784	1.3784
Odour (complies if odour is alcoholic)	complies	complies	complies	complies	complies	complies
Microbial quality TAMC TYMC Spores St. aureus P. aeruginosa gram-neg bact	 0 cfu/10ml 0 cfu/10ml 0 cfu/10ml absent/ml absent/ml absent/ml	not applicable	not applicable	not applicable	not applicable	 0 cfu/10ml 0 cfu/10ml 0 cfu/10ml absent/ml absent/ml absent/ml

*Note: according to the study report, packaging was inspected with regard to the following aspects: cleanliness/damaged/inflation/colour.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
	Read across		Meta SPC 2 Read across from product 1.1. Justification: same active substance contents, same worst-case packaging size (100 ml transparent HDPE bottle), similar compositions. The only difference is a change in the skin care complex (1% of the formulation). Long-term shelf life studies with both products have been started (same batches as accelerated stability studies):		The read across justification is considered acceptable, differences in composition between meta SPC 1 and 2 are not expected to have an effect on stability. Read across from meta SPC 1 is acceptable. The shelf-life of 36 months claimed by the applicant is supported. The shelf-life needs to be confirmed by the ongoing storage stability studies for products 2.1 and 2.2.
	at 25°C/60% RH designed for 3, 6, 12, 24, 36 months in worst case commercial packaging Same parameters/ methods as for accelerated storage. Additionally, microbiological quality (Ph. Eur. 2.6.12, 2.6.13)	***Product 2.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 151018 ***Product 2.2,*** liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 160119	Product 2.1 in 100ml transparent HDPE bottle with PP flip top cap was stored at 25 ± 2 °C / 60 ± 5% RH for 24 months (study still ongoing, results for 36 months not available yet). Results shown in the table below. Product 2.2 in 100ml transparent HDPE bottle with PP flip top cap was stored at 25 ± 2 °C / 60 ± 5% RH for 24 months (study still ongoing, results for 36 months not available yet). Results shown in the table below.	[redacted] 2020, SR04-06-01_24Mo (interim results for 24 months) [redacted] 2020, SR04-07-01_24Mo (interim results for 24 months)	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
	A.S. (validated GC-FID method B46, see 2.2.4)				

Product 2.1: Storage data of reference product 2.1 in 100ml transparent HDPE bottle with PP flip top cap at 25 ± 2 °C / 60 ± 5% RH. Interim results for 24 months (study ongoing, data for 36 months not available yet).

Parameter	t=0 month	t= 3 months	t= 6 months	t= 12 month	t= 24 months	t= 36 months
Propan-1-ol content % w/w	29.8	30.0	30.0	30.0 (% change in a.s.: +0.67)	29.9	
Propan-2-ol content % w/w	44.7	44.8	44.9	44.9 (% change in a.s.: +0.45)	44.9	
Appearance of content	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid	Clear, colourless liquid	Complies	
Appearance of primary packaging*	No change	No change	No change	No change	No change	
Density (g/ml) 20°C	0.852	0.852	0.852	0.851	0.851	
Refractive index	1.3782	1.3782	1.3782	1.3782	1.3782	
Odour (complies if odour is alcoholic)	complies	complies	complies	complies	Complies	
Microbial quality TAMC TYMC Spores St. aureus P. aeruginosa gram-neg bact	 0 cfu/10ml 0 cfu/10ml 0 cfu/10ml absent/ml absent/ml absent/ml	not applicable	not applicable	not applicable	not applicable	

*Note: according to the study report, packaging was inspected with regard to the following aspects: cleanliness/damage/inflation/colour.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results</th><th>Reference</th><th>Evaluation by the eCA</th></tr>
<tr><td></td><td colspan="5">
Product 2.2 in 100ml transparent HDPE bottle with PP flip top cap was stored at 25 ± 2 °C / 60 ± 5% RH for 24 months.
Storage data of reference product 2.2 in 100ml transparent HDPE bottle with PP flip top cap at 25 ± 2 °C / 60 ± 5% RH.
Interim results for 24 months (study ongoing, data at 36 months not available yet).
<table>
<tr><th>Parameter</th><th>t=0 month</th><th>t= 3 months</th><th>t= 6 months</th><th>t= 12 month</th><th>t= 24 months</th><th>t= 36 months</th></tr>
<tr><td>Propan-1-ol content % w/w</td><td>30.0</td><td>30.3</td><td>30.0</td><td>30.0 (% change in a.s.: +/- 0.0)</td><td>29.9 (-0.33%)</td><td></td></tr>
<tr><td>Propan-2-ol content % w/w</td><td>45.1</td><td>45.3</td><td>45.1</td><td>45.1 (% change in a.s.: +/- 0.0)</td><td>45.1 (% change in a.s.: +/- 0.0)</td><td></td></tr>
<tr><td>Appearance of content</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td><td>Clear, colourless liquid</td><td>Complies</td><td></td></tr>
<tr><td>Appearance of primary packaging</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td><td></td></tr>
<tr><td>Density (g/ml) 20°C</td><td>0.851</td><td>0.851</td><td>0.851</td><td>0.851</td><td>0.851</td><td></td></tr>
<tr><td>Refractive index</td><td>1.3783</td><td>1.3783</td><td>1.3783</td><td>1.3783</td><td>1.3783</td><td></td></tr>
<tr><td>Odour (complies if odour is alcoholic)</td><td>complies</td><td>complies</td><td>complies</td><td>complies</td><td>complies</td><td></td></tr>
<tr><td>Microbial quality
TAMC
TYMC
Spores
St. aureus
P. aeruginosa
gram-neg bact</td><td>
0 cfu/10ml
0 cfu/10ml
0 cfu/10ml
absent/ml
absent/ml
absent/ml</td><td>not applicable</td><td>not applicable</td><td>
0 cfu/10ml
0 cfu/10ml
0 cfu/10ml
absent/ml
absent/ml
absent/ml</td><td>Not applicable</td><td></td></tr>
</table>
*Note: according to the study report, packaging was inspected with regard to the following aspects: cleanliness/damage/inflation/colour.
</td></tr>
<tr><td>Storage stability test – low temperature</td><td>CIPAC MT 39.3 at 0°C</td><td>30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001</td><td><u>Meta SPC 1</u>
Reference product 1.1:
One centrifuge tube, stoppered and graduated, with 100 ml of the product was stored at 0 °C for 7 days.</td><td>[redacted] 2017, SR07-05-01</td><td>Data for meta SPC 1 acceptable. Read across justification for meta SPC2 acceptable. Products</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance % (w/w)</th><th>Results</th><th>Reference</th><th>Evaluation by the eCA</th></tr>
<tr><td>stability test for liquids</td><td></td><td></td><td>At the end of the test, visual changes of the liquid with regard to solution homogeneity were evaluated.

<table><tr><td>Parameter</td><td>t = 7 days</td></tr><tr><td>Volume and nature of any separated material</td><td>no separation, no precipitation observed</td></tr></table>The BP is stable for 7 days at 0°C.

<u>Meta SPC 2</u>
Read across from product 1.1.
Justification: same active substance contents, similar compositions.</td><td></td><td>are stable for 7 days at 0°C.</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td>waiver</td><td>-</td><td>The molecular structures of propan-1-ol and propan-2-ol have no chromophores. In addition, for the propanols a cut-off point of 210 nm is given in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 cannot undergo direct photolysis in sunlight. Therefore, the substance is inaccessible for direct photodegradation in sunlight.

In the L+R Propanol PT1 Family, the co-formulants are a small part of the formulations (below 1.5% w/w), the products of meta 1 and meta 2 differ only in two skin care agents (1%). Since the products of the L+R Propanol PT1 Family are intended for indoor use only and furthermore are supposed to be protected from direct sunlight during storage, the UV-stability of the products is considered not relevant.</td><td>CARs A.S., stability report in-use provided</td><td>Waiver justification acceptable. No effect of light on a.s. content expected. Based on the argumentation by the applicant, a label instruction “Protect product from direct sunlight” is required.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
			(see data waiver in IUCLID Section 3.4.2.1 for full argumentation).		
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	See entries above for accelerated storage stability and storage stability at ambient temperature.	See entries above for accelerated storage stability and storage stability at ambient temperature.	Based on stability testing, a humidity of 60 and 75% and a temperature of approx. 20 to 40°C did not influence the a.s. content. All values are within specification limits.	See entries above for accelerated storage stability and storage stability at ambient temperature.	Information acceptable. No effect of temperature (20/40°C) or humidity (60/75% rH) on stability was observed in the storage stability studies.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	See entries above for accelerated storage, long term storage at ambient temperature.	See entries above for accelerated storage, long term storage at ambient temperature.	HDPE packagings are resistant against corrosion and do no react with the substance as proven by the experience. Packaging displayed no evidence of degradation during accelerated and long-term storage.	HDPE Chemical Resistance Guide, INEOS, 2012 See entries above for accelerated storage, long term storage at ambient temperature.	Data/information acceptable. No reactivity towards container materials was observed during stability testing.
Wettability	waiver	-	A study to assess the Endpoints 3.5.1 - 3.5.12 is not relevant for liquid hand disinfectants which are rubbed undiluted into dry hands without spraying.	Guidance on the BPR: Volume I Parts A+B+C Version 2.0 May 2018	Waiver acceptable, products are not intended to be dispersed or dissolved in water.
Suspensibility, spontaneity	waiver	-			Waiver acceptable, products are not

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
and dispersion stability					intended to form suspensions or dispersions.
Wet sieve analysis and dry sieve test	waiver	-			Waiver acceptable, data not required for liquid ready to use products.
Emulsifiability, re-emulsifiability and emulsion stability	waiver	-			Waiver acceptable, products are not intended to form emulsions.
Disintegration time	waiver	-			Waiver acceptable, products are not formulated as tablets.
Particle size distribution, content of dust/fines, attrition, friability	waiver	-			Waiver acceptable as products are not solid/not sprayed.
Persistent foaming	waiver	-			Waiver acceptable, products are not mixed with water for use.
Flowability/Pourability/Dustability	waiver	-			Waiver acceptable, data not required for ready to use liquid products.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
Burning rate — smoke generators	waiver	-			Waiver acceptable products are not smoke generators.
Burning completeness — smoke generators	waiver	-			Waiver acceptable products are not smoke generators.
Composition of smoke — smoke generators	waiver	-			Waiver acceptable products are not smoke generators.
Spraying pattern — aerosols	waiver	-			Waiver acceptable products are not aerosols.
Physical compatibility	waiver	-	The products of the *L+R Propanol PT1 Family* are not intended to be used or marketed in conjunction with other substances, mixtures or biocidal products or non-biocidal products. Therefore, determination of physical compatibility is considered to be not applicable.	-	Waiver acceptable, products not intended to be used with other substances, mixtures or biocidal or non-biocidal products.
Chemical compatibility	waiver	-	The products of the *L+R Propanol PT1 Family* are not intended to be used or marketed in conjunction with other substances, mixtures or biocidal produts or non-biocidal products. Therefore, determination of chemical compatibility is considered to be not applicable.	-	Waiver acceptable, products not intended to be used with other substances, mixtures or biocidal or non-biocidal products.
Degree of dissolution and dilution stability	waiver	-	All products are ready to use and do not have to be diluted.	-	Waiver acceptable as products are ready to use and are not diluted in water.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference	Evaluation by the eCA
Surface tension (mN/m) 20°C	OECD 115 (ring tear-off method)	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 17463A1406	Reference product 1.1: 24 mN/m Meta SPC 2: read across from meta 1. Justification for read across: Since the only difference is a change in the skin care complex (1% of the formulation) and none of the co-formulants is regarded as surface-active, the product of meta SPC 1 is reliable also for the respective characteristics of meta SPC 2.	[redacted] 2020, HD blue/170220/ST	Data for meta SPC 1 acceptable. Based on composition of the products, the read across justification for meta SPC 2 is acceptable. Comment: The products are not intended for dilution with water and do not contain ≥10% hydrocarbons.
Viscosity (mPa·s) 20°C / 40°C	OECD 114 (rotational viscometer)	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 19373A1401	Reference product 1.1: 3.01 / 2.58 Meta SPC 2: read across from meta 1. Justification for read across: Since the only difference is a change in the skin care complex (1% of the formulation) and none of the co-formulants is regarded as thickener or complexing agent, the product of meta SPC 1 is reliable also for the respective characteristics of meta SPC 2.	[redacted] 2020, HD blue/170220/VI	Data for product 1.1 acceptable. Based on composition of the products, the read across justification for meta SPC 2 is acceptable. Comment: The products do not contain ≥10% hydrocarbons.

Conclusion on the physical, chemical and technical properties of the products

Meta SPC 1

Product 1.1 of meta SPC 1 (L+R handdisinfect blue) is a clear, colourless and alcohol-smelling liquid which is fully miscible with water. The pH-value of the diluted product (1% in water) was 6.22 at 20°C and the pH of the undiluted product was 7.0 at 21.5°C. The relative density

is 0.8497 (20°C). The surface tension of the undiluted product is 24 mN/m at 20°C and the viscosity is 3.01/2.58 mPa·s at 20°C/40°C. For meta SPC 1, stability testing has been conducted with product 1.1/L+R handdisinfect blue.
The product is stable when stored at 40ºC/75%rH for 3 months (accelerated storage) and no precipitation or separation was observed at low temperature (0°C) for 7 days. The results of long-term-testing demonstrated that the product is stable when stored at 25ºC (ambient temperature) for up to 36 months.
All results are (i) within the valid specification limits and were (ii) carried out in commercial packaging. There is no reaction of the products with the containers.
Additionally, data indicating in-use stability for 12 months was provided. These data are however considered additional information as there is no agreed test method and no agreement on how to interpret the tests.

Meta SPC 2
Product 2.1 (L+R handdisinfect 03) and product 2.2 (L+R handdisinfect 04) of meta SPC 2 are clear, colourless and alcohol-smelling liquids which are fully miscible with water. The pH value of product 2.1 is 6.08 (diluted, 1% in water)/7.6 (undiluted) at 23°C / 21.5°C and the density is 0.851 (20°C). For product 2.2 a pH of 8.1 (diluted, 1% in water)/7.4 (undiluted) at 23°C / 21.5°C was determined and the relative density is 0.851 (20°C). For the surface tension and viscosity of the products in meta SPC 2, a read across was made from product 1.1 of meta SPC 1 (justified by similar composition).
The products of meta SPC 2 were tested under accelerated storage conditions at 40°C/75% rh for 3 months (product 2.1/L+R handdisinfect 03) and 2 months (product 2.2/L+R handdisinfect 04). For long term storage stability data a read across was made from the product in meta SPC 1 (identical active substance concentrations and only change in 1% skin care complex). The products in meta SPC 2 are expected to be stable for 36 months. This will be confirmed for both products in meta SPC 2 by ongoing long-term-testing at ambient temperature for 36 months (available interim results for 24 months did not show any significant changes in active substance content or technical properties).
All results are (i) within the valid specification limits and were (ii) carried out in commercial packaging. There is no reaction of the products with the containers.
Additionally, data indicating in-use stability for 12 months was submitted. These data are however considered additional information as there is no agreed test method and no agreement on how to interpret the tests.

Overall conclusion for both Meta SPCs
Based on the physical, chemical and technical properties, no classification is required for the products in meta SPC 1 and 2. A label instruction "Protect from direct sunlight during storage" is required for all products of the family. The stability data support the claim of a 3 -year shelf life of all products within meta SPC 1 and 2.

Furthermore, the following storage conditions have been defined: Keep container tightly closed and dry in a cool, well-ventilated place. Recommended storage temperature: 0-30°C. Based on the physical, chemical and technical properties, no classification of the biocidal products is required.

1.2.3 Physical hazards and respective characteristics

The physical hazards and respective characteristics were shown on the reference product *L+R handdisinfect blue* (meta SPC 1). Since the only difference is a change in the skin care complex (1% of the formulation), the product of meta SPC 1 is reliable also for the respective characteristics of meta SPC 2.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
Explosives	EU A.14, Thermal Sensitivity (Koenen-Tester) and Mechanical Sensitivity (Shock)	***Product 1.1***, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	Reference product 1.1, meta SPC 1: Not explosive Meta SPC 2: Read across from meta SPC 1 Justification: The products of meta 1 and 2 only differ in 1% of the skin care complex. According to the MSDS, none of the co-formulants are classified regarding explosivity. Therefore, the non-explosiveness of meta 1 can be applied to meta SPC 2.	Henke, W., 2016, 16012001G958	Data for meta SPC 1 acceptable. Waiver justification for meta SPC 2 acceptable. No classification with regard to explosive properties required.
Flammable gases	waiver	-	Neither of the products is a gas	-	Waiver justification acceptable, only relevant for gases.
Flammable aerosols	waiver	-	Neither of the products is an aerosol	-	Waiver justification acceptable, only relevant for aerosols.
Oxidising gases	waiver	-	Neither of the products is a gas	-	Waiver justification acceptable, only relevant for gases.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
Gases under pressure	waiver	-	Neither of the products is a gas	-	Waiver justification acceptable, only relevant for gases.
Flammable liquids	EU A.9 Non-equilibrium method (Pensky-Martens apparatus; EN ISO 2719-A)	Liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	meta 1: 23.5 °C	Henke, W., 2016, 16012001G964;	Data acceptable. Proposed classification of products in meta SPC 1 and 2 as flammable liquids category 3 (H226: flammable liquid and vapour) is supported by the data.
	EU A.9 Closed cup equilibrium method (EN ISO 1523)	Liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 16513A1401 2018-12	meta 1: 23.5°C	Zakel, S., 2018, 18-68011-V2	
	EU A.9 Abel-Pensky closed cup, non-equilibrium Method (DIN 51755)	Liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 270919	meta 2.1: 23.5 °C	[redacted] 2020, HD03/170220/FP	
	EU A.9 Abel-Pensky closed cup,	Liquid formulation, 30% w/w Propan-1-ol, 45% w/w	meta 2.2: 23.5 °C	[redacted] 2020, HD04/170220/FP	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
	non-equilibrium Method (DIN 51755)	Propan-2-ol, Batch 270919	The biocidal products are classified as flammable based on the flash point being > 23°C and an initial boiling point > 35°C. Therefore, the proposed classification is flammable liquid category 3 (H226: flammable liquid and vapour).	CLP Regulation	
Flammable solids	waiver	-	Neither of the products is a solid	-	Waiver justification acceptable, only relevant for solids.
Self-reactive substances and mixtures	waiver	-	In the active substances/ co-formulants, there are no chemical groups present which are associated with explosivity or self-reactive properties.	-	Waiver justification acceptable. No classification with regard to self-reactive properties is required for the products in meta SPC 1 and 2.
Pyrophoric liquids	waiver	-	Experience in manufacture and handling of the products shows that the liquids do not ignite spontaneously on coming into contact with air at normal temperatures. The products are known to be stable in contact with air at room temperature for prolonged periods of time (days).	Guidance on the Application of the CLP Criteria	Waiver based on experience that products are not pyrophoric is acceptable. No classification as pyrophoric liquid required.
Pyrophoric solids	waiver	-	Neither of the products is a solid.	-	Waiver justification acceptable, only relevant for solids.
Self-heating substances and mixtures	waiver	-	In general, the phenomenon of self-heating properties applies only to solids.	Guidance on the Application of the CLP Criteria	Waiver justification based on physical state of the products is

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
			The given test method is not applicable to liquids. Since all products are liquids, the study is scientifically not necessary.		acceptable. No classification with regard to self-heating properties required for the products in meta SPC 1 and 2.
Substances and mixtures which in contact with water emit flammable gases	waiver	-	Since all products are stable aqueous solutions, flammable gases in contact with water are not expected.	CLP Regulation	Waiver justification based on experience that the products in meta SPC 1 and 2 are stable mixtures containing water is acceptable.
Oxidising liquids	waiver	-	The products are classified as flammable, therefore testing for oxidative properties is technically not feasible, see also Wilrich et al. (2017)[1].	-	Waiver justification is acceptable. No classification with regard to oxidizing properties required for the products in meta SPC 1 and 2.
Oxidising solids	waiver	-	Neither of the products is a solid	-	Waiver justification acceptable, only relevant for solids.
Organic peroxides	waiver	-	None of the products contains any organic substances with bivalent -O-O- structures or may be considered a derivative of hydrogen peroxide. The products do not	CLP Regulation	Waiver justification acceptable, none of the components falls under the definition of organic

[1] UN-GHS — Physical hazard classifications of chemicals: A critical review of combinations of hazard classes Cordula Wilrich, Elisabeth Brandes, Heike Michael-Schulz, Volkmar Schröder, Silke Schwarz, and Klaus-Dieter Wehrstedt Journal of Chemical Health & Safety 2017 24 (6), 15-28

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Evaluation by the eCA</th></tr>
<tr><td></td><td></td><td></td><td>fall under the definition of organic peroxides according to CLP/GHS.</td><td></td><td>peroxides according to the CLP regulation.</td></tr>
<tr><td>Corrosive to metals</td><td>UN 37.4 C.1

Aluminum and steel plates in three positions (fully immersed, half immersed and in vapor phase)

168 ± 1 hours at +55°C ± 1°C</td><td>Product 1.1, Meta SPC 1, batch 20414A1403, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol</td><td>Meta SPC 1, Product 1.1: Not corrosive to steel and aluminum as criteria for corrosion attack are clearly not exceeded.

Results for uniform corrosion attack:<table><tr><td>Exposure time:</td><td>7 days</td></tr><tr><td>Criterion for corrosion mass loss:</td><td>13.5%</td></tr><tr><td>Mass loss found Al, in %:</td><td>0.0</td></tr><tr><td>Mass loss found, Steel, in %:</td><td>0.0</td></tr></table>Results for localized corrosion attack:<table><tr><td>Exposure time:</td><td>7 days</td></tr><tr><td>Criterion for corrosion attack in µm</td><td>120</td></tr><tr><td>Found for Al in µm</td><td>None</td></tr><tr><td>Found for steel in µm</td><td>None</td></tr></table>Applies for the plates in all three positions in the test vessel.</td><td>Lucht L. (2021), Determination of the corrosion of metals by L+R handdisinfect blue following method 37.4 C.1 of the UN Handbook, 21062101N979</td><td>Data acceptable. Based on the data for two tested products, no classification with regard to corrosiveness to metals is required for any of the products of the biocidal products family.</td></tr>
<tr><td></td><td>UN 37.4 C.1 Aluminum and steel plates in three positions (fully immersed, half</td><td>Product 2.2– Meta SPC 2, batch 140621, liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol</td><td>Not corrosive to steel and aluminum as criteria for corrosion attack are clearly not exceeded.

Results for uniform corrosion attack:<table><tr><td>Exposure time:</td><td>7 days</td></tr><tr><td>Criterion for corrosion mass loss:</td><td>13.5%</td></tr><tr><td>Mass loss found Al, in %:</td><td>0.0</td></tr></table></td><td>Lucht L. (2021)., Determination of the corrosion of metals by L+R handdisinfect 04 following method 37.4 C.1 of the UN Handbook,</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
	immersed and in vapor phase) 168 ± 1 hours at +55°C ± 1°C		Mass loss found, Steel, in %: 0.0 Results for localized corrosion attack: Exposure time: 7 days Criterion for corrosion attack in µm 120 Found for Al in µm None Found for steel in µm None Applies for the plates in all three positions in the test vessel.	Study No. 21062102N979	
Auto-ignition temperatures of products (liquids and gases)	EU A.15, method DIN 51794	Liquid formulation, 30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch 15001	Reference product 1.1, meta SPC 1: 435 °C <u>Meta SPC 2</u> Read across from meta SPC 1. Justification: The products in Meta SPC2 differ only in 1% skin care agents. Such a minor change in composition is not expected to have a significant influence on the auto-ignition temperature, the major components 1-propanol and 2-propanol are both flammable and their content is the same (75%) in all three products including the tested one in Meta SPC 1. None of the co-formulants is flammable or have an auto-ignition temperature below 225°C and further testing will be scientifically not necessary.Therefore, the auto-ignition temperature of meta SPC 1 can be applied to meta SPC 2.	Henke, W., 2016, 16012001G962	Data for meta SPC 1 acceptable. Meta SPC 2: Read across from meta SPC 1 acceptable based on similar composition.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Evaluation by the eCA
Relative self-ignition temperature for solids	waiver	-	Neither of the products is a solid	-	Waiver justification acceptable, only relevant for solids.
Dust explosion hazard	waiver	-	Neither of the products is a solid	-	Waiver justification acceptable, only relevant for solids.

Conclusion on the physical hazards and respective characteristics of the reference product

Meta SPC 1

The product in meta SPC 1 (reference product for the product family) has a flash-point of 23.5°C. According to the CLP Regulation, the biocidal product needs to be classified as flammable liquid category 3 (H226: flammable liquid and vapour) based on the flash point being > 23°C and an initial boiling point > 35°C. No further classification of the product in meta SPC 1 with regard to physical hazards is required. The product is not explosive and does not have oxidising properties, it is not self-heating, not corrosive to metals and not self-reactive. The auto-ignition temperature was determined to be 435°C.

Meta SPC 2

Since the only difference between meta SPC 1 and 2 is a change in the skin care complex (1% of the formulation), the product of meta SPC 1 served as reference for meta SPC 2. The flash point of the products in meta SPC 2 was confirmed by separate measurements of products 2.1 and 2.2 in meta SPC 2. Based on the flash points of 23.5°C obtained for both products in meta SPC 2, the proposed classification of the products in meta SPC 2 is flammable liquid category 3 (H226: flammable liquid and vapour). No further classification of the products in meta SPC 2 with regard to physical hazards is required. The reference product (meta SPC 1) is not explosive and has an auto-ignition temperature of 435°C. Furthermore, the products of meta SPC 2 do not have oxidising properties, are not corrosive to metals, are not self-heating and not self-reactive.

1.2.4 Methods for detection and identification

The analytical method B46 was validated in linearity, specificity, accuracy and repeatability according to current ECHA-Guidance[2]. Gas Chromatography (GC), using Butan-1-ol as internal standard, determine the active substance concentrations. All parameters are within the limits. The detection limit (LOD) for unknown impurities and the limit of quantification (LOQ) lie significantly below the disregard limit for impurities.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Propan-2-ol	GC/FID (B46)	n=2 (41.99 and 46.97 % w/w)	a = 0.998 b = 0.074 correlation coefficient r = 1,0000 Sy = 0.030, Concentration range 36.0 – 54.0 % w/w, n=5	Peaks do not interfere significantly	100.2-100.2	100.2	0.0	Concentration range 36.0 – 54.0 % Not relevant. Method validated for relevant concentration range (Validation parameters are linearity, specificity, accuracy and repeatability).	Validation report VAL-93
Propan-1-ol	GC/FID (B46)	n=2 (31.96 and 27.95 % w/w)	a = 0.992 b = 0.196 correlation coefficient r = 0.9999 Sy = 0.055, Concentration range	Peaks do not interfere significantly	100.0-100.3	100.2	0.2	Concentration range 24.0 – 35.9 % Not relevant. Method validated for relevant	Validation report VAL-93

[2] ECHA-Guidance on the BPR: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C Version 2.0 May 2018.

			24.0 – 35.9 % w/w, n=5					concentration range (Validation parameters are linearity, specificity, accuracy and repeatability).	
SoC	HPLC (C21)	n=6 (0.9770, 0.9770, 0.9770, 0.9766, 0.9766 and 0.9700 % w/w)	a = 355.4 b = 2.645 correlation coefficient r = 0,9989 Sy = 2,966 Concentration range 0.50 – 1.50 % w/w, n=5	Peaks do not interfere with other peaks	92.0 - 108.0	100.5	0.6		Validation report VAL-09

Analytical methods for residues in soil, water, body fluids and tissues and Food/feed of plant or animal origin are not considered required since no residues were expected.

Conclusion on the methods for detection and identification of the product
It was shown that the analytical method B46 for detection of the active substances is sufficient in linearity, specificity and recovery rates. In addition, the analytical method C21 for the detection of the SoC was validated in linearity, specificity, accuracy, precision and intermediate precision. All parameters are within the limits given.

1.2.5 Efficacy against target organisms

A skin care agent of product "L+R handdisinfect blue" (meta SPC 1) was exchanged in products "L+R handdisinfect 03" and "L+R handdisinfect 04" of meta SPC 2 by a combination of substances having the same function at an approximately constant concentration (difference: 0.05 g per 100 g). The active substances and other co-formulants remain unchanged in type and concentration.

Although there are no indications for an enhancing effect of the active substances, we excluded an influence on the efficacy of the products by carrying out a phase 2, step 1 tests with bacteria (EN13727) with both compositions. The results indicate a 'non-activity' of the co-formulants, so that the efficacy claims of meta SPC 1 can also be applied to meta SPC 2.

1.2.5.1 Function and field of use

The products of "L+R Propanol PT1 Family (meta SPC 1: L+R handdisinfect blue; meta SPC 2: L+R handdisinfect 03, L+R handdisinfect 04) are ready-to-use leave-on products for hygienic and surgical handrub for use in hospitals and other healthcare institutions.
Their principal field of application is hygienic and surgical rub-in hand disinfection, independently of washbasin and water. The products can be applied for hygienic hand disinfection in all situations necessary, e.g. hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients), hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories and for surgical hand disinfection in hospitals and other health care institutions

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

Target organisms are obligatory or facultative pathogenic bacteria, yeasts, mycobacteria and viruses (including enveloped and a limited number of non-enveloped viruses).
Human health should be maintained and protected.

1.2.5.3 Effects on target organisms, including unacceptable suffering

All products contain Propan-1-ol and Propan-2-ol as active substances. The effectiveness of this biocidal agent against the intended target organisms, e.g. gram-negative and gram-positive bacteria, yeasts, mycobacteria and viruses have been demonstrated in a number of reliable experimental studies (the testing strategy is explained in chapter 2.2.5.5). These studies demonstrate that the active substances are effective in irreversibly inactivating the above-mentioned germs which are representative for the target organisms in the intended field of use.

1.2.5.4 Mode of action, including time delay

All products contain Propan-1-ol and Propan-2-ol as active substances. Propanols exhibit an unspecific mechanism of effect. It affects the outer cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.
Propanol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant). The time required for sufficient inactivation is strongly depending on the formulation, concentrations of propanol contained in the applied biocidal product, the type of target organisms and on the specific use conditions.

1.2.5.5 Efficacy data

The efficacy was shown on the reference product *L+R handdisinfect blue* (meta SPC 1). Since the only difference is a change in the skin care complex (1% w/w of the formulation), the product of meta SPC 1 is also reliable for the efficacy properties of the two products of meta SPC 2.

Although there are no indications for an enhancing effect of the co-formulants on the active substances the influence on the efficacy of the products was excluded by carrying out selected phase 2, step 1 tests with both compositions of meta SPC 2 performed with bacteria (EN13727) and murine norovirus (EN 14476).

Meta SPC 1 and 2

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 (file IUCLID)**
Spectrum of antimicrobial efficacy (Phase 2 / Step 1)							
Hygienic & surgical handrub	health care, institutional, industry, food preparat on and handling (e.g. hospital canteen)	**Meta SPC 1 Reference product** L+R handdisinfect blue (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. # HD1080515)	Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541 Escher chia coli K12 NCTC 10538 Pseudomonas aeruginosa ATCC 15442	EN 13727: 2013	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal[3]) **Contact time:** 15, 30 and 60 sec **Test temperature:** 20°C	Log_{10} reduct on >5 in 15 sec at 50% **(bactericidal)**	Brill, FHH & Gabriel, H, Test report L15/0264.22, 28.01.2016 (01_A01_EN 13727_Br_Bac15Sec_ PB_EN_20160128.pdf)
		Meta SPC 2 L+R handdisinfect 03 (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. 150101803)		EN 13727: 2015	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal) **Contact time:** 15 sec **Test temperature:** 20°C	Log_{10} reduct on >5 in 15 sec at 50% **(bactericidal)**	Kampe, A & Gabriel, H, Test report L18/0734.1, 15.01.2019 (meta 2_L+R handdisinfect 03_EN13727_Bac15Sec_Brill_20190115.pdf)
		Meta SPC 2 L+R handdisinfect 04 (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. 160119)			**Concentration (%):** 10, 50 and 80 **Interfering substances:** clean cond tions (med cal[4]) **Contact time:** 15 sec **Test temperature:** 20°C	Log_{10} reduct on >5 in 15 sec at 50% **(bactericidal)**	Kampe, A & Klock, J, Test report L19/0044.1, 08.02.2019 (meta 2_L+R handdisinfect 04_EN13727_Bac15Sec_Brill_20190108.pdf)
		Meta SPC 1 Reference product L+R handdisinfect blue (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. # HD1080515)	Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541 Pseudomonas aeruginosa ATCC 15442	DGHM 2001: quantitative suspension test (Batch No. not available in test report. Statement of the Batch No. by the appl cant.)	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal) **Contact time:** 15, 30 and 60 sec **Test temperature:** 20°C	Log_{10} reduct on >5 in 15 sec at 80% **(bactericidal)**	Werner, H-P, test report: B 19584b, 10.11.2015; Expertise on the evaluation of the results from test report B 19584b of 10.11.2015, Prof. Dr. H.-P. Werner, HygCen Austria GmbH, 10.11.2015 (11_A01_EN1500_WE _3ml_PB_DE_EN_201 51110.pdf)
			Candida albicans ATCC 10231	EN 13624: 2013	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal) **Contact time:** 15, 30 and 60 sec **Test temperature:** 20°C	Log_{10} reduction >4 in 15 sec at 50% **(yeasticidal)**	Brill, FHH & Gabriel, H, Test report L15/0264.21, 27.01.2016 (02_A01_EN 13624_Br_Lev15Sec_ PB_EN_20160127.pdf)
			Candida albicans ATCC 10231	DGHM 2001: quantitative suspension test (Batch No. not available in test report. Statement of the Batch No. by the appl cant.)	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal) **Contact time:** 15, 30 and 60 sec **Test temperature:** 20°C	Log_{10} reduct on >4 in 15 sec at 80% **(yeasticidal)**	Werner, H-P, test report: B 19584b, 10.11.2015; Expertise on the evaluation of the results from test report B 19584b of 10.11.2015, Prof. Dr. H.-P. Werner, HygCen Austria GmbH, 10.11.2015

[3] Dirty conditions (medical): 3.0 g/L bovine albumin + 3.0 g/L sheep erythrocytes.
[4] Clean conditions (medical): 0.3 g/L bovine albumin.

							(11_A01_EN1500_WE_3ml_PB_DE_EN_20151110.pdf)
			Mycobacterium terrae ATCC 15755 Mycobacterium avium ATCC 15769	EN 14348: 2005	**Concentration (%):** 10, 50 and 80 **Interfering substances:** dirty conditions (med cal) **Contact time:** 30 sec **Test temperature:** 20°C	Log_{10} reduct on >4 in 30 sec at 50% **(mycobactericidal) (tuberculocidal)**	Brill, FHH & Gabriel, H, Test report L16/0264.27, 21.03.2016 (03_A01_EN14348_Br_Myco30sec_PB_EN_20160321.pdf)
			Bovine Viral Diarrhea Virus (BVDV) – surrogate of HCV	German Associat on for the Control of Virus Diseases e.V. (DVV) and of the Robert-Koch-Institute (RKI), dated 01/12/2014	**Concentration (%):** 10 and 80 **Interfering substances:** 10.0% fetal calf serum (FCS) **Contact time:** 15 and 30 sec **Test temperature:** 20°C	Log_{10} reduct on >4 in 15 sec at 80% **(effective against BVDV)**	Steinmann, J, Test report K15L0265aB, 11.07.2015; Expertise on the evaluation of the results from test reports K15L0265aB, 11.07.2015 and K15L0265aV, 10.08.2015, Dr. J. Steinmann, Dr. Brill + Partner GmbH, 01.12.2015 (05_A01_DVV_St_BVDV15Sec_PB_EN_20150711.pdf)
			Vacciniavirus strain Elstree	German Associat on for the Control of Virus Diseases e.V. (DVV) and of the Robert-Koch-Institute (RKI), dated 01/12/2014	**Concentration (%):** 10 and 80 **Interfering substances:** 10.0% fetal calf serum (FCS) **Contact time:** 15 and 30 sec **Test temperature:** 20°C	Log_{10} reduct on >4 in 15 sec at 80% **(effective against Vacciniavirus)**	Steinmann, J, Test report K15L0265aV, 10.08.2015; Expertise on the evaluation of the results from test reports K15L0265aB, 11.07.2015 and K15L0265aV, 10.08.2015, Dr. J. Steinmann, Dr. Brill + Partner GmbH, 01.12.2015 (06_A01_DVV_St_Vac15Sec_PB_EN_20151008.pdf)
			Modified vacciniavirus Ankara (MVA)	EN 14476:2013 + A1:2015	**Concentration (%):** 10, 50 and 80 **Interfering substances:** clean cond tions (med cal) **Contact time:** 15, 30 sec and 30 min **Test temperature:** 20°C	Log_{10} reduct on >4 in 15 and 30 sec at 80% **(**effective **against modified vacciniavirus)**	Steinmann, J, Test report K15L0265aMV, 22.12.2015 (09_A01_EN14476_St_MVA15Sec_PB_EN_20151222.pdf)
			Adenovirus type 5	EN 14476:2013	**Concentration (%):** 10, 50 and 80 **Interfering substances:** clean cond tions (med cal[10]) **Contact time:** 30 and 60 sec and 30 min **Test temperature:** 20°C	Log_{10} reduct on >4 in 30 sec at 80% **(effective against adenovirus)**	Steinmann, J, Test report K15L0265aA, 23.07.2015 (07_A01_EN14476_St_Adeno30Sec_PB_EN_20150723.pdf)
			Murine norovirus (MNV)	EN 14476:2013	**Concentration (%):** 10, 50, 80 and 97% **Interfering substances:** clean cond tions (med cal[10]) **Contact time:** 30, 60, 120 sec and 30 min **Test temperature:** 20°C	Log_{10} reduct on ≥4 in 30 sec at 97% **(effective against murine norovirus)**	Steinmann, J, Test report K15L0265aM, 15.07.2015 (08_A01_EN14476_St_MNV30Sec_PB_EN_20150715.pdf)
		Meta SPC 2 L+R handdisinfect 03 (30% w/w	Murine norovirus (MNV)	EN 14476:2013+ A1:2015/prA2:2016	**Concentration (%):** 10, 50, 80 and 97%	Log_{10} reduct on ≥4 in 30 sec at 97%	Werner, S & Köhnlein, J, Test report 2019-0003, 30.08.2019

		Propan-1-ol, 45% w/w Propan-2-ol, Batch No. 151018)			**Interfering substances:** clean cond tions (med cal²) **Contact time:** 30 sec **Test temperature:** 20°C	**(effective against murine norovirus)**	(meta 2_L+R handdisinfect 03_EN14476_HygCen_MNV30Sec_20190830.pdf)
		Meta SPC 2 L+R handdisinfect 04 (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. 160119)	Murine norovirus (MNV)	EN 14476:2013+A1:2015/prA2:2016	**Concentration (%):** 10, 50, 80 and 97% **Interfering substances:** clean cond tions (med cal²) **Contact time:** 30 sec **Test temperature:** 20°C	Log_{10} reduct on ≥4 in 30 sec at 97% **(effective against murine norovirus)**	Werner, S & Köhnlein, J, Test report 2019-0241, 30.08.2019 (meta 2_L+R handdisinfect 04_EN14476_HygCen_MNV30Sec_20190830.pdf)
		Meta SPC 1 Reference product L+R handdisinfect blue (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. H1080515)	Human rotavirus Wa	EN 14476:2013+A1:2015	**Concentration (%):** 10, 50, 80 and 97% **Interfering substances:** clean cond tions (med cal²) **Contact time:** 15, 30 sec and 30 min **Test temperature:** 20°C	**(effective against human rotavirus)** Log_{10} reduct on ≥4 in 15 sec at 80%	Steinmann, J, Test report K15L0265aR, 18.12.2015 (10_A01_EN14476_St_Rota15Sec_PB_EN_20151218.pdf)
Efficacy under practical conditions for hygienic hand disinfection (Phase 2 / Step 2)							
Hygienic handrub	health care, institutional, industry, food preparat on and handling (e.g. hospital canteen)	**Meta SPC 1 Reference product** L+R handdisinfect blue (30% w/w Propan-1-ol, 45% w/w Propan-2-ol, Batch No. # H1080515)	Escher chia coli NCTC 10536	EN 1500: 2013 (Batch No. not available in test report. Statement of the Batch No. by the appl cant.)	**Concentration (%):** Undiluted **Number of subjects:** 20 **Application time:** 30 sec **Applied volume:** 3 ml	Log_{10} reduct on 5.23; non-inferior to reference procedure **(bactericidal)**	Werner, H-P, test report: B 19584b, 10.11.2015; Expertise on the evaluation of the results from test report B 19584b of 10.11.2015, Prof. Dr. H.-P. Werner, HygCen Austria GmbH, 10.11.2015 (11_A01_EN1500_WE_3ml_PB_DE_EN_20151110.pdf)
Surg cal handrub			Res dent hand flora	prEN 12791:2014 (Batch No. not available in test report. Statement of the Batch No. by the appl cant.)	**Concentration (%):** Undiluted **Number of subjects:** 25 **Application time:** 90 sec **Applied volume:** As many portions of 3 ml as necessary to keep hands wet for 90 sec	Log_{10} reduct on 2.27 (immediate effect) and 2.22 (3 h effect); non-inferior to reference procedure **(bactericidal)**	Werner, H-P, test report: B 19584c, 10.11.2015; Expertise on the evaluation of the results from test report B 19584c of 10.11.2015, Prof. Dr. H.-P. Werner, HygCen Austria GmbH, 10.11.2015 (13_A01_EN12791_WE_1,5Min_PB_DE_EN_20151110.pdf)

Conclusion on the efficacy of the products

Meta SPC 1

For *meta* SPC 1 tests of efficacy were performed with product 1.1. Suspension tests (20°C, dirty conditions/medical, 30 sec contact time). They demonstrated efficacy against bacteria/mycobacteria and yeasts at a concentration of 30% w/w Propan-1-ol and 45% w/w Propan-2-ol. Furthermore, suspension tests demonstrated efficacy against enveloped viruses (20°C, - Bovine Viral Diarrhea Virus (BVDV); Vacciniavirus Elstree 10.0% FCS/DVV, 30 sec contact time; 20°C, Murine Vaccinia Ankara clean conditions/medical, 30 sec contact time) and against a limited number of non-enveloped viruses (20°C, Murine NoroVirus; adenovirus; rotavirus clean conditions/medical, 30 sec contact time).

Simulated-use tests (EN 1500, prEN12791) were performed with product 1.1 with bacteria (number of subjects: 20, applied volume: 3 ml, 30 sec contact time) and

resident hand flora (number of subjects: 25, applied volume: as many portions of 3 ml as necessary to keep hands wet during the 90 sec contact time).

The results demonstrate efficacy for hygienic handrub in 30 sec contact time and for surgical handrub in 90 sec contact time. Independently of the soiling used in the suspension tests the disinfecting solution should be rubbed into visibly clean and dry hands only.

Meta SPC 2
A skin care agent of product 1.1 was exchanged in products 2.1 and 2.2 of meta SPC 2 by a combination of substances having the same function at an approximately constant concentration (difference: 0.05 g per 100 g). The active substances and other co-formulants of meta SPC 1 and 2 remain unchanged in type and concentration.

Although there are no indications for an enhancing effect of the co-formulants on the active substances an influence on the efficacy of the products was excluded by carrying out selected phase 2, step 1 tests with both products 2.1 and 2.2: performed with bacteria (EN 13727, 20°C, dirty conditions/medical, 30 sec contact time) and the non-enveloped murine norovirus (EN 14476, 20°C, clean conditions/medical, 30 sec contact time).
The results indicate a 'non-activity' of the co-formulants, so that the efficacy claims of meta SPC 1 can also be applied to meta SPC 2.

1.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of the active substances propan-1-ol and propan-2-ol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where propanol is ineffective at any concentration. Likewise, propanol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.
For this reason, the efficacy against Norovirus is low and a concentration of 80%, as tested in EN Norms, has not demonstrated a sufficient efficacy at contact time of 120 seconds. A concentration of 97% was necessary.

1.2.5.7 Known limitations

No limitations known.

1.2.5.8 Evaluation of the label claims

The supported label claims for meta SPC 1 (*L+R handdisinfect blue*) and meta SPC 2 (*L+R handdisinfect 03/04*) are:

- for hygienic handrub – 30 s
- for surgical handrub– 90
- effective against bacteria
- effective against yeasts
- effective against mycobacteria
- virucidal against enveloped viruses
- limited spectrum virucidal activity

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

All biocidal products of meta SPC 1 and 2 are not intended to be used in combination with other biocidal products.

1.2.6 Risk assessment for human health

The risk assessment for human health is based on the toxicological properties of the active substances Propan-1-ol and Propan-2-ol. These are presented in the Documents II-A (Effects and Exposure for the Active Substance) of the Dossiers "Propan-1-ol" (2015) and "Propan-2-ol" (2015) of the ASD Consortium Alcohol and in the published Assessment Reports of Propan-2-ol (2015) and Propan-1-ol (2017). For each of the individual co-formulants in the L+R Propanol PT1 Family, valid data on the intrinsic properties are available from safety data sheets. None of the components is considered as substance of concern in regards to human health.
The co-formulants used in the products are well known from standard formulations in health care and from cosmetic use and no synergistic effects in similar formulations are reported (see also the confidential annex for characterisation of co-formulants). According to Larson et al (2006)[5] and the WHO Guidelines on Hand Hygiene in Health Care: A Summary (WHO 2009)[6], skin care agents/ emollients in alcoholic hand-rubs contribute significantly to an intact skin of health care workers and therefore improving the compliance of those products. Allergic contact dermatitis attributable to alcohol-based handrubs is very uncommon[11] and it is assumend that the range of co-formulants used do not contribute to the skin corrosion and irritation potential of the L&R Propanol PT1 family products.

For the *L+R Propanol PT1 Family*, the product L+R handdisinfect blue (meta-SPC 1) is considered as reference formulation for the family as it contains the highest amount of classified co-formulant (the active substance content is equal within the whole family).

According to the BPR guidance, no testing on the biocidal products is necessary, if valid data on each of the components in the mixture is available and considered sufficient to allow classification of the mixture. For some human health endpoints, human or *in vitro* studies are available. Therefore, human health classification of the *L+R Propanol PT1 Family* is either based on available studies or on available data on the individual components in the defined reference formulation (meta-SPC 1).

Toxicokinetics of the active substances
Propan-1-ol and Propan-2-ol are rapidly absorbed following oral or inhalation exposure, metabolized and excreted. The metabolism of the linear isomer Propan-1-ol predominantly occurs via oxidation through alcohol dehydrogenase to the corresponding aldehyde and further to propionic acid, which subsequently may be converted to carbon dioxide and water or enter other biochemical pathways. There are two metabolism pathways of the branched isomer Propan-2-ol. The major route is the oxidation of Propan-2-ol to acetone as the major metabolite, which may subsequently be converted to carbon dioxide. The

[5] Larson et al, 2006 Skin reactions related to hand hygiene and selection of hand hygiene products. Am J Infect Control 2006;34:627-35.
[6] WHO 2009, WHO Guidelines on Hand Hygiene in Health Care: A Summary. https://apps.who.int/iris/bitstream/handle/10665/70126/WHO_IER_PSP_2009.07_eng.pdf;jsessionid=EA6D19CFFAABAC4732FE0A4566F3470E?sequence=1

volatile fraction, which is exhaled with breath, consist of acetone, CO_2, and Propan-2-ol. The minor pathway of metabolism is the glucuronidation of Propan-2-ol to Propan-2-ol glucuronide.

Effects and Classification of the active substances
Propan-1-ol is of low acute toxicity regarding oral, dermal or inhalation exposure but it is shown to cause severe eye damage. Thus, it is classified for serious eye damage, category 1, and requires the label "H318 – Causes serious eye damage". Furthermore Propan-1-ol may cause drowsiness or dizziness and is classified as STOT SE 3; H336.

Propan-2-ol is of low acute toxicity regarding oral, dermal or inhalation exposure, but it is shown to have irritating effects to the eye. Thus, it is classified for serious eye irritation, category 2, and requires the label "H319 – Causes serious eye irritation". Furthermore, Propan-2-ol may cause drowsiness or dizziness and is classified as STOT SE 3; H336.

1.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation
No in vitro data or animal studies on skin corrosion and irritation of products pertaining to Meta SPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance/ Reference product**	**Relevant information about the study**	**Observations**	**Reference**
Human Repeated Insult Patch Test, HRIPT, Reliability 1, key GCP	L+R handdisinfect blue, 0.2 ml per patch Batch no. 15001	215 volunteers, 24 h exposure under semi-occluded conditions, 9 applications during 3 weeks (induction period), challenge after 2 weeks rest period.	No observation of dermal irritation	[redacted] 2017, Repeated Insult Patch Test (HRIPT)-Shelanski Method Final report Study No. CRL115815-1 V2
Human open Patch Test, Reliability 2 Non-GCP	L+R alkoholische Lösung 03, 1ml Batch #151018 (according to a separate document provided by the applicant, alkoholische Lösung 03 is identical to L+R handdisinfect 03, product of meta SPC 2)	30 volunteers with sensitive skin, exposure 60 min, open conditions, skin assessment after 20, 30, and 60 min. The study has shortcomings: - no description of criteria for volunteer skin diagnosis for sensitive skin at beginning of study, - no concurrent positive control - no quality standards followed (e.g. GCP)	No observation of dermal irritation However, due to the study's deficiencies, the sensitivity of the study is unclear. Therefore, the study can only be used as supportive information for hazard identification.	Schlippe G. (2018) Dermatological Report on human Open Patch Test L+R alkoholische Lösung 03, Labornummer S002/02

Human open Patch Test, Reliability 2 Non-GCP	L+R alkoholische Lösung 04, 1ml Batch #160119 (according to a separate document provided by the applicant, alkoholische Lösung 04 is identical to L+R handdisinfect 04, product of meta-SPC 2)	30 volunteers with sensitive skin, exposure 60 min, open conditions, skin assessment after 20, 30, and 60 min. The study has shortcomings: - no description of criteria for volunteer skin diagnosis for sensitive skin) at beginning of study, no concurrent positive control - no quality standards followed (e.g. GCP)	No observation of dermal irritation However, due to the study's deficiencies, the sensitivity of the study is unclear. Therefore, the study can only be used as supportive information for hazard identification.	Schlippe G. (2019) Dermatological Report on human Open Patch Test *L+R alkoholische Lösung 04 Labornummer S002/03*

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin corrosive or irritant
Justification for the value/conclusion	Classification is based on data on each of the components in the mixture. According to the AS dossiers/CARs, Propan-1-ol and Propan-2-ol are not classified as skin irritants. None of the co-formulants are classified for skin corrosion or skin irritation. Supportive to the classification based on the data of the components of the mixture, the provided human data, e.g epicutaneous occlusive patch test with *L+R handdisinfect blue* as well as two open patch tests with *L+R handdisinfect 03* and *L+R handdisinfect 04,* indicate no potential for dermal irritation. Thus, the product family does not meet the criteria for classification for skin corrosion or irritation. According to the CAR, local skin effects and reactions have been described for human individuals exposed to formulations containing Propan-1-ol or Propan-2-ol and both active substances are proposed for additional classification with EUH066 (Repeated exposure may cause skin dryness or cracking). Therefore, EUH066 should be assigned as supplemental hazard statement to *L+R Propanol PT1 Family.*
Classification of the product according to CLP and DSD	The MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified for skin corrosion or irritation, but are additionally classified for EUH066 (Repeated exposure may cause skin dryness or cracking).

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Isolated chicken eye test OECD 438, GLP, Reliability 1	*L+R handdisinfect blue*, 30 µl	Evaluation pre-treatment and up to 240 min post-treatment, positive and negative control	Overall ICE class: 3xIII	no deviations	Buda, I. (2016), 863-438-1260 and Amendment (2018)
EpiOcular Test OECD 492, GLP, Reliability 1	*L+R handdisinfect blue (batch #16513A1401)*, 50 µl/unit	Exposure time 30 min, positive and negative control	Mean tissue viability 3%	no deviations	Buda, I. (2018), 863-492-3498

No animal studies, or human data on eye irritation of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* cause serious eye damage.
Justification for the value/conclusion	Two *in vitro* tests were conducted as a tiered approach following IATA guidance (OECD, 2017). The provided *in vitro* ICE Test (OECD 438) can be used for the identification of i) test chemicals inducing serious eye damage (UN GHS Cat. 1), and ii) test chemicals not requiring classification for eye hazard (UN GHS No Cat.). The results could exclude a classifcation of *L+R handdisinfect blue* as "UN GHS Category 1" as well as as "No Category" for eye hazard. However for the obtained overall ICE class, no prediction for classification can be made. The second in vitro test, the EpiOcular Test, can be used for the identification of test chemicals not requiring classification for eye hazard (UN GHS No Cat.). The test results of the EpiOcular test (OECD 492) indicate a classification of *L+R handdisinfect blue* in Category 1 or 2 for eye hazard. The test method cannot resolve between Category 1 and 2. Further testing is required to decide on final classification.

	With the presented *in vitro* assays, the tested product could neiher be predicted as UN GHS Cat. 1 nor as UN GHS No Cat. To establish a definitive classification additional WoE evaluation with other existing information and if still needed additional testing (in vitro and/or in vivo) as a last resort would be needed. Thus, in the present situation without further testing, classification is based on data on each of the components in the mixture. The active substance Propan-1-ol has a harmonised classification under Regulation (EC) No 1272/2008 (CLP) as a category 1 for eye damage (H318) and is present in the product at levels exceeding the 10% cut-off level for classification of a mixture. Therefore, the *L+R Propanol PT1 Family* meets the criteria for classification for serious eye damage Category 1.
Classification of the product according to CLP and DSD	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family are* classified as eye damaging Cat.1 H318

Respiratory tract irritation

No in vitro data, animal studies, or human data on respiratory irritation of products pertaining to the *L+R Propanol PT1 Family* are available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not irritating to the respiratory tract.
Justification for the conclusion	According to the AS dossier/CARs, Propan-1-ol and Propan-2-ol are of low inhalational toxicity. None of the co-formulants are volatile or classified regarding respiratory tract irritation. No synergistic effects are expected.
Classification of the product according to CLP and DSD	According to the CLP Regulation (EC) No 1272/2008,MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified regarding respiratory irritation.

Skin sensitization

No in vitro data or animal studies on skin sensitization of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Human Repeated Insult Patch Test, HRIPT, Reliability 1 GCP	L+R handdisinfect blue, 0.2 ml per patch Batch no. 15001	215 volunteers, 24 h exposure under occluded conditions, 9 inductions during 3 weeks, challenge after 2 weeks rest period	No observation of skin sensitisation.	[redacted] 2017, Repeated Insult Patch Test (HRIPT)-Shelanski Method Final report Study No. CRL115815-1 V2
Human open Patch Test, Reliability 2 Non-GCP	L+R alkoholische Lösung 03, 1ml Batch #151018 (according to a separate document provided by the applicant, alkoholische Lösung 03 is identical to L+R handdisinfect 03, product of meta SPC 2)	30 volunteers with sensitive skin, exposure 60 min, open conditions, skin assessment after 20, 30, and 60 min. The study has shortcomings: - no description of criteria for volunteer skin diagnosis for sensitive skin) at beginning of study, no concurrent positive control - no quality standards followed (e.g. GCP)	No observation of skin sensitisation. However, due to the study's deficiencies, the sensitivity of the study is unclear. Therefore, the study can only be used as supportive information for hazard identification.	Schlippe G. (2018) Dermatological Report on human Open Patch Test L+R alkoholische Lösung 03, Labornummer S002/02

Human open Patch Test, Reliability 2 Non-GCP	L+R alkoholische Lösung 04, 1ml Batch #160119 (according to a separate document provided by the applicant, alkoholische Lösung 04 is identical to L+R handdisinfect 04, product of meta-SPC 2)	30 volunteers with sensitive skin, exposure 60 min, open conditions, skin assessment after 20, 30, and 60 min. The study has shortcomings: - no description of criteria for volunteer skin diagnosis for sensitive skin) at beginning of study, no concurrent positive control - no quality standards followed (e.g. GCP)	No observation of skin sensitisation. However, due to the study's deficiencies, the sensitivity of the study is unclear. Therefore, the study can only be used as supportive information for hazard identification.	Schlippe G. (2019) Dermatological Report on human Open Patch Test *L+R alkoholische Lösung 04 Labornummer S002/03*

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not skin sensitising
Justification for the value/conclusion	Classification is based on data on each of the components in the mixture. The active substances Propan-1-ol and Propan-2-ol are not classified as skin sensitizers. In one of the co-formulants the preservation substance 5-chloro-2-methylisothiazol-3(2H)-one (C(M)IT) and 2-methylisothiazol-3(2H)-one (MIT) (CAS 55965-84-9). However, the concentration of this substance in MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* is far below the SCL of 0.0015%. None of the other co-formulants are classified regarding skin sensitisation or contain skin sensitizing components. No synergistic effects are expected. Supportive to the classification based on the data of the components of the mixture, the provided human data, e.g epicutaneous occlusive patch test with *L+R handdisinfect blue* as well as two open patch tests with *L+R handdisinfect 03* and *L+R handdisinfect 04,* indicate no potential for skin sensitization. In summary, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* do not meet the criteria for classification for skin sensitisation.

Classification of the product according to CLP and DSD	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified regarding skin sensitisation.

Respiratory sensitization (ADS)

No in vitro data, animal studies, or human data on respiratory sensitization of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family are n*ot sensitizing to the respiratory tract.
Justification for the value/conclusion	According to the AS dossier, Propan-1-ol and Propan-2-ol are of low inhalation toxicity. The a.s. and other co-formulants are not classified for respiratory tract sensitisation and no synergistic effects are expected. Therefore, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* do not meet the criteria for classification for respiratory tract sensitisation.
Classification of the product according to CLP and DSD	According to the CLP Regulation (EC) No 1272/2008, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified regarding respiratory sensitization.

Acute toxicity

Acute toxicity by oral route

No in vitro data, animal studies, or human data on acute toxicity by the oral route of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not acutely toxic by the oral route.
Justification for the selected value	According to the CARs, Propan-1-ol and Propan-2-ol are of low oral toxicity. None of the components of the mixtures are classified as acutely toxic by the oral route and no synergistic effects are expected. Therefore, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* do not meet the criteria for classification for acute oral toxicity.
Classification of the product according to CLP and DSD	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified regarding acute oral toxicity.

Acute toxicity by inhalation

No in vitro data, animal studies, or human data on acute toxicity by the inhalation route of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Value used in the Risk Assessment – Acute inhalation toxicity

Value	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not acutely toxic by the inhalation route, but it may cause drowsiness or dizziness.
Justification for the selected value	According to the CARs, Propan-1-ol and Propan-2-ol are of low inhalation toxicity. However, both are classified as STOT SE 3; H336: may cause drowsiness or dizziness. The active substances are present in the product at levels exceeding the 20% cut-off level for classification. None of the co-formulants is classified regarding acute inhalation toxicity. Therefore, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* do not meet the criteria for classification for acute inhalation toxicity.
Classification of the product according to CLP and DSD	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified for acute inhalation toxicity, but is classified for specific target organ toxicity: STOT SE 3, H336.

Acute toxicity by dermal route

No in vitro data, animal studies, or human data on acute toxicity by the dermal route of products pertaining to MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not acutely toxic by the dermal route.
Justification for the selected value	According to the CARs, Propan-1-ol and Propan-2-ol are of low dermal toxicity and the co-formulants do not influence the classification of the mixtures based on the rules laid down in eg. (EC) No 1272/2008 (CLP) and no synergistic effects are expected. Therefore, MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* do not meet the criteria for classification for acute dermal toxicity.
Classification of the product according to CLP and DSD	MetaSPC 1 & 2 of the *L+R Propanol PT1 Family* are not classified regarding the acute dermal toxicity.

Information on dermal absorption

No in vitro data, animal studies, or human data on dermal absorption of products pertaining to the *L+R Propanol PT1 Family* are available.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Total alcohol content of Propan-1-ol and Propan-2-ol
Value	Transdermal flux rate of 0.85 mg/cm² (value from CAR of propan-2-ol, according to the CAR for propan-1-ol, the same flux rate applies to propan-1-ol)
Justification for the selected value(s)	Please see confidential annex

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

The products of the *L+R Propanol PT1 Family* do not contain any substance of concern regarding toxicological effects on humans.
The information on non-active parts of the formulation are described in the Confidential Annex.

Available toxicological data relating to a mixture

No further data available.

Assessment of the endocrine properties relating to the product

According to the assessment reports of propan-1-ol and propan-2-ol, both active substances are not considered to have endocrine disrupting properties based on the provisional criteria specified in Article 5(3), second and third subparagraphs, of Regulation (EU) No 528/2012. The active substances have not been assessed according to the new ED criteria[7].
The non-active substances were assessed for their endocrine properties according to a tiered approach approach described in the document *"CG-34-2019-02 AP 16.5 e-c ED potential of c-formulant_revUKb".* None of the non-active substances did show sufficient indications to be considered as an endocrine disruptor.
In conclusion, the biodical product family is not considered to have endocrine disrupting properties.

1.2.6.1.1 Exposure assessment

The products of the *L+R Propanol PT1 Family* are used as hygienic and surgical hand disinfectants for the disinfection of intact and uninjured hands and lower arms (PT1). Professional and industrial users may be exposed to Propan-1-ol and Propan-2-ol by the use of the biocidal products. The partial pressures of the active substances are high; therefore, inhalation exposure is possible. In addition, dermal exposure can occur but oral exposure is considered negligible.
The exposure assessment was conducted according to the Documents II-A (Effects and Exposure for the Active Substance) of the respective Dossiers "Propan-1-ol" and "Propan-2-ol" of the ASD Consortium Alcohol 2015 and the published Assessment Reports of Propan-2-ol (2015) and Propan-1-ol (2017). Exposure scenarios are based on the TNSG models, additional models and default values from HEEG opinions and recommendations No.1 (2014) and No.9 (2017) of the BPC Ad hoc Working Group were used.

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

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

[7] The Commision Delegated Regulation (EU) 2017/2100

List of scenarios

List of scenarios / Summary table: scenarios			
Scenario n°	**Scenario** (e.g. mixing/loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
Hand disinfection in hospitals, non-intensive care unit			
1	application	Primary exposure of the professional user resulting from application of an alcohol based disinfectant in form of a ready to use product for hand disinfection in naturally ventilated rooms.	Industrial, professional
2	application	Secondary exposure of a professional bystander who is present where the hand disinfection is carried out can be expected.	Bystanders (professional)
Secondary exposure			
3	Secondary exposure in patient room	Secondary exposure of patients resulting from professional application of an alcohol based disinfectant in form of a ready-to-use product for hand disinfection in naturally ventilated rooms. This scenarios serves as worst-case to cover non-intensive care units and intensive care units.	General public (adults, toddlers)

According to the published Assessment Reports of Propan-2-ol (2015) and Propan-1-ol (2017) the exposure scenarios as presented below were considered. In the Documents II-A (Effects and Exposure for the Active Substance) of the Dossiers "Propan-1-ol" and "Propan-2-ol" of the ASD Consortium Alcohol 2015 less scenarios were mentioned

General

Mixing/loading
The biocidal product is applied as ready to use solution. Therefore, no exposures have to be considered during mixing and loading.

Post application phase
The biocidal product is applied as ready-to-use solution. Due to high volatility of the active substances, the main path of exposure is via inhalation during the application phase, which is described in the following task specific scenarios. Therefore no exposure has to be considered during the post-application phase.

Industrial exposure

Industrial exposure during use is covered by the exposure assessment by professionals since the applied volumes in the hygienic hand disinfection by professional health-care workers are considered as the worst-case scenario (BPC Ad hoc Working Group recommendation 9)

Professional exposure

Scenario 1: disinfection in hospitals by professional users
According to the recommendation No.9 of the BPC Ad hoc Working Group for professional users an application rate of 25 applications per working day of 8 hours per health-care worker is assumed as realistic default value for the hygienic disinfection. Due to the high frequency of this scenario, the general use of hygienic hand rub is the worst case and covers the scenario of the surgical hand disinfection (BPC Ad hoc Working Group recommendation 9).

In accordance to the ARs for the application of the products of *L+R Propanol PT1 Family* no contact to the eyes is expected since only small amounts of product are used in a controlled way. Moreover, the liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye exposure. Thus, eye protection for hand disinfection in hospitals is not needed.

The following parameter were used for describing the scenario of 1:

	Parameter		**Value**	**Source**
	Room volume		80 m^3	1
	Air exchange rate		1.5 /h	1
	Inhalation rate	adult	1.25 m^3/h	5
	Body weight	adult	60 kg	5
	Concentration of a.s. BP	Propan-1-ol	300 g/kg	2
		Propan-2-ol	450 g/kg	2
		Total alcohol	750 g/kg	2
Inhalation exposure				
Tier 1	ConsExpo: Exposure to vapour		Instantaneous release	1
	Quantity used (3 ml/event, 25x/day)		63.75 g (75 ml)	1
	Exposure duration (1 event max. 60s, 25x/d)		25.0 min	1
Tier 2	ConsExpo: Exposure to vapour		Constant rate release	1
	Quantity used		2.55 g / event	1
	Exposure duration – 1 event		10 min	1

	Exposure duration – 3 event (3 hand rubs)		20 min	1
	Vapour pressure (30 °C) [Pa]: Propan-1-ol		3600	3
	Vapour pressure (30 °C) [Pa]: Propan-2-ol		7600	3
	Application temperature		30 °C	1
Dermal exposure				
Tier 1	Dermal flux of propanol isomers		0.85 mg/ cm² h	1
	Hands surface		820 cm² (adult)	1
	m: total mass		1912.50 mg	4
	Vapour pressure (30 °C, skin temperature) [Pa]: Total alcohol BP		6377	2
	Emission (evaporation) duration		66.4 s	4

Sources

1) BPC Ad hoc Working Group on Human Exposure: Recommendation No. 9
2) The vapour pressure of the alcoholic phase is calculated according to Raoults law
3) CAR Propan-1-ol / Propan-2-ol
4) Calculation in Annex 3.2
5) Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products

The volatile components in the biocidal product are the alcohols Propan-1-ol and Propan-2-ol. Since both alcohols are present in high concentrations in the mixture and both alcohols are volatile, they will influence each other during evaporation. Especially the relatively short evaporation time used in the dermal exposure calculation could be underestimated by not using a combined vapour pressure. For the dermal exposure calculation, it is therefore important to consider the total alcohol fraction which is the sum of the active substances propan-1-ol and propan-2-ol. For the inhalation exposure however, the vapour pressure of each active substance was used.

The emission (evaporation) duration for the total alcoholic phase was calculated using the following equation as described:

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

Parameters used for the calculation of emission (evaporation) duration

m: mass of total alcohol on surface	1912.50 mg
R: gas constant	8.314 J/K/mol
M: molar mass	60.01 g/mol
β: mass transfer coefficient	8.7 m/h
p: vapour pressure (30°C)	6377 Pa
A: surface area (for both hands)	820 cm^2
K: conversion factore	36000
T: skin/surface temperature	303.15 K

***t*: time [s] (calculated)**	**63.44**

The exposure assessment was conducted according to the recommendation No. 1 of the BPC Ad hoc Working Group (2014) and according to the recommendation No.9 (2017).
The ready to use products are poured on the skin area or into the palm and let to dry. Thereby it is assumed that 3 ml product are applied resulting in an amount of 2.55 g by considering a density of 0.85 g/ml.

Inhalation

Tier 1:
For describing this unrealistic worst-case scenario it is assumed that the professional in a hospital performs 25 hand rubs per shift applied in one room successive without break. The biocidal product is released at once in the room, the vapour pressure of the substances was not considered in this Tier 1 approach.

Tier 2:
For a refinement of the exposure calculation and in accordance with HEAdhoc recommendation No. 9 it is assumed that one nurse is responsible for 8 patients in four rooms. During her stay in a room, 3 hand disinfections are performed. The nurse stays for 20 minutes in each room. After visiting all four rooms and performing 12 hand rubs, she enters the first room again and performs 3 further disinfections in every room. Additionally, one hand rub is performed e.g. at the beginning of the shift in an 80 m^3 room and staying for 10 minutes. In summary 25 disinfections are performed.
The calculation of the inhalation exposure for the first hand rub is based on the model ConsExpo (Web version) "Exposure to vapour: Constant rate release". The two next hand rubs performed in the same room are calculate by means of the excel file provided in the annex of recommendation 9.

For details of the calculation of inhalation exposure and the ConsExpo web reports, please refer to Annex 3.2 of this PAR.

Results of the inhalation exposure estimation			
Inhalation [mg/kg bw/day]		Propan-1-ol	Propan-2-ol
BP			
Tier 1	Internal dose on day of exposure	1.54	2.31
Tier 2	Internal dose on day of exposure	0.72	1.08

Dermal

The dermal exposure was calculated considering the dermal flux of 0.85 mg/ cm^2 h for propanol isomers and an exposed skin surface area of 820 cm^2 (two hands). With an evaporation time of 63.4 s, the resulting exposure is as follows:

Dermal exposure = dermal flux rate x evaporation time x hand surface / body weight

The result of this calculation leads to the dermal uptake of the total alcoholic phase. However, assuming this value is equal to the dermal intake of each single active substance leads to an underestimation. Therefore, the total alcoholic uptake is used and then separated proportionally (percentage of each substance of the total alcoholic phase) to result in the particular dermal intakes.

Results of dermal exposure estimation			
	total alcoholic phase	Propan-1-ol	Propan-2-ol
BP	75%	30%	45%
Daily dermal intake [mg/kg bw/day]	5.12	2.05	3.07

Scenario 2: Secondary exposure of professionals:

As a worst case scenario it is assumed, that the professional bystander (e.g. nurse or cleaning staff) stays 8 hours in the room where the disinfection is performed. Therefore, the inhalational exposure is the same as for the professional performing the disinfection. Dermal exposure is not expected.

Combined scenarios

A combination of scenarios is not applicable as the scenario is restricted to a specific occupation so that the combination of two different occupations can be excluded.
Secondary exposure of professionals does not need to be accumulated to the primary exposure estimates since it is already integrated in the primary exposure assessment as discussed above.

Summary of exposure assessment of professionals

Summary table: estimated exposure from professional uses		
Scenario	BP	
	Propan-1-ol	Propan-2-ol
	Estimated total uptake (inhalation +dermal) [mg/kg bw/d]	
Scenario 1: Hand disinfection in hospitals, non-intensive care unit (Tier 1)	3.59	5.38
Scenario 1: Hand disinfection in hospitals, (Tier 2)	2.77	4.15

Non-professional exposure

The *L+R Propanol PT1 Family* products are not intended for non-professional users.

Exposure of the general public

Scenario [3]
Secondary exposure of general pulic (adults/toddlers) in hospital rooms:

This scenario is based on the scenario 1 where the professional user disinfects their hands when entering hospital rooms. Inhalation exposure may occur to bystanders (e.g. visitors or patients) in patients' rooms where 3 hand disinfections are performed within 20 min. It is assumed that bystanders will not leave the room for this time. Due to the assumption that 3 hand disinfection by the professional is done every 4 hours (twice a day), the patient (adult and toddler) is the worst-case bystander. This scenario serves as worst-case to cover non-intensive care units and intensive care units.

Description of Scenario [3]

Patients or visitor (adults and toddlers) may be indirectly exposed when professional users (nurses) disinfect their hands. Toddlers represent the worst case for inhalation exposure. This scenarios serves as worst-case to cover non-intensive care units and intensive care units.

Based on information in HEAdhoc recommendation 9, one nurse is responsible for 8 patients. Two patients are in one patient room of 80 m^3 size with a ventilation rate of 1.5 air changes per hour. During work in the patient room, 3 hand disinfections are performed. The nurse stays for 20 minutes in every room. After visiting 4 patient rooms and 12 hand disinfections, the nurse enters the first room again and performs 3 hand disinfections in each room resulting in additional 12 hand rubs. There is a 240 minute interval before the nurse re-enters a room. Based on this information, it is reasonable to assume that every 4 hours, 3 applications of "Handsan" will be made in an 80 m3 room.

Inhalation exposure is assessed according HEAdhoc Recommendation No. 9. The Tier II inhalation exposure is performed using ConsExpo model "Exposure to vapour"; release mode: "constant rate". See scenario 1 for exposure assessment.

According to scenario 1, the 4 hour TWA is:

- Propan-1-ol: 12.46 mg/m^3 (12.34 mg/m^3 after 3 applications and 0.12 mg/m^3 remaining air concentration)
- Propan-2-ol: 18.71 mg/m^3 (18.53mg/m^3 after 3 applications and 0.18 mg/m^3 remaining air concentration)

After the initial hand disinfection, the nurse will re-enter the room and disinfect their hands a further 3 times every 240 minutes. The air concentration after the initial 3 hand disinfections will have declined considerably before the next applications. As the remaining air concentration is minimal compared to the 4 hour TWA it could be argued that this will have a negligible effect on exposure. However, using a pre-cautionary approach, the remaining air concentration has been summed with the 4 hour TWA.

The air concentration is converted to a systemic dose using the following equation:

Systemic dose via the inhalation route (mg/kg bw/day) = [(4 hour TWA + remaining) x long term inhalation rate] / bodyweight

Dermal exposure is not assumed for this exposure scenario.

Parameter		Value	Source
Room volume		80 m^3	1
Air exchange rate		1.5 /h	1
Inhalation rate	adult patient	16m^3/d (resting) 8m^3/d (resting)	3

		toddler patient		
	Body weight	Adults Toddlers	60 kg 10 kg	3
	Concentration of a.s. BP	Propan-1-ol	300 g/kg	2
		Propan-2-ol	450 g/kg	2
		Total alcohol	750 g/kg	2
	Exposure duration		240 min	1

Sources:
1. BPC Ad hoc Working Group on Human Exposure: Recommendation No. 9
2. Applicant data
3. BPC Ad hoc Working Group on Human Exposure: Recommendation No. 14

Calculations for Scenario [3]

Summary table: systemic exposure for general public during professional hand disinfection in hospital rooms – Propan-1-ol						
Exposure scenario	**Tier/PPE**	**Mean event concentration mg/m³**	**Estimated inhalation uptake mg/kg bw d**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake mg/kg bw d**
Scenario [3] Adults	1/-	12.46	0.55	-	-	0.55
Scenario [3] Toddlers	1/-	12.46	1.66	-	-	1.66

Summary table: systemic exposure for general public during professional hand disinfection in hospital rooms – Propan-2-ol						
Exposure scenario	**Tier/PPE**	**Mean event concentration mg/m³**	**Estimated inhalation uptake mg/kg bw d**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake mg/kg bw d**
Scenario [3] Adults	1/-	18.71	0.83	-	-	0.83
Scenario [3] Toddlers	1/-	18.71	2.49	-	-	2.49

Calculations are provided in Annex 3.2

Further information and considerations on scenario [3]

none

Combined scenarios

A combined assessment for the general public is not required.

Monitoring data

No monitoring data are available.

Dietary exposure

No residues in food or feed from the intended use in PT1 are expected.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

No exposure is expected.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not applicable.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not applicable.

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

The biocidal products are manufactured in the same processes as the active substances not intended for biocidal use. Only a minor fraction of total Propan-1-ol and Propan-2-ol manufactured in the EU are used as biocidal product. The exposure associated with the production, formulation and disposal of the biocidal product is covered in the assessment reports of the active substances.

Aggregated exposure

The biocidal product is only intended to be use in PT1. Therefore, no aggregated exposure is considered.

1.2.6.2 Risk characterisation for human health

The risk assessment for L+R Propanol PT1 Family, which is focused on its use as a human hygiene biocidal product (PT1), is based on the already evaluated assessment reports of the active substances with the respective acceptable exposure limits. The most significant route of exposure to the propanol-isomers as biocides is by inhalation due to their volatile nature.

Reference values to be used in Risk Characterisation

Substance	Reference value		Critical Effect (Study)	Remarks
Propan-1-ol	AEL_{acute}	27.6 mg/kg bw	Foetal skeletal malformations (rat inhalation developmental toxicity studies)	
	$AEL_{medium-term}$	18.3 mg/kg bw	Impairment in male fertility parameters (13 wk rat inhalation study)	
	$AEL_{long-term}$	9.2 mg/kg bw	Impairment in male fertility parameters (13 wk rat inhalation study)	
	ARfD	27.6 mg/kg bw/day	Inhalation – developmental toxicity study in rats	
	ADI	9.2 mg/kg bw/day	Inhalation – 13 week repeat dose studies in rats	
Propan-2-ol	$AEL_{acute/medium-term/long-term}$	10.7 mg/kg bw/d	Neurological effects (Exposure to vapours, human volunteer study)	general population
	$AEL_{acute/medium-term/long-term}$	17.9 mg/kg bw/d	Neurological effects (Exposure to vapours, human volunteer study)	professional workers
	AEC* acute/medium-term/long-term	31.25 ppm	Neurological effects (Exposure to vapours, human volunteer study)	general population
	AEC* acute/medium-term/long-term	52.6 ppm	Neurological effects (Exposure to vapours, human volunteer study)	professional workers
*AEC is assumed to also sufficiently cover local irritant effects in the eyes/airways. ** AEC corresponds to the systemic/internal reference dose, thus the AEL is based on determined AEC.				

According the AR of propan-2-ol, the AEL is based on the derived NOAEC of 200 ppm for neurological effects in humans and it is assumed that this sufficiently covers local irritant effects in the eyes/airways.
However, as the biocidal product is classified for serious eye damage a qualitative local risk assessment was performed.

Maximum residue limits or equivalent
Not relevant.

Specific reference value for groundwater

The maximum permissible concentration which is laid down by Directive 98/83/EC is used.

Risk characterisation for professional and industrial users

Risk for industrial users

The risk for industrial users related to the use of biocidal products of *L+R Propanol PT1 Family* is covered by the risk assessment for professional users as presented in section "Risk for professional users" (see below). For details refer to this section.

Risk for professional users

Systemic effects

The product contains two different active substances; therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, Part B of 2015.

The first step of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL. There is an unacceptable risk if HQ is ≥ 1.

Risk Assessment of substance by substance of the b.p. - professionals						
Scenario	Estimated total uptake [mg/kg bw/d]		AEL [mg/kg bw/d]		HQ	
	Propan-1-ol	Propan-2-ol	Propan-1-ol	Propan-2-ol	Propan-1-ol	Propan-2-ol
Scenario 1 (Tier 1)	3.59	5.38	9.2	17.9	0.39	0.30
Scenario 1 (Tier 2)	2.77	4.15	9.2	17.9	0.30	0.23

The estimated hazard quotients HQ of the active substances in the products of the *L+R Propanol PT1 Family* as disinfectants in the worst-case scenarios are < 1. No adverse health effects are expected for the professional user and bystander through use of the biocidal product by using them for hygienic hand disinfection.

Assessment of combined exposure to mixture by concentration (dose) addition

In a second step, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 the risk related to use of the mixture will be considered unacceptable; a refinement is needed.

Risk Assessment from combined exposure to mixture - professionals				
Scenario	HQ		HI	Acceptable (yes/no)
	Propan-1-ol	Propan-2-ol		
Scenario 1 (Tier 1)	0.39	0.30	0.69	Yes
Scenario 1 (Tier 2)	0.30	0.23	0.53	Yes

Conclusion

The HI is ≤1 for the professional scenario. The risk related to the use of the mixture is considered acceptable and no unacceptable adverse health effects are expected for the professional user as well as the bystander during the use of the biocidal products of *L+R Propanol PT1 Family*.

Local effects

The products of the *L+R Propanol PT1 Family* are classified as eye damaging (H318). An additional labelling as EUH066 (Repeated exposure may cause skin dryness or cracking) is required. Therefore, a qualitative risk assessment for local effects regarding skin and eye contact is necessary. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2017) the allocated hazard categories are "high" for Eye Dam 1 (H318) and "low" for EUH066.

Task	**Concentration**	**Local effects**	**Hazard cat.**	**User**	**Exposure**		**Relevant RMM & PPE**	**Acceptable Risk (Y/N)**
					Route	**Frequency & duration**		
PT1: hygienic hand rub in hospitals by professional users								
2.55 g / event product is poured on the skin area	RTU products 30% Propan-1-ol & 45% Propan-2-ol	H318	high	Professional	no contact to the eyes is expected	25 x/d	labelling "Avoid contact with eyes.", professional is following use instructions	Yes
				professional bystander		1 – 3x/d		
								Yes
		EUH066	low	Professional	Skin (2 hands (840 cm^2))*	25 x/d		Yes
*Dermal exposure is expected only in the moment of application and it is limited due to quickly evaporation within ~1 min; adverse effect is only expected after repeated prolonged exposure								

Conclusion

The ready-to-use products are applied in low amounts directly on skin as hand and skin disinfectant. Due to the volatile character of the active substances, they will evaporate within 1-2 minutes. Dermal contact to the disinfection solution is the intended use and thus corresponding personal protective measures are simply not adequate. This is reasonable since only small amounts of product are used in a controlled way. Contact to eyes is not expected. In summary, there is no unacceptable risk for professional users and bystanders.

Risk for non-professional users

The *L+R Propanol PT1 Family* products are not intended for non-professional users.

Risk for the general public

The product contains two different active substances; therefore, a risk assessment from exposure to the two active substances is performed according to the Guidance on the Biocidal Product Regulation, Volume III Human Health – Assessment & Evaluation (Parts B+ C).

The first step of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL. There is an unacceptable risk if HQ is ≥ 1.

Risk Assessment of each active substance of the biocidal product – general public						
Task/Scenario	**Estimated total uptake [mg/kg bw/d]**		**AEL [mg/kg bw/d]**		**HQ**	
	Propan-1-ol	Propan-2-ol	Propan-1-ol	Propan-2-ol	Propan-1-ol	Propan-2-ol
Scenario 3 Adults Tier I	0.55	0.83	18.3	10.7	0.03	0.08
Scenario 3 Toddlers Tier I	1.66	2.49	18.3	10.7	0.09	0.23

In a second step, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 the risk related to use of the mixture will be considered unacceptable; a refinement is needed.

Risk Assessment of each active substance of the biocidal product – general public				
Task/Scenario	**HQ**		**HI (Σ HQ a.s)**	**Acceptable (Yes/No)**
	Propan-1-ol	Propan-2-ol		

Scenario 3 Adults Tier I	0.03	0.08	0.11	Yes
Scenario 3 Toddlers Tier I	0.09	0.23	0.32	Yes

Combined scenarios
Not relevant.

Local effects

Not relevant.

Conclusion
The exposure estimates for the general public are below the systemic AELs. Thus, it is concluded that secondary exposure of the general public to propan-1-ol and propan-2-ol after use of biocidal product of the *L+R Propanol PT1 Family* is acceptable.

Risk for consumers via residues in food

Residues in food or feed from the intended use of propan-1-ol and propan-2-ol in PT1 are not expected, as no direct or indirect contact with food or feed is intended.

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

According to the Guidance for Human Health Risk Assessment, Volume III, Part B+C hazard assessment of biocidal products rely only on data on individual ingredients of the product regarding systemic effects.

1.2.7 Risk assessment for animal health

Not relevant.

1.2.8 Risk assessment for the environment

1.2.8.1 Effects assessment on the environment

For each of the individual components in the products of the *L+R Propanol PT1 Family*, valid data on the intrinsic properties are available from state-of-the-art safety data sheets. In the Biocidal Product *L+R handdisinfect blue* the co-formulant Tetradecanol (0.95%) is identified as a substance of concern (SoC) with regard to the environnemnt due to its

aquatic toxicity (H410, Aquatic Chronic 1). There is no other potential SoC present in the products of the *L+R Propanol PT1 Family*.
Thus, the product of meta 1 (*L+R handdisinfect blue*) is to be handled as worst-case product and an environmental risk assessment considering the SoC has to be provided.

There is no indication of synergistic effects between any of the components. Thus, the risk assessment for the environment is based on the toxicological properties of the relevant substances. These are presented in the Documents II-A (Effects and Exposure for the Active Substance) of the respective Dossiers "Propan-1-ol" and "Propan-2-ol" of the ASD Consortium Alcohol 2015 and in the published and already evaluated Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015).

In respect to the SoC specific information on the effects were given by the supplier. PNECs are listed in the safety data sheet and the REACh dossier.
The environmental risk assessment for the *L+R Propanol PT1 Family* is based on the already evaluated assessment reports of the active substances with the respective PNECs.

Summary table on PNEC values					
	$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sed}$**	**$PNEC_{soil}$**	**MPC_{GW}**
	mg/l	**mg/l**	**mg/kg_{wwt}**	**mg/kg_{wwt}**	**[µg/l]**
Propan-1-ol	10	2.3	1.998	0.432	0.1
Propan-2-ol	10	2.82	2.41	0.496	0.1
SoC	0.13	0.00063	0.466	0.378	0.1

GW: Groundwater – wwt: wet weight – MPC: maximum permissible concentrations

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

Not required. In respect to the SoC specific information on the effects were given by the supplier. PNECs are listed in the safety data sheet and the REACh dossier.

Further Ecotoxicological studies

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	meta 1: Aquatic chronic 3 (H412) meta 2: not classified
Justification for the value/conclusion	According to the CLP Regulation (EC) No 1272/2008 *L+R handdisinfect blue* (meta SPC 1) has to be classified as harmful to aquatic life with long lasting effects. The other products of the *L+R Propanol PT1 Family* (meta SPC 2) are not classified regarding environmental hazards. Due to the envisaged indoor use, no further studies are needed. Due to lack of exposure neither further studies on non-target organisms

	nor further compartment related risk assessments were considered to be relevant for the alcohol disinfectant product.

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

Conclusion used in Risk Assessment – Effects on specific, non-target organisms	
Value/conclusion	No data available
Justification for the value/conclusion	Due to the ready biodegradability as well as volatility of Propanols, no exposure of water and soil organisms is expected. Propanols are expected to undergo rapid degradation in the sewage treatment plants and therefore the exposure for the environment is considered to be negligible. Due to lack of exposure neither further studies on non-target organisms nor further compartment related risk assessments were considered to be relevant for the alcohol disinfectant product. According to the published Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015) the distribution in the sewage treatment plant results in: release fractions to air 0.3 %, water 12.5 %, sludge 0 % and degraded fraction 87.1 %. However, according to TAB 2.0 ENV9, the distribution in the sewage for Propan-1-ol, Propan-2-ol and the SoC has been recalculated using SimpleTreat 4.0.

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

Conclusion used in Risk Assessment – supervised trial to non-target organisms in field conditions	
Value/conclusion	No data available
Justification for the value/conclusion	Data on the active substances give sufficient information and there are no indications of risk due to specific properties of the biocidal products of meta 1 and 2. Indoor use only.

Data waiving	
Information requirement	No data available
Justification	Data on the active substances give sufficient information and there are no indications of risk due to specific properties of the biocidal products of meta 1 and 2. Indoor use only.

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

Conclusion used in Risk Assessment – Acceptance by ingestion by non-target organisms	
Value/conclusion	Not applicable
Justification for the value/conclusion	Due to the envisaged indoor use, no further studies are needed.

Data waiving	
Information requirement	Not applicable
Justification	Due to the envisaged indoor use, no further studies are needed.

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

Not relevant.

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

The alcohol-based disinfectant products are intended for the indoor use only. Thus, no direct exposure to the product of aquatic and soil organisms is expected. Only indirect emissions to soil and water might be possible via discharging the alcohol solution into sewage treatment plants (STP). Additionally, Propan-1-ol and Propan-2-ol are volatile substances. The use of the biocidal products will cause an emission to air implying that only a very small fraction might reach wastewater.

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

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	No data available.
Justification for the value/conclusion	Due to the ready biodegradability as well as volatility of Propanols, no exposure of water and soil organisms is expected. Propanols are expected to undergo rapid degradation in the sewage treatment plants and therefore the exposure for the environment is considered to be negligible. Due to lack of exposure neither further studies on non-target organisms nor further compartment related risk assessments were considered to be relevant for the alcohol handdisinfectant product.

Leaching behaviour (ADS)

The agreed LoEP for both active substances have been used for the risk assessment.

Testing for distribution and dissipation in soil (ADS)

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	Not required.
Justification for the value/conclusion	The agreed LoEP for both active substances have been used for the risk assessment.

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

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment	
Value/conclusion	Not required.
Justification for the value/conclusion	The agreed LoEP for both active substances have been used for the risk assessment.

Testing for distribution and dissipation in air (ADS)

Conclusion used in Risk Assessment –distribution and dissipation in air	
Value/conclusion	Not required.
Justification for the value/conclusion	The agreed LoEP for both active substances have been used for the risk assessment.

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

The biocidal products are not sprayed near to surface waters and data on overspray behaviour is not required as there is no potential for large scale formation of dust.

Acute aquatic toxicity

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion Propan-1-ol	$PNEC_{water}$ 2.3 mg/L
Value/conclusion Propan-2-ol	$PNEC_{water}$ 2.82 mg/L
Value/conclusion SoC	$PNEC_{water}$ 0.00063 mg/L
Justification for the value/conclusion	Values are presented in published Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015), the REACh dossier of the SoC.

Chronic aquatic toxicity

Conclusion used in Risk Assessment- Chronic Aquatic toxicity	
Value/conclusion Propan-1-ol	$PNEC_{water}$ 2.3 mg/L
Value/conclusion Propan-2-ol	$PNEC_{water}$ 2.82 mg/L
Value/conclusion SoC	$PNEC_{water}$ 0.00063 mg/L
Justification for the value/conclusion	Values are presented in published Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015), the REACh dossier of the. Due to the SoC (H410, Aquatic Chronic 1), the product of meta 1 has to be classified as H412 according to CLP Regulation (EC) No 1272/2008. meta 2: not classified as toxic for the aquatic environment

Estimated aquatic bioconcentration

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	Aquatic bioconcentration not expected
Justification for the value/conclusion	According to the published Assessment Reports of Propan-1-ol (2017) and Propan-2-ol (2015), Propanols are not considered to have a potential to bioconcentrate indicated by the very low partition coefficient and ready biodegradability. According to the REACH Dossier, the SoC is readily biodegradable and the bioaccumulation in aquatic species is unlikely.

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)

The biocidal products of the *L+R Propanol PT1 Family* are not sprayed outside and data on overspray behaviour is not required as there is no potential for large scale formation of dust.

1.2.8.2 Exposure assessment

General information

Assessed PT	PT 1
Assessed scenarios	The product is applied for hygienic and surgical hand disinfection in hospitals and other health care institutions
ESD(s) used	Emission Scenario Document for Product Type 1: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001

	Technical Agreement on Biocides 2.0 (2018) : Estimation of th consumtion of product for surgical and nursing staff (ENV41)
Approach	Scenario 1: Disinfectants used for skin and hand application in hospitals based on average consumption Tonnage and consumption based approach
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (2017)
Groundwater simulation	FOCUS PEARL has been used if necessary
Confidential Annexes	No

Emission estimation

Emission estimation

According to the emission scenario document for PT1 (Emission Scenario Document (ESD) PT1 (Royal Haskoning, 2004)), the scenarios and the average consumption/application rate were used to estimate the emission of the active substances and the substance of concern to the environment.
The environmental exposures are assessed applying the Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (2017) and the ESD PT1 (Royal Haskoning, 2004). The environmental exposure assessment is based on the AR of the active substances and the product specific information provided by the Applicant in case of SoC.

Due to volatilisation during use as hand disinfectant, the active substances Propan-1-ol and Propan-2-ol are mainly released to the air compartment. In contrast, based on the low vapour pressure, the SoC is expected to be released solely to waste water. Therefore, for the local emissions the fractions released to air (Fair) and water (Fwater) have to be set differently in comparison to the active substances due to the specific physico-chemical properties of the evaluated SoC.

Scenario1: professional use

Tonnage based approach
The emission has been estimated based on annual tonnage using the scenario for disinfectant used for skin and hand application in hospitals as described in Table 4.4 (ESD PT1, 2004). The resulting emissions to wastewater and air for both active substances and the SoC based on tonnage are presented in the confidential Annex.

Consumption based approach
Emission has been estimated based on consumption in hospitals as given in the ESD PT1. As the products are intended to be used by nursing staff as well as surgical staff, the quantity of product consumed per bed by both user groups has been estimated according to TAB 2.0 ENV41. The efficient dose rate for hand disinfection by both user groups and the product density have been set to 3 mL and 0.85 kg/L, respectively, as given by the Applicant.

The emission estimation is based on the consumption of the active substances per bed considering a total alcohol concentration of 750 g/kg. As a worst-case it is assumed that the complete consumption in a hospital is based on the product containing the active substances Propan-1-ol (40% total alcohol = 300 g/kg in B.P.) and Propan-2-ol (60% total alcohol = 450 g/kg in b.p.).

Parameters for calculating the consumption of active substances and SoC by surgical and nursing staffs (TAB 2.0 ENV41)				
Parameter	**Nomenclature**	**Value**	**Unit**	**Remarks**
Number of beds in model hospital	Nbedspres	400		default for alcohols
Fraction released to wastewater (alcohols)	Fwater(alcohols)	0.1		according to the AR Propan-2-ol
Fraction released to wastewater (SoC)	Fwater(SoC)	1		default

Fraction released to the air (alcohols)	Fair(alcohols)	0.9		according to the AR Propan-2-ol
Fraction released to the air (SoC)	Fair(SoC)	0		default
Number of hospital personal per bed	N_FTE/bed	1.5	FTE/bed	default for nursing and surgical staff*
Efficient dose rate of the hand disinfectant	Q_form	0.003	L/event	according to applicant, for nursing and
Density of the product	RHO_form	0.85	kg/L	according to applicant
Fraction of propan-1-ol in the hand disinfectant	F_form (propan-1-ol)	0.3		
Fraction of propan-2-ol in the hand disinfectant	F_form (propan-2-ol)	0.45		
Fraction of SoC in the hand disinfectant	F_form (SoC)	0.0095		
Number of disinfection events/FTE/day (nursing staff)	N_applN	25	1/FTE/day	default for hand rubs*
Number of disinfection events/FTE/day (surgical staff)	N_applS	4	1/FTE/day	default for hand rubs*
Consumption of propan-1-ol per bed for nursing staff	Qsubst_bedN (propan-1-ol)	2.87E-02	kg/bed*day	
Consumption of propan-2-ol per bed for nursing staff	Qsubst_bedN (propan-2-ol)	4.30E-02	kg/bed*day	
Consumption of SoC per bed for nursing staff	Qsubst_bedN (SoC)	9.08E-04	kg/bed*day	
Consumption of propan-1-ol per bed for surgical staff	Qsubst_bedS (propan-1-ol)	4.59E-04	kg/bed*day	
Consumption of propan-2-ol per bed for surgical staff	Qsubst_bedS (propan-2-ol)	6.89E-04	kg/bed*day	
Consumption of SoC per bed for surgical staff	Qsubst_bedS (SoC)	1.45E-05	kg/bed*day	
Consumption of propan-1-ol per bed for nursing and surgical staff	**Qsubst_bedN+S (propan-1-ol)**	**2.91E-02**	**kg/bed* day**	
Consumption of propan-2-ol per bed for nursing and surgical staff	**Qsubst_bedN+S (propan-2-ol)**	**4.37E-02**	**kg/bed* day**	
Consumption of SoC per bed for nursing and surgical staff	**Qsubst_bedN+S (SoC)**	**9.23E-04**	**kg/bed* day**	

Resulting local emission to relevant environmental compartments		
	Local emission ($E_{localwater}$)[kg/d]	Local emission ($_{Elocalair}$)[kg/d]
Propan-1-ol	1.17	10.49
Propan-2-ol	1.75	15.74
SoC	0.37	---

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Freshwater	Sediment	Seawater	STP	Air	Soil	Groundwater
Propanol isomers	Yes, via STP	Yes, via STP	not relevant	yes	yes	Yes, via air	Yes, via air
SoC					no	Yes, via STP-sludge	Yes, via STP-sludge

Products used in PT1 release in the sewage treatment plant primary. In case of volatile substances, the main release pathway is via evaporation to air.

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	**1-Propanol**	**2-Propanol**	**SoC**	**Remarks**
Molecular weight [g/mol]	60.1	60.1	214.4	
Melting point [°C]	-126.1	-89.5	39	
Boiling point [°C]	97.2	82.3	294	
Vapour pressure [Pa] (at 25 °C)	2726	5780	0.014(25°C)	
Water solubility (at 25 °C) [mg/l]	1000000	1000000	1.3*	*at 23°C and pH 5.5
H [Pa m^3/mol]	0.76	0.82	7.5*	* at 12°C
log K_{OW}	0.25	0.05	5.5	
K_{OC} [l/kg]	3.96**	3.3**	33983	**calculated from K_{OW} (see LoE); REACH dossier; last update 22/02/2019
Biodegradability	Ready biodegradable			
Half-life in soil $t_{1/2}$ [d, at 12°C]	30***	30***	300****	
BCF earthworm			---	
BCF fish [L/kg ww]			1000	REACH dossier; last update 22/02/2019
Biomagnification factor			1	REACH dossier; last update 22/02/2019
Rate constant for degradation in air			18.3	REACH dossier; last update 22/02/2019
Rate constant for biodegradation in STP [h-1]	1	1	100	REACH dossier; last update 22/02/2019
Rate constant for biodegradation in Water [d-1]			0.33	REACH dossier; last update 22/02/2019
Rate constant for biodegradation in sediment [d-			1.155	REACH dossier; last update 22/02/2019

***As default for readily biodegradable substances with low adsorption potential, the guidance recommends to use a half-life in soil of 30 d. The half-life of propanol isomers in air and soil is estimated as 55 h (= 2.29 d) by QSAR (ChemProp method) and supported by available handbook data (Howard 1991). In conclusion, the half-life in soil is definitely lower than the conservative default value for readily biodegradable substances. Therefore, in the tier 2 FOCUS PEARL calculation a half-life of 10 d in soil and groundwater was considered for propanol isomers as a worst-case and includes a factor for uncertainty of about 4 on the QSAR estimated value.

**** Default DT50soil (BPR Guidance Vol. IV Table 6), considered as conservative. According to REACh dossier and the explanation of REACh consortium a suitable value for half-life in soil of 3 days at 12°C was derived, based on a stability test with long-chained alcohols like dodecanol.

Calculated fate and distribution in the STP (EUSES v.2.1.2 and SimpleTreat 4)				
Compartment	Percentage [%]			Remarks
	Propan-1-ol	Propan-2-ol	SoC	
Air	0.2602	0.2736	0.7254	Simple Treat 4 Calculated with SimpleTreat 4.0 (with settings from TAB ENV v2.1, 2019, entry ENV 9)
Water	7.958	7.956	3.375	
Sludge	0.037	0.031	60.385	
Degradedin STP	91.74	91.74	35.52	

Calculated PEC values

Summary table on PEC values							
Scenario		PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}[1]	PEC_{GW}	PEC_{Air}
		mg/l	mg/l	mg/kg_{wwt}	mg/kg_{wwt}	µg/l	mg/m^3
1	Propan-1-ol	4.64E-02	4.64E-03	4.03E-03	2.43E-04	1.29E+0	2.40E-03
	Propan-2-ol	6.96E-02	6.96E-03	5.95E-03	3.55E-04	2.01E+0	3.60E-03
	SoC	6.24E-03	5.94E-04	4.39E-01	8.74E-04	1.22E-	6.07E-07

Procedure to derive PECsoil[1]

Calculation of soil removal rate constants

Given that propan-1-ol and propan-2-ol are volatile substances, volatilisation as an additional route of removal from soil was considered appropriate when calculating the PEC_{soil}. Following the ECHA guidance on risk assessment, Volume IV Part B+C (2017), the total rate constant for removal is made up of several parts;

- Biodegradation rate constant (30 days based on ready biodegradability of both a.s.) $kbio_{soil}$
- Volatilisation of substance from soil k_{volat}
- Leaching to deeper soil layer k_{leach}

The overall rate constant is given by

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

The diffusive transfer from soil to air is estimated according to equation 54:

$$\frac{1}{k_{volati}} = \left(\frac{1}{kasl_{air} \times \frac{K_{air-water}}{K_{soil-water}}} + \frac{1}{kasl_{soil,air}} \right) \times DEPTH_i$$

Where:

$Kasl_{air}$	= partial mass transfer coeff. at air-side of the air soil-interface [m/d^{-1}] (**90.72** based on 1.05E-03 m s^{-1} x 60 x 60 x 24 a unity correction of Vol IV Part B+C of 2017 from the TGD of 2003)
$Kasl_{soil}$	= partial mass transfer coeff. at soilair-side of the air soil-interface [m/d^{-1}] (calculated value see footnote at end of emissions)
$K_{air-water}$	= air-water partitioning coefficient [m^3/m^{-3}]
$K_{soil-water}$	= soil-water partitioning coefficient [m^3/m^{-3}]
$Depth_i$	= mixing depth of soil [m] (0.1 (grassland); 0.2 (agricultural soil))
$K_{volat\ i}$	= rate constant for volatilisation from soil I [d^{-1}]

$$K_{air-water} = \frac{HENRY}{R \times TEMP}$$

Where:

HENRY	= Henry's law constant [Pa/m^3/mol^{-1}] (at 25°C corrected at 12°C using equation 25 Volume IV Parts B + C 2017 as HENRY was derived experimentally)
R	= Gas constant [Pa/m^3/mol^{-1}k^{-1}] (8.314)
TEMP	= temperature at the air-water interface [k] (285)
$K_{air-water}$	= air-water partitioning coefficient [m^3/m^{-3}]

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

Where:

$Fair_{comp}$	= fraction air in soil compartment [m^3/m^{-3}] (0.2)
$Fwater_{comp}$	= fraction water in soil compartment [m^3/m^{-3}] (0.2)
$Fsolid_{comp}$	= fraction solids in soil compartment [m^3/m^{-3}] (0.6)
Kp_{comp}	= solids-water part. coeff. in soil compartment [L/kg] (Koc x Foc_{soil})
RHOsolid	= density of the solid phase [kg/m^{-3}] (2500)
$K_{soil-water}$	= soil-water partitioning coefficient [m^3/m^{-3}]

As the mixing depth for soil varies between the different soil types, two values for kvolat can be calculated:

- Ecosystem and arable soil kvolat
- Grassland kvolat

When combined with the soil rate constant derived from the default value of 30 days the values for k are calculated:

- Ecosystem and arable soil k
- Grassland k

These values are then used in equation 60 to calculate the deposition to soil following 10 years of use.

$$Cdep_{soil\ 10}(0) = \frac{D_{air}}{k} - \frac{D_{air}}{k} \times e^{-365 \times 10 \times k}$$

As only a negligible amount of a.s. reaches the sludge via STP the contribution from Csludge$_{soil\ 10}$ (0) can be ignored and the concentration of propan-2-ol in soil can be assumed to come only via deposition.

$$C_{soil\ 10}\ (10) = Cdep_{soil\ 10}\ (10) + Csludge_{\ soil\ 10}\ (0)$$

This initial soil concentration can then be used in equation 66 to calculate the average concentration in soil over 180 or 30 days:

- PECsoil ecosystem 30 days
- PECsoil arable 180 days
- PECsoil grassland 180 days

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}\ (0) - \frac{D_{air}}{k}\right] \times [1 - e^{-kT}]$$

Primary and secondary poisoning

Primary poisoning

Primary poisoning of hand disinfectants is not expected.

Secondary poisoning

A.S.: Due to the physico-chemical properties, like solubility, vapour pressure, BCFs and mainly due to log Kow (0.05 and 0.25), of the a.s., it is very unlikely for the propanol isomers to bioaccumulate in aquatic or terrestrial environment. Furthermore, all relevant ingredients in the products are readily biodegradable. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals. No further assessment of secondary exposure via the food chain is considered necessary.

Co-formulant: No data is available. Based on information in the AR, safety data sheet by the supplier, significant accumulation in organisms is not to be expected. This is supported by information given in the REACh dossier. No further assessment of secondary exposure via the food chain is therefore considered necessary.

1.2.8.3 Risk characterisation

The environmental risk assessment for biocidal product family L+R Propanol PT1 Family is based on the already evaluated assessment reports of the active substances with the respective PNECs and on the REACH-dossier of the co-formulant.

Summary table on PNEC values					
	PNEC$_{STP}$	**PNEC$_{water}$**	**PNEC$_{sed}$**	**PNEC$_{soil}$**	**PNEC$_{Gw.*}$**
	mg/l	**mg/l**	**mg/kg$_{wwt}$**	**mg/kg$_{wwt}$**	**µg/l**

Propan-1-ol	10	2.3	1.998	0.432	0.1
Propan-2-ol	10	2.82	2.41	0.496	0.1
SoC	0.13	0.00063	0.466	0.378	0.1

GW: Groundwater – wwt: wet weight – MPC: maximum permissible concentrations

Atmosphere

The data requirement recommends a qualitative discussion of potential breakdown products, as well as an assessment of the global warming potential, stratospheric ozone depletion potential, the potential for tropospheric ozone formation and the acidification potential.
A.S.: According to the AR the main emission pathway during application step will be via air. The half-life's of propanol isomers in the troposphere was estimated to be <4 days. Therefore, the active substances have a potential for long-range environmental transport. On the other hand, effects on stratospheric ozone and acidification are not expected. The potential for global warming cannot be characterized because there is no information available in the absorption spectrum in the range from 800 to 1200 nm. However, propanol are not dangerous for the atmospheric environment at a low concentration. Furthermore, inhalation studies with mammals can be used as indicators of adverse effects of volatile compounds on animals and according to the ARs there are no adverse effect of the volatile compound on terrestrial animals expected.
Overall, due to the intended use which is limited to indoor application and on basis of the available information the environmental risk for the atmosphere can be assumed to be very low.
Co-formulant: Vapour pressure and Henry's Law Constant indicate no significant volatilization. According to REACh dossier the rate constant for the phototransformation in air was predicted as 21.021E-12 cm^3/molecule.sec which is equivalent to a half-life of 18.3 hours. No indication for warming potential or other hazardous properties in relation to the atmosphere have been identified.

Conclusion: The substances are expected to have no warming potential, stratospheric ozone depletion potential, no potential for tropospheric ozone formation and no acidification potential.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values		
		RCR = $PEC/PNEC_{STP}$
Scenario 1	Propan-1-ol	4.64E-03
	Propan-2-ol	6.96E-03
	SoC	4.80E-02

Conclusion: The estimated PEC/PNEC values for microorganism in sewage treatment plant are below the trigger of 1. Thus, there is no unacceptable risk for the sewage treatment plant.

Aquatic compartment

Summary table on calculated PEC/PNEC values			
		RCR = PEC/PNEC$_{water}$	RCR = PEC/PNEC$_{sed}$
Scenario 1	Propan-1-ol	2.02E-03	2.02E-03
	Propan-2-ol	2.47E-03	2.47E-03
	SoC	9.42E-01	9.42E-01

Conclusion: The estimated PEC/PNEC values for aquatic compartments are below the trigger of 1. Thus, there is no unacceptable risk for the aquatic compartment.

It should be noted that the risk quotient of scenario 1 for the SoC is close to 1. However, this risk can be put into perspective. The REACH dossier mentions that the long-chain alcohols have also been shown to be rapidly biodegraded in sewage treatment plant simulation tests; under anaerobic conditions; in soil; in activated sludges from sewage treatment plants; in fresh water die-away tests; and also in ecotoxicological aqueous test media. Depending on test methodology, the rate of degradation may decrease as carbon number of fatty alcohols increases. But this is largely related to the decrease of the water solubility limit in relation to the carbon number, which may artificially limit the rate of biodegradation.

The results of a STP-simulation test (Wind, et al., 2006[8]) from the REACH dossier show indeed that the degradation rate of ethoxylated alcohols could be higher than usually assigned to readily-biodegradable substances. Furthermore, the small amount of alcohol which does not degrade was found in the solids in recovery at the end of the study. This study indicates that the extent of removal of alcohols is high at the STP. As a result, the removal rate in SimpleTreat simulations could be increased up to 98% (compared to the 36% estimated by SimpleTreat) and the fraction emitted from STP to surface water could be reduced by a factor 10. Thus, the risk quotient could actually be much lower.

Terrestrial compartment

Summary table on calculated PEC/PNEC values		
		RCR = PEC/PNECSoil
Scenario 1	Propan-1-ol	5.63E-04
	Propan-2-ol	7.15E-04
	SoC	2.31E-03

Conclusion: The estimated PEC/PNEC value for terrestrial compartment are below the trigger of 1. Thus, there is no unacceptable risk for the terrestrial compartment.

[8] Wind, T., R.J. Stephenson, C.V. Eadsforth, A. Sherren, R. Toy. (2006) Determination of the fate of alcohol ethoxylate homologues in a laboratory continuous activated sludge unit. Ecotox and Environ Safety, 64: 42-60.

Groundwater

According to BPR Annex VI point 68 a risk is indicated if the foreseeable concentration (PEC) of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in groundwater, exceeds the lower of the following concentrations:

• the maximum permissible concentration laid down by Directive 98/83/EC, or

• the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

Summary table on calculated PEC/PNEC values		
		RCR = PEC/PNEC$_{GW}$
Scenario I	Propan-1-ol	1.30E+00
	Propan-2-ol	2.02E+00
	SoC	1.46E-03

The calculated results of $PEC_{groundwater}$ for for Propan-1-ol as well as for Propan-2-ol exceed the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 2006/118/EC and 98/83/EC).

Therefore, the groundwater assessment should be refined with the FOCUS PEARL 4.4.4 model, taking into account adsorption, distribution and degradation of the propanol isomers in soil. However, 1-propanol as well as 2-propanol are volatile substances. Due to the intended applications the product is only applied on a very small surface area of <0.1 m² per event, 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 (WG-VII-2018 and TAB ENV (2019)).
Furthermore, it should be have in mind, that the default for the fraction of the population applying the product every day is unrealistic high and consequently the assumed related emissions to air and water are too high as well.
Therefore, some exceedance of the trigger value for the intended uses of the products can be considered acceptable.

Conclusion:

The calculated results of $PEC_{groundwater}$ for Propan-1-ol as well as for Propan-2-ol exceed the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 2006/118/EC and 98/83/EC) in tier 1. A refinement using FOCUS Pearl 4.4.4 model, taking into account adsorption, distribution and degradation of the propanol isomers in soil is however not necessary and not appropriate. 1-propanol as well as 2-propanol are volatile substances. Due to the intended applications the product is only applied on a very small surface area of <0.1 m² per event. In accordance to WG-VII-2018 and TAB ENV (2019) for volatile substances which are applied on small surfaces, 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.
Therefore, some exceedance of the trigger value for the intended uses of the products can be considered acceptable.

Furthermore it should be have in mind, that the default for the fraction of the population applying the product every day is unrealistic high and consequently the assumed related emissions to air and water are too high as well.

Primary and secondary poisoning

Primary poisoning

As direct exposure of birds and mammals to the product is not expected, primary poisoning of birds and mammals is not considered relevant.

Secondary poisoning

Active substances: Due to the physico-chemical properties, like solubility, vapour pressure, BCFs and mainly due to log Kow (0.05 and 0.25), of the a.s., it is very unlikely for the propanol isomers to bioaccumulate in aquatic or terrestrial environment. Furthermore, all relevant ingredients in the products are readily biodegradable. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals. No further assessment of secondary exposure via the food chain is considered necessary.

Co-formulant: No data is available. Based on information in the AR, safety data sheet by the supplier, significant accumulation in organisms is not to be expected. This is supported by information given in the REACh dossier. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Mixture toxicity

Tiered approach

A tier 1. Approach was conducted to assess the mixture toxicity

Tier 1. PEC/PNEC summation

The results of the risk assessment of the worst-case scenario is provided in the following table. As mentioned before, due to the presence of a SoC only in BP L+R handdisinfect blue, this product is the worst-case product of the *L+R Propanol PT1 Family*.

Summary table on calculated PEC values

	RCRSTP [mg/m3]	**RCRwater** [mg/l]	**RCRsed.** [mg/kgwwt]	**RCRsoil** [mg/kgwwt]
Propan-1-ol	4.64E-03	2.02E-03	2.02E-03	5.63E-04
Propan-2-ol	6.96E-03	2.47E-03	2.47E-03	7.15E-04
SoC	4.80E-02	9.42E-01	9.42E-01	2.31E-03

RQ (cumulative) L+R handdisinfect 1	**5.96E-02**	**9.47E-01**	**9.47E-01**	**3.59E-03**

Tier 1. PEC/PNEC summation

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Y	Please see further explanation regarding emission and risk assessment for groundwater.

As mentioned before, the single estimated PEC values for groundwater for both volatile active substances are above the the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 2006/118/EC and 98/83/EC) in tier 1. Further refinement should be applied. In accordance to WG-VII-2018 and TAB ENV (2019) for volatile substances which are applied on small surfaces, 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. Therefore, some exceedance of the trigger value for the intended uses of the products can be considered acceptable.

Conclusion: Based on mixture toxicity assessment no risk for the environment is indicated.

Aggregated exposure (combined for relevant emission sources)

The active substnaces of the biocidal products are propan-1-ol and propan-2-ol which are general used in a wide dispersive way in diverse industrial market areas. The main usage of small chain alcohols is the solvent market for the formulation of pharmaceutical products, cleaning agents, paints, coating materials, paints, printing inks and cosmetics (OECD SIDS Dossier (1997), BUA report - GdCH, 1996). In the respective AR of propan-1-ol and propan-2-ol, it is stated that less than 10 % of the annual tonnage produced 2-propanol is used for biocidal purposes. In case of 1-propanol this amount is less than 5 % of the total production and import.

In compliance with the "Decision tree on the need for estimation of aggregated exposure "Annual tonnage of a.s. for biocide use" the requirement for aggregated exposure estimations was checked.
The main emission pathways for both alcohols is via air (90%) and STP (10%); but this emission routes are not limited to biocidal products. Specific biocidal emission patterns are not identified. The intended uses (hand and skin disinfection (leave-on-product) are widely dispersive and do not represent a specific emission pattern. Therefore, according to the decision tree it is not required to perform aggregated exposure estimation.

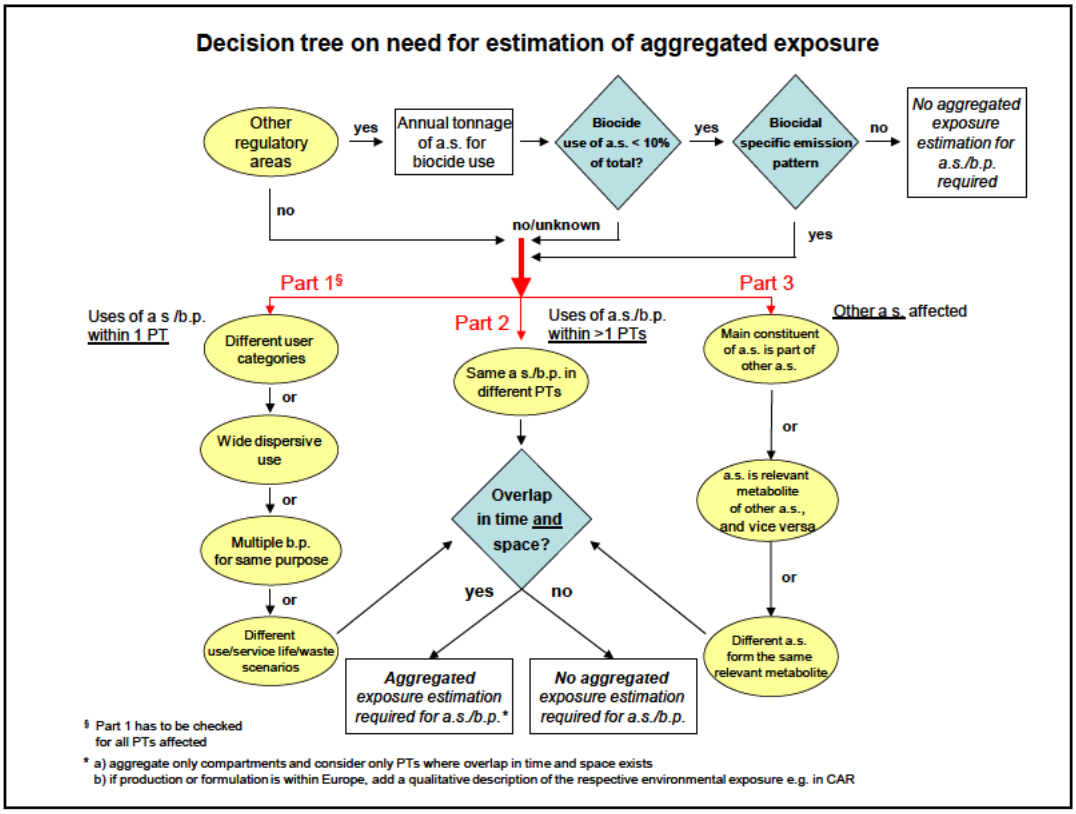


Figure 1: Decision tree on the need for estimation of aggregated exposure

Conclusion: The products of the *L+R Propanol PT1 Family* are based on propanol isomers as active substances which parallel represents the main fraction in the products. Since short-chain alcohols are predominantly used as solvents in other industries and the proportion of total use for biocidal purposes is <10%, estimation of aggregated exposure not necessary.

Overall conclusion on the risk assessment for the environment of the product
According to the "Decision tree on the need for estimation of aggregated exposure" (BIP6.7 Decision Tree Agg Expo, see Figure 8-1Figure 8-1), the requirement for aggregated exposure estimations was checked for both alcohols. It has been concluded that no aggregated exposure assessment for propan-1-ol or propan-2-ol has to be performed as less than 10 % of the total tonnage produced are used for biocidal purposes and no specific biocidal emission patterns are identified. Other uses beyond biocidal uses will mainly contribute to an aggregated exposure of propan-1-ol and propan-2-ol in the environment.

1.2.9 Measures to protect man, animals and the environment

According to the risk assessment, safety measures to prevent skin contact are not necessary. Reduction of respiratory exposure is desirable and, if necessary, possible by enhancing the air exchange rates. The air exchange rate cannot be prescribed for hospitals but has to comply with other factors (e.g. hygienic reasons, sensation of patients). Furthermore, contact with the eyes should be avoided because it can lead to eye irritation and measures to prevent a fire should be taken.

Animals are not expected to be exposed to propan-2-ol or to the active substance during production, formulation and use. No potential secondary poisoning of non-target animals towards propan-2-ol is anticipated. Therefore, special protection measures to protect animals are not required.
Because of the volatility of the active substances, the main exposure pathway to the environment is via air. As the intended use of the product is mainly indoors special precaution measures to air are not necessary.
Due to volatilisation potential and ready biodegradation of the active substance exposure to soil is negligible. Therefore, special measures or decontamination of soil is not necessary.
The active substance Propan-2-ol is highly flammable and is classified as hazardous waste according to the European Waste List 2001/118/EC. The product and its container must be disposed of in a safe way, in compliance with any relevant legislation on the disposal of hazardous waste. Controlled disposal or incineration in accordance with the local registrations is recommended.The main emission pathway during application step of the biocidal products of the L+R Propanol PT1 Family 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.
For PEC estimation we assumed that this air is emitted to the local outside air without deposition indoors. The exact distribution between air and wastewater is not known, but as a reasonable worst-case it is assumed that 90 % of a.s. is emitted to air and 10 % to waste water.
The half-life of propan-1-ol in the troposphere was estimated to be 2.8 days.
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. Due to the intended use of the biocidal products for product type 1 which is limited to indoor application and on basis of the available substance information the environmental risk of propan-1-ol for the atmosphere can be assumed as low.

1.2.10 Assessment of a combination of biocidal products

Not intended to be authorised for the use with other biocidal products.

1.2.11 Comparative assessment

Not relevant.

2 Annexes

2.1 List of studies for the biocidal product (family)

The reference list (*Reference list_L+R Propanol PT1 Family*) and the list of attachments (*List of attachments_ L+R Propanol PT1 Family*) are attached as separate files (see also Section 13 of the IUCLID6 dossier).

Literature reference list.rtf

List of attachments rev 01_21.rtf

2.2 Output tables from exposure assessment tools

2.2.1 Professional Exposure

Professional scenarios.zip

2.2.2 general public exposure

L&R Propanol PT1 Family non-prof_gen

2.3 New information on the active substance

No new information on the active substances is available

2.4 Residue behaviour

Information on the residue behaviour of propan-1-ol, propan-2-ol or the biocidal products are not required.

2.5 Summaries of the efficacy studies

Robust study summaries for all the efficacy studies are given in the IUCLID6 Dossier.

2.6 Confidential annex

The confidential annex is included in the dossier as a separate file.

2.7 Other