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)

Brenntag GmbH Propan-2-ol Product Family

Product type(s) 1, 2, 4

Propan-2-ol as included in the Union list of approved active substances

Case Number in R4BP: BC-BL025673-43

Evaluating Competent Authority: Germany

Date: [27/10/2021]

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1 CONCLUSION

The outcome of the assessment for the biocidal product family "Brenntag GmbH Propan-2-ol Product Family" based on Propan-2-ol is specified in the BPC opinion following discussions at the BPC-40 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product family assessment

2.1.1 Administrative information (first information level)

2.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
Brenntag GmbH Propan-2-ol Product Family	European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Brenntag GmbH
	Address	Stinnes Platz 1, 45472 Mülheim an der Ruhr, Germany
Pre-submission phase started on	30.12.2015	
Pre-submission phase concluded on	22.03.2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Kesla Pharma Wolfen GmbH
Address of manufacturer	Kesla-Str. 1, 06803 Bitterfeld, Germany
Location of manufacturing sites	Kesla Pharma Wolfen GmbH Kesla-Str. 1, 06803 Bitterfeld, Germany

Name of manufacturer	Dreve GmbH
Address of manufacturer	Max-Planck-Str. 31, 59423 Unna, Germany
Location of manufacturing sites	Kesla Pharma Wolfen GmbH Kesla-Str. 1, 06803 Bitterfeld, Germany

Name of manufacturer	Buzil-Werk Wagner GmbH & Co. KG
Address of manufacturer	Fraunhoferstr. 17, 87700 Memmingen, Germany
Location of manufacturing sites	Fraunhoferstr. 17, 87700 Memmingen, Germany

Name of manufacturer	Wigol W. Stache GmbH
Address of manufacturer	Textorstr. 2, 67547 Worms, Germany
Location of manufacturing sites	Textorstr. 2, 67547 Worms, Germany

Name of manufacturer	KiiltoClean Oy
Address of manufacturer	Tengströminkatu 6, FI-20630, Turku, Finland

Location of manufacturing sites	KiiltoClean Oy PL 157, FI-20101, Turku, Finland

Name of manufacturer	Witty GmbH und Co. KG
Address of manufacturer	Herrenrothstr. 12, 86424 Dinkelscherben, Germany
Location of manufacturing sites	Herrenrothstr. 12, 86424 Dinkelscherben, Germany

Name of manufacturer	Carl Roth GmbH und Co. KG
Address of manufacturer	An der Mole 5, 76189 Karlsruhe, Germany
Location of manufacturing sites	An der Mole 5, 76189 Karlsruhe, Germany

Name of manufacturer	Pro-cura Hy-med GmbH
Address of manufacturer	Stresemannstrasse 364, 22761 Hamburg Germany
Location of manufacturing sites	A.F.P. Otto-Brenner-Str. 16, 21337 Lüneburg, Germany

Name of manufacturer	Pico-medical GmbH
Address of manufacturer	Fangdieckstr. 24, 22547 Hamburg, Germany
Location of manufacturing sites	A.F.P. Otto-Brenner-Str. 16, 21337 Lüneburg, Germany

Name of manufacturer	Anti-Germ International GmbH
Address of manufacturer	Oberbrühlstr. 16, 87700 Memmingen, Germany
Location of manufacturing sites	Oberbrühlstr. 16, 87700 Memmingen, Germany

Name of manufacturer	LCI FLOWEY
Address of manufacturer	2 ZAC Klengbusbierg, 7795 Bissen, Luxembourg
Location of manufacturing sites	2 ZAC Klengbusbierg, 7795 Bissen, Luxembourg

Name of manufacturer	Hofmann & Sommer GmbH und Co. KG
Address of manufacturer	Lindenstr.11, 07426 Königsee-Rottenbach, Germany
Location of manufacturing sites	Lindenstr.11, 07426 Königsee-Rottenbach, Germany

Name of manufacturer	Girelli Alcool srl
Address of manufacturer	Via Thomas Edison 5, 20080 Zibido San Giacomo (MI), Italy
Location of manufacturing sites	Via Thomas Edison 5, 20080 Zibido San Giacomo (MI), Italy

Name of manufacturer	Brenntag S.p.A.
Address of manufacturer	Via Cusago 150/4, 20158 Milano (MI), Italy
Location of manufacturing sites	Via Cusago 150/4, 20158 Milano (MI), Italy

Name of manufacturer	I.C.F. Srl
Address of manufacturer	Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR), Italy
Location of manufacturing sites	Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR), Italy

Name of manufacturer	Brenntag SA
Address of manufacturer	90 Avenue du Progrès, 69 680 Chassieu, France
Location of manufacturing sites	90 Avenue du Progrès, 69 680 Chassieu, France

Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1, 45472 Muelheim a.d. Ruhr, Germany
Location of manufacturing sites	Stinnes-Platz 1, 45472 Muelheim a.d. Ruhr, Germany

Name of manufacturer	BCD Chemie GmbH
Address of manufacturer	Schellerdamm 16, 21079 Hamburg, Germany
Location of manufacturing sites	Schellerdamm 16, 21079 Hamburg, Germany

Name of manufacturer	HYDRACHIM
Address of manufacturer	Z.A. ROUTE DE ST POIX, 35370 LE PERTRE, France
Location of manufacturing sites	Z.A. du piquet, 35370 Etrelles, France

Name of manufacturer	Langguth Chemie GmbH
Address of manufacturer	Wandalenstrasse 6 , 86343 Königsbrunn, Germany
Location of manufacturing sites	Wandalenstrasse 6 , 86343 Königsbrunn, Germany

Name of manufacturer	Burgess Galvin & Co
Address of manufacturer	Jamestown Road, Finglas, Dublin 11, Ireland
Location of manufacturing sites	Jamestown Road, Finglas, Dublin 11, Ireland

Name of manufacturer	Tristel
Address of manufacturer	Lynx Business Park, Fordham Road, Snailwell, Cambridge, CB8 7NY, United Kingdom
Location of manufacturing sites	Lynx Business Park, Fordham Road, Snailwell, Cambridge, CB8 7NY, United Kingdom

Name of manufacturer	Brenntag Schweizerhall
Address of manufacturer	Elsässerstrasse 231, 4056 Basel, Switzerland
Location of manufacturing sites	Elsässerstrasse 231, 4056 Basel, Switzerland

Name of manufacturer	ORAPI

Address of manufacturer	5 Allee des Cerdes, Pi de la Plaine de L'ain, 01150, Saint Vulbas, France
Location of manufacturing sites	ORAPI 5 Allee des Cerdes, Pi de la Plaine de L'ain, 01150, Saint Vulbas, France

Name of manufacturer	Copak S.A.
Address of manufacturer	Z.I. du Madrillet, rue de la Chênaie, 76800 Saint-Etienne-du-Rouvray, France
Location of manufacturing sites	Z.I. du Madrillet, rue de la Chênaie, 76800 Saint-Etienne-du-Rouvray, France

Name of manufacturer	Water Technology Limited
Address of manufacturer	TOGHER INDUSTRIAL EST, T12KPF2 CORK, DUBLIN, Ireland
Location of manufacturing sites	TOGHER INDUSTRIAL EST, T12KPF2 CORK, DUBLIN, Ireland

Name of manufacturer	AF International, Electrolube: Divisions of H K Wentworth Ltd
Address of manufacturer	AASHBY PARK, COALFIELD WAY, ASHBY DE LA ZOUCH, LEICESTERSHIRE, LE65 1JF, United Kingdom
Location of manufacturing sites	ASHBY PARK, COALFIELD WAY, ASHBY DE LA ZOUCH, LEICESTERSHIRE, LE65 1JF, United Kingdom

Name of manufacturer	Bello Mondo bvba
Address of manufacturer	Helststraat 150-159, 2630 Aartselaar, Belgium
Location of manufacturing sites	Laboratoria Smeets N.V., Fotografielaan 42, B-2610 Antwerpen-Wilrijk, Belgium

Name of manufacturer	CERICHEM BIOPHARM SRL
Address of manufacturer	Viale Einaudi snc (z.i.) 71042 Cerignola (FG), Italy
Location of manufacturing sites	Viale Einaudi snc (z.i.), 71042 Cerignola (FG), Italy

Name of manufacturer	Otto Fischar GmbH & Co. KG
Address of manufacturer	Kaiserstr. 221, 66133 Saarbruecken, Germany
Location of manufacturing sites	Kaiserstr. 221, 66133 Saarbruecken, Germany

Name of manufacturer	Caesar & Loretz GmbH
Address of manufacturer	Herderstr. 31, 40721 Hilden, Germany
Location of manufacturing sites	Herderstr. 31, 40721 Hilden, Germany

Name of manufacturer	Karl-Josef Kost Alkohole & Produkte aus Alkohol KG
Address of manufacturer	Rauentalshöhe 4, 56073 Koblenz, Germany

Location of manufacturing sites	Rauentalshöhe 4, 56073 Koblenz, Germany

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

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway, LA 70897, Baton Rouge, Louisiana United States
Location of manufacturing sites	Exxon Mobil Chemical Plant 4999 Scenic Highway LA 70897, Baton Rouge, Louisiana United States
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK, Vodelingenenplaat, Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601 3196 KK, Vodelingenenplaat, Rotterdam Netherlands
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	Römerstr. 733 47443 Moers Germany Shamrockstraße 88 44623 Herne Germany

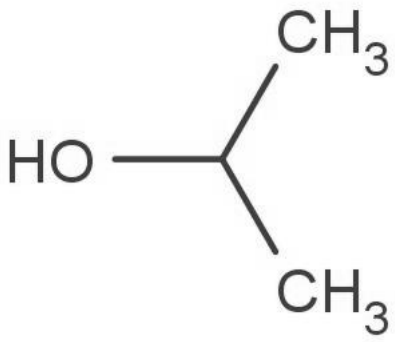
2.1.2 Product family composition and formulation (first information level)

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 ☒

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

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

No candidate for substitution was identified.

2.1.2.3 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-2-ol	Propan-2-ol	Active substance	67-63-0	200-661-7	62.7	70

Information on the full composition is provided in the confidential[1] annex.

2.1.2.4 Information on technical equivalence

Is the source of the active substance(s) the same as the one 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 ☒ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-0014505-0000, EU-0014506-0000, EU-0017008-0000 and EU-0017009-0000.

2.1.2.5 Information on the substance(s) of concern

No substance of concern was identified.

2.1.2.6 Type of formulation

Meta SPCs 1 and 3: CL - Contact gel or Liquid
Meta SPC 2: XX – Others: Ready-to-Use trigger spray

[1] Access level: "Restricted" to applicant and authority

2.1.3 Meta SPC(s) (second information level)

2.1.3.1 Meta SPC No. 01

2.1.3.1.1 Administrative information

2.1.3.1.1.1 Meta SPC identifier

Meta SPC 1

2.1.3.1.1.2 Suffix to the authorisation number

01

2.1.3.1.1.3 Product type(s) of the products in the meta SPC

1 (Human hygiene)

2.1.3.2 Composition and formulation of the products within the meta SPC

2.1.3.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	Propan-2-ol	Active substance	67-63-0	200-661-7	62.7	70

2.1.3.2.1.1 Type(s) of formulation of the products in the meta SPC

CL - Contact gel or liquid

2.1.3.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.

The current harmonised classification of the active substance is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

Based on the data submitted from the applicant for a 3rd party dossier, labelling with EUH066 is required. In addition, the biocidal product family has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

The active substance is not classified for environmental hazards.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.1.3.4

Table 1

Classification Hazard classes, Hazard categories	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness and dizziness.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
Supplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	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/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P312	Call a POISON CENTER/doctor if you feel unwell.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulations.
Note	-	-

2.1.3.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.1.3.4.1 Use 1 appropriate for authorisation – Contact Gel or Liquid - Hygienic handrub - Professional user

Product Type(s)	1
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria (incl. Mycobacteria), Yeast, Enveloped viruses
Field(s) of use	For professional use only. For use in private, public, healthcare and industrial areas and in areas for professional activities. Indoor
Application method(s)	Direct application to both hands, rubbing
Application rate(s) and frequency	3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application. Up to 25 disinfections per day, 5 day(s) per week
Category(ies) of users	Professional user
Pack sizes and packaging material	• Bottle HD-PE: 0,1L - 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) • Can HD-PE: 5L - 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE) • Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) • IBC container HD-PE: 1000L; (Screw caps (HD-PE)

2.1.3.4.1.1 Use-specific instructions for use

See general directions for use.

2.1.3.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.3.4.1.5 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.

2.1.3.5 General directions for use of the products in the meta SPC

2.1.3.5.1 Instructions for use

1) For professional use only.
2) Products must be shaken before use.
3) Only apply on dry and visibly clean hands.
4) For hand disinfection a ready-to-use gel or liquid (3 ml) is poured into the palms of one hand and the complete surface of both hands are moistened and rubbed for 60 seconds per application.

2.1.3.5.2 Risk mitigation measures

1) Avoid contact with eyes.
2) Keep out of reach of children and pets.
3) Use only in well-ventilated areas.
4) For refilling a funnel must be applied.
5) The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:
   The use of eye protection during refilling of the product is recommended.

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

1) IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

2.1.3.5.4 Instructions for safe disposal of the product and its packaging

1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
2) Do not let product enter drains.
3) Contact waste disposal services.
4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
5) Do not burn, or use a cutting torch on the empty drum. Risk of explosion.

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

1) Store in a well-ventilated place.
2) Keep cool.
3) Keep container tightly closed.
4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
5) Shelf-life: 24 months

2.1.3.5.6 Other information

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

2.1.3.6 Individual products in the meta SPC(s) (third information level)

Information on the specific composition of each individual product is provided in the confidential annex.

2.1.4 Meta SPC(s) (second information level)

2.1.4.1 Meta SPC No. 02

2.1.4.1.1 Administrative information

2.1.4.1.1.1 Meta SPC identifier

Meta SPC 2

2.1.4.1.1.2 Suffix to the authorisation number

02

2.1.4.1.1.3 Product type(s) of the products in the meta SPC

2 (Disinfectants and algaecides not intended for direct application to humans or animals) 4 (Food and feed area)

2.1.4.2 Composition and formulation of the products within the meta SPC

2.1.4.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	Propan-2-ol	Active substance	67-63-0	200-661-7	62.8	70

2.1.4.2.1.1 Type(s) of formulation of the products in the meta SPC

XX: Others: (ready-to-use) trigger spray

2.1.4.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The active substance is not classified for environmental hazards.
The current harmonised classification of the active substance propan-2-ol (CAS-No. 67-63-0) is based on Annex VI of Commission Regulation (EU) No 1272/2008.

For labelling according to article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.1.4.4.

Table 2

Classification Hazard classes, Hazard categories	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit. 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
	GHS 02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness and dizziness.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
Supplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	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/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P312	Call a POISON CENTER/doctor if you feel unwell.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulations.

2.1.4.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.1.4.4.1 Use 1 appropriate for authorisation – Liquid Spray –Small surface disinfection – Professional user

Product Type(s)	2
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria (incl. Mycobacteria), Yeast
Field(s) of use	Disinfection of small non-porous surfaces, materials, equipment and furniture in private, public, healthcare, industrial areas and in areas for professional activities. Indoor.
Application method(s)	Spraying
Application rate(s) and frequency	For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Application according to requirements, one application per use, 4 times per day. Small surface disinfection(other than healthcare): Bactericidal and yeasticidal: contact time at least 1 min In healthcare area: Bactericidal and yeasticidal: contact time at least 5 min
Category(ies) of users	Professional user
Pack sizes and packaging material	• Bottle HD-PE: 0,1L - 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) • Can HD-PE: 5L - 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE) • Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) • IBC container HD-PE: 1000L: (Screw caps (HD-PE)

2.1.4.4.1.1 Use-specific instructions for use

1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for 1 minute (general surface disinfection) or 5 minutes (surfaces in healthcare area)
2) For use at room temperature.
3) Application according to requirements, one application per use, 4 times per day.

2.1.4.4.1.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:

The use of eye protection during handling of the product is recommended.

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

See general directions for use.

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

See general directions for use.

2.1.4.4.1.5 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.

2.1.4.4.2 Use 2 appropriate for authorisation – Liquid Spray - Disinfection for small food contact surfaces – Professional user

Product Type(s)	4
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, Yeast
Field(s) of use	Disinfection of small non-porous surfaces in food sector or food processing industries (including breweries, dairy industry and meat industry). Indoor
Application method(s)	Spraying
Application rate(s) and frequency	For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Application according to requirements, one application per use, 4 times per day. Small surface disinfection: Bactericidal and yeasticidal: contact time at least 1 min In Breweries/ meat industry: Bactericidal and yeasticidal: contact time at least 5 min In dairy industry: Bactericidal and yeasticidal: contact time at least 15 min
Category(ies) of users	Professional user
Pack sizes and packaging material	• Bottle HD-PE: 0,1L - 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) • Can HD-PE: 5L - 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)

	• Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) • IBC container HD-PE: 1000L; (Screw caps (HD-PE)

2.1.4.4.2.1 Use-specific instructions for use

1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for at least 1 min (general surface disinfection), 5 min (surface disinfection in breweries or meat industry) or at least 15 min (surface disinfection in dairy industry).
2) For use at room temperature.
3) Application according to requirements, one application per use, 4 times per day.

2.1.4.4.2.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures:

The use of eye protection during handling of the product is recommended.

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

See general directions for use.

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

See general directions for use.

2.1.4.4.2.5 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.

2.1.4.5 General directions for use of the products in the meta SPC

2.1.4.5.1 Instructions for use

1) Products must be shaken before use.
2) Do not apply more than 20 mL/m^2.
3) Used wipes must be disposed in a closed container.

2.1.4.5.2 Risk mitigation measures

1) Avoid contact with eyes.
2) For refilling a funnel must be applied.

3) The product must only be applied for disinfection of small surfaces.
4) Keep out of reach of children and pets.
5) Use only in well-ventilated areas.
6) Keep children and pets away from rooms where disinfection is taking place.
7) Provide adequate ventilation before children and pets enter treated rooms.

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

1) IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

2.1.4.5.4 Instructions for safe disposal of the product and its packaging

1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
2) Do not let product enter drains.
3) Contact waste disposal services.
4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

1) Store in a well-ventilated place.
2) Keep cool.
3) Keep container tightly closed.
4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
5) Shelf-life: 24 months

2.1.4.5.6 Other information

1) The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

2.1.4.6 Individual products in the meta SPC(s) (third information level)

Information on the specific composition of each individual product is provided in the confidential annex.

2.1.5 Meta SPC(s) (second information level)

2.1.5.1 Meta SPC No. 03

2.1.5.1.1 Administrative information

2.1.5.1.1.1 Meta SPC identifier

Meta SPC 3

2.1.5.1.1.2 Suffix to the authorisation number

03

2.1.5.1.1.3 Product type(s) of the products in the meta SPC

1 (Human hygiene)

2.1.5.2 Composition and formulation of the products within the meta SPC

2.1.5.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	Propan-2-ol	Active substance	67-63-0	200-661-7	62.7	70

2.1.5.2.1.1 Type(s) of formulation of the products in the meta SPC

CL - Contact gel or liquid

2.1.5.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.

The current harmonised classification of the active substance is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

The active substance is not classified for environmental hazards.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.1.5.4.

Table 3

Classification Hazard classes, Hazard categories	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness and dizziness.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
Supplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P312	Call a POISON CENTER/doctor if you feel unwell.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulations.
Note	-	-

In fact H319 would trigger P280 (Wear eye protection/face protection.). However, for non-professional use correct use of personal protective equipment cannot be assumed. Based on a qualitative risk assessment an additional advice (labelling) with "Avoid contact with

eyes" and the other precautionary statements P305 + P351 + P338 and P337 + P313 are considered sufficient to protect the non-professional user from the corresponding risk. H319 also trigger P264 (Wash … thoroughly after handling.). This precautionary statement is also not required since the biocidal product is also intended for use on hands and other body parts. If it is washed away efficacy might not be sufficient. In addition, propan-2-ol is very volatile and will evaporate from treated skin rapidly. Thus, washing of hands or other body parts is not necessary.
H336 would trigger P304 + P340 (IF INHALED: Remove person to fresh air and keep comfortable for breathing.). According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation toxicity of the biocidal product this precautionary statement is not required for the non-professional user.

2.1.5.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.1.5.4.1 Use 1 appropriate for authorisation – Contact Gel or Liquid - Hygienic handrub - Non-professional user

Product Type(s)	1
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria (incl. Mycobacteria), Yeast, Enveloped viruses
Field(s) of use	For use in private and public areas. Indoor
Application method(s)	Direct application to both hands, rubbing
Application rate(s) and frequency	3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application. Up to 5 disinfections per day, 5 day(s) per week
Category(ies) of users	Non-professional user
Pack sizes and packaging material	Bottle HD-PE: 0,1L - 1,0L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP))

2.1.5.4.1.1 Use-specific instructions for use

See general directions for use.

2.1.5.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5.4.1.5 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.

2.1.5.5 General directions for use of the products in the meta SPC

2.1.5.5.1 Instructions for use

1) Comply with the instructions for use.
2) Products must be shaken before use.
3) Only apply on dry and visibly clean hands.
4) For hand disinfection a ready-to-use gel or liquid (3 ml) is poured into the palms of one hand and the complete surface of both hands are moistened and rubbed for 60 seconds per application.
5) The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:

Trigger spray: Apply 3 or 4 spray strokes (depending on the trigger spray cap)
Pump spray: Apply 3 pump strokes
Bottle: Visual observation

2.1.5.5.2 Risk mitigation measures

1) Avoid contact with eyes.
2) Use by children only under supervision of an adult.
3) Use only in well-ventilated areas.

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

1) If medical advice is needed, have product container or label at hand.
2) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for five minutes.
3) Call a POISON CENTER or doctor if you feel unwell.
4) If eye irritation persists: Get medical advice/attention.
5) IF INHALED OR SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

2.1.5.5.4 Instructions for safe disposal of the product and its packaging

1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
2) Do not let product enter drains.
3) Contact waste disposal services.
4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

1) Store in a well-ventilated place.
2) Keep cool.
3) Keep container tightly closed.

4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. 5) Keep out of reach of children and pets. 6) Shelf-life: 24 months

2.1.5.5.6 Other information

-

2.1.5.6 Individual products in the meta SPC(s) (third information level)

Information on the specific composition of each individual product is provided in the confidential annex.

2.1.6 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Bottle	0.1L-2.5L	High-density polyethylene (HD-PE)	Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)	professionals,	Yes
Bottle	0.1L-1.0L	High-density polyethylene (HD-PE)	Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)	non-professionals	Yes
Can	5L-60L	High-density polyethylene (HD-PE)	Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)	professionals	Yes
Drum	200 L	High-density polyethylene (HD-PE)	Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or	professionals	Yes

			seal caps (HD-PE)		
IBC container	1000 L	High-density polyethylene (HD-PE)	Screw caps (HD-PE)	professionals	Yes

2.1.7 Documentation

2.1.7.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 of this PAR.

2.1.7.2 Access to documentation

The applicant provided a letter of access to the dossier for the active substance "propan-2-ol" recorded under the asset no. EU-0011803-0000. This dossier is satisfying the requirements set out in Annex II of Regulation (EU) No 528/2012 for use in PT1 (Human Hygiene), PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

2.1.7.3 Similar conditions of use

Communication D(2016)0921, dated 30.12.2015, from ECHA and addressed to Brenntag GmbH states the following:

The biocidal product family "Brenntag GmbH Propan-2-ol Product Family" is deemed to be eligible for Union authorisation subject to the adoption of the Commission's draft decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on propan-2-ol containing products used for hand disinfection.

This document can be found in section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product family Meta-SPC 01

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

Meta SPC identifier: Meta SPC 01

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

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

Intended use # 1a – Contact Gel or Liquid - Hand disinfection

Product Type(s)	01
Where relevant, an exact description of the authorised use	Human hygiene products that are applied on human skin for (primary) disinfecting purposes
Target organism (including development stage)	Vegetative bacteria, yeast and enveloped viruses
Field of use	For use in private, public, healthcare and industrial areas and in areas for professional activities. Indoor.
Application method(s)	Direct application to both hands, rubbing
Application rate(s) and frequency	3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 30 to 60 seconds per application. Up to 25 disinfections per day, 5 day(s) per week
Category(ies) of user(s)	professional user
Pack sizes and packaging material	• Bottle HD-PE: 0,1L - 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) • Can HD-PE: 5L - 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE) • Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) • IBC container HD-PE: 1000L; (Screw caps (HD-PE)

Intended use # 1b – Contact Gel or Liquid - Hand disinfection

Product Type(s)	01
Where relevant, an exact description of the authorised use	Human hygiene products that are applied on human skin for (primary) disinfecting purposes
Target organism (including development stage)	Vegetative bacteria, yeast and enveloped viruses
Field of use	For use in private and public areas. Indoor.
Application method(s)	Direct application to both hands, rubbing
Application rate(s) and frequency	3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 30 to 60 seconds per application. Up to 25 disinfections per day, 5 day(s) per week
Category(ies) of user(s)	non-professional user
Pack sizes and packaging material	Bottle HD-PE: 0,1L - 1,0L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP))

2.2.2 Physical, chemical and technical properties

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. **However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.**

The physico-chemical data of meta SPC 1 and 2 are stated in different sections (2.2.2 and 2.3.2). In Meta SPC 2 a product was tested comprising the least amount of ingredients. In Meta SPC 1 the product "IPA-Co-Formulants-Stability-Test-Formulation" was generated only to test physico-chemical data with the highest amount of all "functions" like dye, thickener, and so on. The composition of this "artificial" product is stated in the confidential annex. By this the whole frame of compositions is covered.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual	Wofasept AHA, Batch No. 031015, AS (active substance) content: 62.0%	liquid	M Casco Palau, 2016, Report no. XD38JQ;
Colour at 20 °C and 101.3 kPa	visual	Wofasept AHA, Batch No. 031015, AS content: 62.0%	Product without dye: colourless Product with dye: blue	M Casco Palau, 2016, Report no. XD38JQ;
Odour at 20 °C and 101.3 kPa			For products comprising perfume, the odour is characteristic perfume-like. For products that do not comprise perfume, the odour is characteristic alcohol-like (deriving from >62% propan-2-ol.	
Acidity / alkalinity	CIPAC MT 75.3	Wofasept AHA, Batch No. 031015, AS content: 62.0% Easysept, Batch No. k30781	pH = 7.4 pH = 7.9	Wofasept AHA: M Casco Palau, 2016, Report no. XD38JQ; For all other BP (biocidal products):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Esept Gel, Batch No. 176-17001 mobilomed Skinsoft expert, Batch No. 17012018-04 Desmila VSI, Batch No. 17012018-02 HD 18 Mano Germs, Batch No. 000350/00118 Frend Hand Sanitizer Gel, Batch No. 110118	pH = 6.5 pH = 5.4 pH = 5.4 pH = 8.0 pH = 5.9	F. Maytssek, 2018, Report no. Mo6100
Relative density / bulk density	OECD Method 109 / EC Method A.3	Wofasept AHA, Batch No. 031015, AS content: 62.0%	D^{20}_{4} = 0.879 at 20°C	M Casco Palau, 2016, Report no. XD38JQ;
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Wofasept AHA, Batch No. 031015	Wofasept AHA, 18 weeks at 30°C in PP containers; AS content: 62.0% w/w before, 61.1% w/w after storage, loss of 1.45 % Appearance before and after storage:	M Casco Palau, 2016, Report no. XD38JQ;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Colourless, transparent, homogenous liquid. No signs of precipitation or sedimentation observed. No change in packaging observed, packaging integrity remained after storage. Weight loss: 0.05% after 4 weeks, 0.25% after 18 weeks. pH: before storage 7.4, after storage 7.6	
		IPA-Co-Formulants-Stability-Test-Formulation, Batch No. 04/2018/BG The study was conducted on two test items that differ in packaging. Test item 1 is stored in 500 mL PET containers, test item 2 is stored in 100 mL HDPE containers The identity of this test product can be found in the confidential annex.	18 weeks at 30°C; AS-content of test item 1: 63.1% w/w before, 62.2% w/w after storage, loss of 1.43 % content of test item 2: 64.0% w/w before, 61.1% w/w after storage, loss of 4.5 % Appearance: before and after storage for both test items: Dark blue slightly turbid homogeneous liquid with medium odour of active ingredient; Weight loss: Test item 1: 0.7% after storage Test item 2: 0.17% after storage pH: Test item 1: before storage 6.8, after storage 6.4	Mack, L. 2020, Report No. Mo6080

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Test item 2: before storage 6.9, after storage 6.5 relative density: Test item 1: before storage 0.883 (20°C), 0.866 (40°C), after storage: 0.882 (20°C), 0.865 (40°C) Test item 2: before storage 0.883 (20°C), 0.866 (40°C), after storage: 0.883 (20°C), 0.866 (40°C) Viscosity (before storage): Test item 1: 5.6 mPa*s at 20°C, 2.0 mPa*s at 40°C Test item 2: 4.9 mPa*s at 20°C, 2.9 mPa*s at 40°C Surface tension (before storage): Test item 1: 25.1 mN/m at 25°C (undiluted BP); 42.6 mN/m at 20°C (1g/L solution in purified water) Test item 2: 25.2 mN/m at 25°C (undiluted BP); 42.8 mN/m at 20°C (1g/L solution in purified water)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**		Wofasept AHA, Batch No. 031015	Storage over 24 months at 25 ± 2 °C in PP bottles. AS content: T0 = 62.0% T6 months = 62.2% T12 months = 61.1%, T18months = 62.5%, T24months = 61.2% Decrease of AS content of 1.3% after 24 months. Appearance of the formulation or packaging did not change during storage of 24 months. Packaging integrity remained. Weight loss: T0 = 0% T6 = 0.23% T12 = 0.45%, T18 = 0.63%, T24 = 0.81% pH: T0 = 7.4 T6 = 7.4 T12 = 7.38 T18 = 7.29 T24 = 7.82 Relative density T0 = 0.879 T24 = 0.878 Kinematic viscosity	O'Connor, B. J., 2018, Report no. LS17YH;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T0 = 79.2 mm^2/s (20°C) 29.5 mm^2/s (40°C) T24= 80.2 mm^2/s (20°C) 29.9 mm^2/s (40°C)	
		IPA-Co-Formulants-Stability-Test-Formulation, Batch No. 04/2018/BG The study was conducted on two test items that differ in packaging. Test item 1 (two samples) is stored in 500 mL PET containers, test item 2 (two samples) is stored in 100 mL HDPE containers The identity of this test product can be found in the confidential annex.	Storage over 24 months at 25 ± 2 °C in PP bottles. AS content of test item 1: T0 = 63.1% T12 months = 61.6%, T24months = 62.0% Decrease of AS content of 1.7% after 24 months. AS content of test item 2: T0 = 64.0% T12 months = 61.3%, T24months = 61.9% Decrease of AS content of 3.3% after 24 months. Appearance and integrity of packaging did change during storage of 24 months. Both test items were dark blue, slightly turbid homogenous liquids at start. After 12 months as well as 24 months a phase separation was observed. 1.5 cm sediment deposited. Upper phase: dark blue, clear transparent liquid, lower phase: not transparent, turbid (sediment). However, after shaking the starting conditions were obtained. Together with instruction for use	Mack, L. 2020, Report No. Mo6080

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			"Products must be shaken before use" the reversible phase separation is acceptable. All packaging were in sound condition during the course of the study and no changes were observed. Mean weight loss of test item 1: T12 = 0.55% T24 = 1.1% Mean weight loss of test item 2: T12 = 0.6% T24 = 0.16% pH of test item 1: T0 = 6.8 T12 = 6.8 T24 = 6.8 pH of test item 2: T0 = 6.9 T12 = 6.9 T24 = 6.8 Relative density at 20°C of test item 1: T0 = 0.883 T24 = 0.881 Relative density at 20°C of test item 2: T0 = 0.883 T24 = 0.883	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			A storage stability of 24 months can be granted.	
Storage stability test – **low temperature stability test for liquids**	Waiving acceptable.		A water/propan-2-ol mixture (60-70% IPA) has a freezing and melting point significantly below 0°C. Therefore a test at 0°C for 7 days would not lead to a freezing of the solutions. Effects that could result from freezing and defrosting cannot happen. Hence, a test is not deemed necessary.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver		Propan-2-ol does not absorb ultraviolet radiation (No absorption > 290 nm). Consequently photolysis could not be a route of degradation of propan-2-ol, i.e. the stability of a binary propan-2-ol/water mixture will not be affected by luminous intensity. Additionally, many of the products being registered are contained within opaque containers. Data on the dyes within the formulations has been provided by the manufacturer that states they have very good light fastness in aqueous solutions. Manufactures of the dyes and perfumes featured within formulations in this product family have confirmed the dyes and perfumes should be stable to light so would not be expected to be significantly impacted by natural light. All products should be stored within UV protected HDPE and in cardboard boxes prior to use. Only indoor use is supported by this product family which should further reduce the likelihood of exposure to intense light.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver		According to label claim: Keep cool and in a well-ventilated place. Furthermore BPF contains water. Thus effects of humidity can be excluded.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packing material (HDPE) is sufficient. Not reactive towards container material after ambient storage.	Dangerous Goods Database http://www.dgg.bam.de/en/ Number 734
Wettability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Suspensibility, spontaneity and dispersion stability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Wet sieve analysis and dry sieve test	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Disintegration time	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Particle size distribution, content of dust/fines, attrition, friability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming	Waiver		Not applicable. The products are not intended to be diluted.	
Flowability/Pourability/Dustability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Burning rate — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Burning completeness — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Composition of smoke — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Spraying pattern — aerosols	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Physical compatibility	Waiver		The product is not intended to be used in direct combination with any other product.	
Chemical compatibility	Waiver		The product is not intended to be used in direct combination with any other product.	
Degree of dissolution and dilution stability	Waiver		Not applicable. The products are not intended to be diluted.	
Surface tension	OECD Method 115 / EC Method A.5 (ring method)	"70:30 IPA:Water RTU", Batch No. 15014 Wofasept AHA. Batch No. 0915.17	26.0 mN/m at 20°C (undiluted BP); 71.3 mN/m at 20°C (1g/L solution in purified water) 48.9 mN/m at 20°C (1g/L solution in water)	For 70:30 IPA:Water RTU: M Casco Palau, 2016, Report no. JS24WB For Wofasept AHA: F. Maytssek, 2018, Report no. Mo6100

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Viscosity	OECD Test Guideline 114 (capillary viscometer (static))	Wofasept AHA, Batch No. 031015, AS content: 62.0%	79.2 mm²/s at 20°C; 29.5 mm²/s at 40°C	M Casco Palau, 2016, Report no. XD38JQ

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

The products in this meta SPC without dye are colourless and with dye blue. For products comprising perfume, the odour is characteristic perfume-like. For products that do not comprise perfume, the odour is characteristic alcohol-like. The pH of the products within the meta SPC ranges from approximately 5.4 to 7.9, the relative density is around 0.88.
The products (ready-to-use liquids) have a shelf life of 24 months based on the results of the accelerated storage studies as well as on the long term storage studies at ambient temperature. Yet, an instruction for use "Products must be shaken before use" shall be used because of a reversible phase separation after storage.
The surface tension of the products within the meta SPC ranges from approximately 48.9 mN/m to 71.3 mN/m as 1 g/L solutions in water at 20°C, the kinematic viscosity is around 79.2 mm²/s at 20°C and 29.5 mm²/s at 40°C.

2.2.3 Physical hazards and respective characteristics

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in propan-2-ol, water and the other non-active substances which are associated with explosive properties.	IUCLID[2]
Flammable gases	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids.	IUCLID
Flammable aerosols	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Oxidising gases	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Gases under pressure	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	

[2] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable liquids	ASTM D93 Guideline 440/2008(EC) Annex A.9	Deogel Mani (Batch No. 20201029), 70% w/w 2-Propanol Easysept (Batch No. 13102020) 63% w/w 2-Propanol	Flash point: () Deogel Mani: 13.5 °C Easysept: 13 °C Boiling point: 80.6 °C of azeotropic mixture	Flammable liquid, Category 2 based on GHS/CLP Criteria	Mack, L., 2020 (Report No. Mo6857) Mack, L., 2020 (Report No. Mo6858)
Flammable solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids.	IUCLID
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in propan-2-ol, water and the other non-active substances which are associated with explosive or self-reactive properties.	IUCLID
Pyrophoric liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the products are known to be stable in contact with air at room temperature for prolonged periods of time (days).	IUCLID
Pyrophoric solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Self-heating substances and mixtures	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the substances are known to be soluble in water to form a stable mixture.	IUCLID
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the products are classified as Flam. Liq. 2; H225: Highly flammable liquid and vapour. Actual testing of oxidising properties with highly flammable substances and mixtures according to UN Test O.2 is very difficult due to burning of the flammable liquid. Correct interpretation of the test results and application of the classification criteria are not possible. Additionally, none of the organic substances in the BPF are expected to have oxidising properties based on the fact that the contained oxygen or halogens are only bound to carbon or hydrogen.	IUCLID
Oxidising solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids.	IUCLID
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the products do not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Corrosive to metals	UN Guideline C.1, Section 37.4	Desmila VSI (Batch No. 100920-02), 62.8% (w/w) 2-Propanol	Maximum weight loss 0.35 % after 7 d No localized corrosion observed.	The product is not considered corrosive to metals in the sense of the guideline.	Mack, L., 2020 (Report No Mo6861)
Auto-ignition temperature (liquids and gases)	study scientifically not necessary		Auto-ignition temperature: 425 °C (for pure propan-2-ol)	Waiver: Assuming the lowest available auto-ignition temperature of propan-2-ol (425 °C) as worst case is considered to be sufficiently protective for the usage of the product.	Chemsafe (2017)
Relative self-ignition temperature for solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids.	IUCLID
Dust explosion hazard	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids.	IUCLID

Conclusion on the physical hazards and respective characteristics of the product

The data provided by the applicant was acceptable.
The measured flashpoints of representative samples are < 23 °C and the boiling point is > 35 °C. Therefore, all liquid products of the BPF should be considered as flammable liquids, category 2.
Propan-2-ol has an upper explosion limit of 12% (V) and a lower explosion limit of 2% (V). The auto-ignition temperature of propan-2-ol is 425 °C and can also be used for the products of the BPF "Brenntag GmbH Propan-2-ol Product Family" as a worst case.
The products of the BPF are not expected to have any explosive or oxidising properties. A study on a representative sample led to the conclusion that the products of the BPF are not corrosive to metals. Based on experience in production and handling it can be concluded that the products of the BPF are not pyrophoric and do not evolve any flammable gases in contact with water or humid air.
According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified as follows:

Flam. Liq. 2; (Flammable liquids, category 2) H225: Highly flammable liquid and vapour

2.2.4 Methods for detection and identification

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

Table 4

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance Isopropanol (Test product: 70:30 IPA:Water RTU and Wofasept AHA (only repeatybility)	SANCO/3030/99 GC- FID/MS	Given, test conducted with blank, standard and sample solution, no interference	R^2=0.9997	1500 mg/L (n=2), 2000 mg/L (n=2), 2500 mg/L (n=3)	97,8% – 103%	100%	1.69%	Not relevant;	M Casco Palau, 2016, Report no. TH36LB
Active substance Isopropanol (Test product: IPA-Co-Formulants-Stability-Test-Formulation;	SANCO/3030/99 GC- FID	Specificity is given, test conducted with blank, standard and sample solution, no interference	R^2 = 1	1400 mg/L (n=3), 2000 mg/L (n=2) and 2600 mg/mL (n=3)	98.5 - 100.4%	99.4%	0.6%	Not relevant;	Matyssek, F, 2018, Report No. Mo6079

Please refer to confidential annex for composition)									

Table 5

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Drinking water	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Surface water	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Air	propan-2-ol	3.2 mg/m³	$AEL_{acute/medium\text{-}term/long\text{-}term}$:10.7 mg/kg bw/d (general population) AR for PT1, PT2, PT4; LoEP (01/2015)
Animal and human body fluids and tissues	no relevant residues	N/A	not classified as toxic or very toxic
Food of plant origin	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Food of animal origin	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)

Table 6:

Analytical methods for air									
Analyte (type of analyte e.g. active	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

substance)									
propan-2-ol	GC-FID, DB-5MS column	confirmation by GC-MS possible	Calibration in solvent: 0.34 - 3.4 µg/mL R^2=0.9983 matrix-matched calibration: 0.50 - 12.56 mg/mL R^2=0.9998	Air 21 °C, 80 % rel. humidity (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6 Dry air (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6	99.2-101 102-103.6 102.7-104.9 102.1-104.8 103.2-104.3 102.6-104.6 101.1-103.4 102.3-104.5 102.5-104.4 104-106.1 103.3-105.3 103.1-107.3	100.2 102.9 103.6 103.2 103.7 103.8 102.5 103.3 103.4 104.8 104.5 105.4	0.8 0.8 1.0 1.1 0.3 0.7 1.0 0.9 0.7 0.8 0.7 1.7	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit of 0.05 * OSHA target concentration of 983 mg/m³)	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997
propan-2-ol	GC-MS using DB-5 column, m/z 59 as	confirmation not included, since for second fragment ion no	0.025 - 7.4 mg/mL R^2=0.995 - 1.000	Air (considering maximum sample volume of 23.8 L of				LOQ of the method is dependent on sampling	DocIIIA, 4.1; 11/2015 Alcohol

	quantifier and m/z 45 as qualifier	validation data presented		OSHA-method 9.4 mg/m³ / 5 93.8 mg/m³ / 5 250 mg/m³ / 4 750 mg/m³ / 5	97.3-103 106-115 105-110 104-110	99.2 111 107 107	2.6 3.1 2.1 2.3	volume: the lowest concentration of 0.025 mg/mL corresponds to 3.1 mg/m³ propan-2-ol in air at the maximum sampling volume of 23.8 L in the OSHA method (9.4 mg/m³ - it refers to the validated QC-standard of 0.075 mg/mL and the supposed maximum sample volume of 23.8 L of OSHA-method)	Task Force, 2015

Table 7

Data waiving was acceptable for the following information requirements	
Information requirement	1. Air: For analytical methods for air; the applicant refers to the 3rd party active substance dossier for propan-2-ol, which was submitted by the ASD Consortium Alcohol for Inclusion into the List of Active Substances and Suppliers according to Article 95 (1) of the BPR. 2. Soil: Data waving is accepted.

	3. Water (including drinking water) and sediment: Data waving is accepted. 4. Animal and human body fluids and tissues: Data waving is accepted. 5. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waving is accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s) was acceptable. The information provided regarding the residues was acceptable. Methods regarding substances of concern were not necessary.

2.2.5 Efficacy against target organisms

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.
The assessment of meta SPC 2 is also included in the following text.

2.2.5.1 Function and field of use

The Brenntag GmbH Product Family consists of three meta SPCs containing ready-to-use disinfectant products based on the active substance propan-2-ol for product types 1 (meta SPC 1 and 3), 2 and 4 (meta SPC 2). The products in meta SPC 1 are intended to be used as hygienic handrub in private, public, healthcare and industrial areas, and food preparation and/or food processing areas by professional users. The products in meta SPC 2 are intended to be used for disinfection of non-porous surfaces in private, public, healthcare and industrial areas as well as for food sector and food processing industry (including breweries, dairy and meat industry) by professional users. The products in meta SPC 3 are intended to be used as hygienic handrub in private and public areas by non-professional users.
Products are applied as either handrub (meta SPC 1 and 3) or by spraying (meta SPC 2).

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

The products of the family are intended to have bactericidal (including mycobactericidal) and yeasticidal activity. Originally, a limited spectrum virucidal claim was made for all meta SPCs. However, this claim was withdrawn by the applicant during evaluation for meta SPC 2 and changed for meta SPC 1 to an enveloped virus claim.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Application of the products within the biocidal product family leads to the irreversible inactivation of bacteria,yeasts and enveloped viruses.

2.2.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.
Propan-2-ol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant). The time required for sufficient inactivation is strongly depending on the formulation, concentrations of propan-2-ol contained in the applied biocidal product, the type of target organisms and on the specific use conditions.
After thorough contact of the active substance with the target organisms, a continuous contact of the active substance with the target cells is not required since the initial contact already results in non-reversible damage of the cells, that triggers biological processes which ultimately kill the target organism.

2.2.5.5 Efficacy data

Bactericidal and yeasticidal efficacy of the product family was tested according to currently available efficacy guidelines (EN guidances) with two test products.

As the biocidal product is intended to be applied for disinfection, the product was tested in a tiered approach with quantitative suspension tests (phase 2, step 1 tests) and by simulating practical conditions (phase 2, step 2 tests).

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**
PT1, 2, 4 bactericidal	Handrub, surface disinfection	Wofasept AHA (62,7 % w/w AS)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536 *Pseudomonas aeruginosa* ATCC 15442	EN 1276 (2009)	Suspension test 20°C, dirty conditions (3g/l BA), 80%, 50%, 10% product concentration 30s	>5 log reduction at 50% and 80% product concentration in 30s under dirty conditions	Prof, Dr. med. H.-P. Werner (2016) *6.7-01*
PT 1, 2, 4 yeasticidal	Handrub, surface disinfection	Wofasept AHA (62,7 % w/w AS)	*Candida albicans* ATCC 10231	EN 1650 (2013)	Suspension test 20°C, dirty conditions (3g/l BA) 80%, 50%, 10% product concentration 30s	>4 log reduction at 80% product concentration in 30s under dirty conditions	Prof, Dr. med. H.-P. Werner (2016) *6.7-02*
PT 1, 2, 4 bactericidal	Handrub, surface disinfection – medical area	Wofasept AHA (62,7 % w/w AS)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	EN 13727 (2013)	Suspension test 20°C, Dirty conditions (3g/l BA+3ml/l sheep erythrocytes)	>5 log reduction at 50% product concentration in 60s and at 80% in 30s	Werner (2016) *6.7-05*

			Pseudomonas aeruginosa ATCC 15442 *Escherichia coli* K12 NCTC 10538		80%, 50%, 10% product concentration, 30s, 60s		
PT 1, 2, 4 yeasticidal	Handrub, surface disinfection – medical area	Wofasept AHA (62,7 % w/w AS)	*Candida albicans* ATCC 10231	EN 13624 (2013)	Quantitative suspension test 20°C, Dirty conditions (3g/l BA + 3ml/l sheep erys) 80%, 50%, 10% product concentration, 30s, 60s	>4 log reduction at 80% product concentration in 30s	Werner (2016) 6.7-06
PT1	Handrub	Wofasept AHA (62,7 % w/w AS)	*Escherichia coli* K12 NCTC 10538	EN 1500 (2013)	Phase 2, step 2 100% product concentration 3ml, 60s	The tested product is suitable as hygienic hand rub under the test conditions.	Werner (2016) *6.7-07*
PT 2, 4 bactericidal	Surface disinfection	Wofasept AHA (62,7 % w/w AS)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536 *Pseudomonas aeruginosa* ATCC 15442 *Candida albicans* ATCC 10231	EN 13697 (2015)	Quantitative surface test 20°C, Dirty conditions (3g/l BA) 100%, 50%, 10% product concentration 1min, 5min	>4 log reduction for bacteria and >3log reduction for yeasts at 50% and 100% product concentration in 1min and 5 min under dirty conditions	Werner (2016) *6.7-03*
PT 1, 2, 4 tuberculocidal	Handrub, surface disinfection	Wofasept AHA (62,7 % w/w AS)	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769	EN 14348 (2005)	Quantitative suspension test 20°C, Dirty conditions (3g/l BA+3ml/l sheep erys) 80%, 50%, 10% product concentration, 30s, 60s	>4 log reduction at 80% product concentration in 60s	Werner (2016) *6.7-09*

PT 4 bactericidal	Surface disinfection in dairy industry	Curacid HD-sept (62,8 % w/w AS)	*Staphylococcus aureus ATCC 6538* *Enterococcus hirae ATCC 10541* *Escherichia coli ATCC 10536* *Pseudomonas aeruginosa ATCC 15442*	EN 1276 (2010)	Quantitative suspension test 20°C 10g/l reconstituted milk 89%, 80%, 50%, 25% product concentration 1 min, 5 min	≥ 5 log reduction at 89% product concentration in 1min	Werner (2018) *6.7-20*
PT 4 yeasticidal	Surface disinfection in dairy industry	Curacid HD-sept (62,8 % w/w AS)	*Candida albicans ATCC 10231*	EN 1650 (2013)	Quantitative suspension test 20°C 10 g/l reconstitued milk 80%, 50%, 10% product concentration 1 min	≥4 log reduction at 80% product concentration in 1 min	Werner (2018) *6.7-21*
PT 4 bactericidal	Surface disinfection in dairy industry	Curacid HD-sept (62,8 % w/w AS)	*Staphylococcus aureus ATCC 6538* *Enterococcus hirae ATCC 10541* *Escherichia coli ATCC 10536* *Pseudomonas aeruginosa ATCC 15442* *Candida albicans ATCC 10231*	EN 13697 (2015)	Quantitative surface test 22°C 10 g/l reconstituted milk 100%, 50%, 10% product concentration 1 min, 5 min, 15 min	≥4 log reduction for bacteria and ≥3 log reduction for yeasts at 100% product concentration in 15 min	Werner (2018) *6.7-22*
PT 4 bactericidal	Surface disinfection in meat industry	Curacid HD-sept (62,8 % w/w AS)	*Staphylococcus aureus ATCC 6538* *Enterococcus hirae ATCC 10541* *Escherichia coli ATCC 10536* *Pseudomonas aeruginosa ATCC 15442*	EN 1276 (2010)	Quantitative suspension test 20°C 3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes 80, 50, 25 % 1 min, 5 min	≥5 log reduction at 80% product concentration in 1 min	Werner (2018) *6.7-23*

PT 4 yeasticidal	Surface disinfection in meat industry	Curacid HD-sept (62,8 % w/w AS)	*Candida albicans ATCC 10231*	EN 1650 (2013)	Quantitative suspension test 20°C 3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes 80%, 50%, 25% product concentration, 1 min, 5 min	≥4 log reduction at 80% product concentration in 1min	Werner (2018) *6.7-24*
PT 2, 4 Bactericidal, yeasticidal	Surface disinfection in meat industry / medical area	Curacid HD-sept (62,8 % w/w AS)	*Staphylococcus aureus ATCC 6538* *Enterococcus hirae ATCC 10541* *Escherichia coli ATCC 10536* *Pseudomonas aeruginosa ATCC 15442* *Candida albicans ATCC 10231*	EN 13697 (2015)	Quantitative surface test 23°C 3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes 100%, 50%, 10% product concentration 1 min, 5 min	≥4 log reduction for bacteria and ≥3 log reduction for yeasts at 100% product concentration in 5 min	Werner (2018) *6.7-25*
PT 4 yeasticidal	Surface disinfection in breweries	Curacid HD-sept (62,8 % w/w AS)	*Saccharomyces cerevisiae ATCC 9763* *Saccharomyces cerevisiae ATCC 18824*	EN 1650 (2013)	Quantitative suspension test 20°C 10g/l yeast extract 80%, 50%, 10% product concentration, 5 min	>4 log reduction at 50% product concentration in 5 min	Werner (2018) *6.7-18*
PT 4 yeasticidal	Surface disinfection in breweries	Curacid HD-sept (62,8 % w/w AS)	*Saccharomyces cerevisiae ATCC 9763* *Saccharomyces cerevisiae ATCC 18824*	EN 13697 (2015)	Quantitative surface test 20°C-24°C 10g/l yeast extract 100%, 50%, 10% product concentration, 5 min	>3 log reduction at 50% product concentration in 5 min	Werner (2018) *6.7-19*
PT 1 Virucidal	Hygienic Hand disinfection	Wofasept AHA (62,7 % w/w AS)	*Murine Norovirus strain S99 Berlin*	EN 14476 (2013+A1:2015)	Quantitative suspension test 20 °C Clean cond (0.3 g/L BSA)	> 4 log reduction at 80 % product concentration in 60 s	Werner (2018) 6.7-04

					80, 50, 10 % product concentration 30 s, 60 s		
PT 1 Virucidal	Hygienic Hand disinfection	Wofasept AHA (62,7 % w/w AS)	*Adenovirus Type 5*	EN 14476 (2013+A1:2015)	Quantitative suspension test 20 °C Clean cond (0.3 g/L BSA) 80, 50, 10 % product concentration 60 s, 120 s	> 4 log reduction at 80 % product concentration in 60 s	Werner (2018) 6.7-08
PT 1 Virucidal	Hygienic Hand disinfection	Wofasept AHA (62,7 % w/w AS)	*Human Rotavirus A RVB-031*	EN 14476 (2013+A1:2015)	Quantitative suspension test 20 °C No soiling 90, 50, 10 % product concentration 30 s, 60 s	> 4 log reduction at 50 % product concentration in 30 s	Werner (2018) 6.7-10
Bridging study bacteria		Anfosan (70 % w/w AS) Anfosan Forte[3] (70 % w/w AS) Curacid HD-sept (62,8 % w/w AS)	*Staphylococcus aureus* ATCC 6538	EN13727 (2015)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys) 80%, 50%, 40%, 30%, 20%, 10% product concentration 30s	>5 log reduction Anfosan: at 40% (but flocculation observed) and at 50% product concentration Anfosan Forte: at 30% (but flocculation observed) and at 50% product concentration Curacid HD-sept: at 50% product concentration	Werner (2018) *6.7-12*

[3] Test products "Anfosan" and "Anfosan forte" were at the beginning of the assessment products of the BPF. During evaluation the applicant has withdrawn both products. As both products were used as test products the composition is given in the confidential annex.

Bridging study bacteria		Frend Hand Sanitiser Gel (65,3 % w/w AS) Easysept (63 % w/w AS) HD 18 Mano Germs (63 % w/w AS) Wofasept AHA (62,7 % w/w AS) Esept Gel (63,4 % w/w AS)	*Staphylococcus aureus* ATCC 6538	EN13727 (2015)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys) 80%, 50%, 10% product concentration 30s	HD 18 Mano Germs: >5 log reduction at 50% product concentration Wofasept AHA: >5 log reduction at 80% product concentration Esept Gel, Frend Hand Sanitiser Gel, Easysept: Flocculation of product at relevant product concentration	Werner (2018) *6.7-13*
Bridging study yeasts		Anfosan (70 % w/w AS) Anfosan Forte (70 % w/w AS)Curacid HD-sept (62,8 % w/w AS)	*Candida albicans* ATCC 10231	EN13624 (2013/prA1: 2017)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys) 80%, 50%, 10% product concentration 30s	>4 log reduction Anfosan: at 80% product concentration Anfosan Forte: 80% product concentration Curacid HD-sept: 80% product concentration	Werner (2018) *6.7-14*
Bridging study yeasts		Frend Hand Sanitiser Gel (65,3 % w/w AS) Easysept (63 % w/w AS)	*Candida albicans* ATCC 10231	EN13624 (2013)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys)	HD 18 Mano Germs: >4 log reduction at 80% product concentration (but flocculation observed),	Werner (2018) *6.7-15*

		HD 18 Mano Germs (63 % w/w AS) Wofasept AHA (62,7 % w/w AS) Esept Gel (63,4 % w/w AS)			80%, 50%, 10% product concentration 30s	2.3 log reduction at 50% product concentration Wofasept AHA: >4 log reduction at 80% product concentration, 2.4 log reduction at 50% product concentration Esept Gel, Frend Hand Sanitiser Gel, Easysept: Flocculation of product at relevant product concentration	
Bridging study bacteria		Anfosan (70 % w/w AS) Anfosan forte (70 % w/w AS) Wofasept AHA (62,7 % w/w AS) Desmila VSI (62,8 % w/w AS) Curacid HD-sept (62,8 % w/w AS) Deogel Mani	*Staphylococcus aureus* ATCC 6538	EN13727 (2015)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys) 80%, 50%, 10% product concentration 30s	>5 log reduction Anfosan: 50% product concentration Anfosan forte: 50% product concentration Wofasept AHA: 80% product concentration Curacid HD-sept: 50% product concentration Deogel Mani: 80% product concentration Desmila VSI:	Werner (2018) *6.7-16*

		(70 % w/w AS)				Flocculation of product at relevant product concentration	
Bridging study yeasts		Anfosan (70 % w/w AS) Anfosan forte (70 % w/w AS) Wofasept AHA (62,7 % w/w AS) Desmila VSI (62,8 % w/w AS) Curacid HD-sept (62,8 % w/w AS) Deogel Mani (70 % w/w AS)	*Candida albicans* ATCC 10231	EN 13624 (2013/prA1: 2017)	Quantitative suspension test 20°C Dirty cond (3g/l BA + 3ml/l sheep erys) 80%, 50%, 10% product concentration 30s	>4 log reduction Anfosan: 80% product concentration Anfosan forte: 50% product concentration Wofasept AHA: 80% product concentration Curacid HD-sept: 80% product concentration Deogel Mani: 50% product concentration Desmila VSI: Flocculation of product at relevant product concentration	Werner (2018) *6.7-17*
Bridging study bacteria		Wofasept AHA (62,7 % w/w AS) Esept Gel (63,4 % w/w AS) Easysept	*Staphylococcus aureus* ATCC 6538	EN13727 (2015)	Quantitative suspension test 20°C Clean cond (0,3 g/l BA) 80%, 70%, 60%, 50% product concentration	>5 log reduction Wofasept AHA 60% product concentration	Werner (2018) *6.7-26*

		(63 % w/w AS)			30s	Esept Gel 50% product concentration Easysept 50% product concentration	
Bridging study yeasts		Wofasept AHA (62,7 % w/w AS) Esept Gel (63,4 % w/w AS) Easysept (63 % w/w AS)	*Candida albicans* ATCC 10231	EN 13624 (2013/prA1: 2017)	Quantitative suspension test 20 °C Clean cond (0,3 g/l BA) 80%, 70%, 65%, 60%, 50% product concentration 30s	>4 log reduction Wofasept AHA 65% Esept Ge 60%l Easysept 60%	Werner (2018) *6.7-27*

Choice of the test products

Products within the family may contain different co-formulants (e.g. moisturiser, thickener, etc., for detailed information please refer to conf Annex) which might have an impact on efficacy. In products in meta-SPC 1 and 3, moisturisers and thickeners in various concentrations may be present. Initially, the composition of meta-SPC 2 included several surfactants which were then removed during the evaluation.

Efficacy tests were conducted with the product Wofasept AHA (belongs to meta-SPC 1, contains moisturiser and thickener but no surfactants) and the product Curacid HD-sept (belongs to meta-SPC 1, but is identical to the product Curacid Food Rapid, which belongs to meta-SPC 2), contains no moisturiser, no thickener, no surfactants)
.
Bridging studies (according to EN 137272 and EN13624) were conducted with different products within the family containing various amounts of the co-formulants (e.g. no moisturiser, no thickener, highest concentration of different surfactants).
In these studies, products of the BPF containing highest amounts of the different surfactants and no moisturiser and no thickener and products containing none of these co-formulants showed sufficient efficacy at lower or at least the same product concentrations as the test product Wofasept AHA. This was also the case for the test product Curacid HD-sept.
Furthermore, products of meta-SPC2 containing the highest amounts of the different surfactants showed efficacy at lower or at least the same product concentrations as the test product Curacid HD-sept.
Therefore the test product Wofasept AHA was regarded as acceptable as worst case test product for the whole family and the test product Curacid HD-sept as the worst case for meta SPC 2.
The test product Wofasept AHA was used to derive the contact time for hygienic handrub, for surface disinfection (other than healthcare) in PT 2 and for general surface disinfection in PT 4.
The test product Curacid HD-sept was used to derive contact time for disinfection in meat industry (3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes) and to derive contact times for disinfection in breweries and dairy industry.
Both test products were used to derive contact time for disinfection in healthcare area.

Table 8

Conclusion on the efficacy
Efficacy tests were conducted on the product Wofasept AHA. Bridging studies (Phase 2 Step 1, according to EN 13727 and EN 13624) were carried out to demonstrate that the product Wofasept AHA can be regarded as worst case covering all products within the family. Efficacy test to demonstrate bactericidal and yeasticidal efficacy on non-porous surfaces in breweries, dairy and meat industry were conducted on the product Curacid HD-sept. Bridging studies confirmed that the test product can be regarded as worst case for meta SPC 2. All tests were conducted according to the relevant EN standards within a quality assured laboratory. All controls were valid. The test products demonstrated bactericidal (including mycobactericidal) and yeasticidal efficacy according to EN 1276, EN 13697, EN 13727, EN 1500, EN 14348, EN 1650, EN 13624) under test conditions defined for hygienic handrub, for the

disinfection of non-porous surfaces in private, public, healthcare and industrial areas as well as for food sector and food processing industry.
Furthermore, bactericidal and yeasticidal efficacy was demonstrated on non-porous surfaces in breweries, dairy and meat industry according to EN 1276, EN 1650 and EN 13697 (soiling: dairy industry: 10g/l reconstitued milk, meat industry: 3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes; test strain: breweries: Saccharomyces cerevisiae, 10g/l yeast extract).
Activity against viruses was demonstrated according to EN 14476 for Noro- and Adenovirus. The intended claim "activity against enveloped virus" of the applicant is substantiated by that information.
For surface disinfection, efficacy was proven under dirty conditions. For hygienic handrub, efficacy was only proven under clean conditions.

Meta SPC 1 & 3, Use 1 Hygienic Handrub

Bactericidal (including mycobactericidal), yeasticidal and activity against enveloped viruses - contact time at least 1 min when rubbing at least 3 ml product over both hands

Meta SPC 2, Use 2, Disinfection of non-porous surfaces in private, public, healthcare and industrial areas

General surfaces disinfection
Bactericidal (including mycobactericidal) and yeasticidal – contact time at least 1 min

In healthcare area:
Bactericidal (including mycobactericidal) and yeasticidal – contact time at least 5 min

Meta SPC 2, Use 3 Disinfection of non-porous surfaces in food sector and food processing industry

Bactericidal and yeasticidal – contact time at least 1 min

in Breweries:

Yeasticidal and bactericidal – contact time at least 5 min

in dairy industry:

Bactericidal and yeasticidal – contact time 15 min

in meat industry:

Bactericidal and yeasticidal – contact time at least 5 min

It is concluded that products within the family are expected to be efficacious if used in accordance with the use instructions proposed in the SPC.

To ensure the efficacy of the products, the following use conditions have to be indicated on the product label

- for surface disinfectants (meta-SPC 2):

  "Make sure to wet surfaces completely".
- For hygienic handrub (meta-SPC 1 & 3):
  "Only apply on dry and visibly clean hands"

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of 2-propanol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where 2-propanol is ineffective at any concentration. Likewise, 2-propanol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.
No management strategies have been developed since no occurrence of resistance has been observed.

2.2.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of the test product Wofasept AHA and Curacid HD-sept.

2.2.5.8 Evaluation of the label claims

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

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

Brenntag GmbH Product Family disinfectant products are not intended to be used with other biocidal products.

2.2.5.10 Data waiving and conclusion

Table 9

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	

2.2.6 Risk assessment for human health

For professional user the following assessment covers the use of meta SPC 1.

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

For the general public the following assessment covers the use of meta SPC 1, 2 and 3.

2.2.6.1 Assessment of effects of the active substance on human health

Table 9

Propan-2-ol	**Value**	**Study**	**Safety factor**
AEL acute/medium/long-term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	6.4
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	3.8

Table 10

Propan-2-ol	**Value**	**Reference**
Inhalative absorption	100 %	Assessment-Report (RMS DE (2014))
Oral absorption	Nearly complete following oral, inhalation and intravenous exposure.	Slauter et al., 1994
Dermal absorption	Absorption rate (transdermal flux) in rat study: 0.85 mg/cm^2/h for aqueous solution containing 70 % propan-2-ol (by weight) The composition of the test formulation and biocidal products of meta-SPC 1 are considered comparable.	Boatman et al., 1998

	25 % for biocidal products of the BPF containing higher amounts of surfactants (meta-SPC 2)	Default according to the EFSA Guidance on Dermal Absorption (2012)

2.2.6.2 Assessment of effects on Human Health

This assessment is valid for all Meta-SPCs.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta SPC 1, 2 and 3: Not irritating to the skin. Repeated exposure may cause skin dryness or cracking.
Justification for the value/conclusion	Conclusions are based on the toxicological properties of the single components. Meta-SPC 1, 2 and 3: According to Annex VI, Regulation (EC) No 1272/2008 propan-2-ol is not skin irritating in rabbits. Studies on skin irritation in human subjects reveal no skin irritating properties. The biocidal products do not contain other components classified for this endpoint in relevant concentrations. Hence, the individual biocidal products of the Meta-SPC, and thus the Meta-SPC themselves, do not need to be classified with respect to local effects on the skin according to the CLP criteria. However, according to the third party dossier for propan-2-ol local skin effects and reactions have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. Therefore, an appropriate labelling for skin dryness and cracking is indicated. The biocidal product family does not contain other components in relevant concentrations leading to a classification as skin-irritant. For details on the toxicity of the components refer to the Confidential Annex.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: Classification for skin corrosion or irritation is not required. Supplemental hazard statement: EUH066 (Repeated exposure may cause skin dryness or cracking)

Data waiving	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product family are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.1 "Skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according

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

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Meta-SPC 1, 2 and 3: Irritating to the eyes.
Justification for the value/conclusion	Classification of the biocidal product family is based mainly on the classification of the active substance according to Regulation (EC) No 1272/2008 and its concentration in the biocidal product: Propan-2-ol (64.73 %, w/w): Eye Irrit. 2, H319; Generic concentration limit: 10 % (w/w) Biocidal products of this family also contain other co-formulants classified for eye irritation and damage in minor concentrations. For details refer to the Confidential Annex.
Classification of the product according to CLP	Meta-SPC 1, 2 and 3: Eye Irrit. 2, H319 (Causes serious eye irritation.)

Data waiving	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product family are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Meta-SPC 1, 2 and 3: Not irritating to the respiratory tract
Justification for the conclusion	Based on the known intrinsic properties of individual components and their concentration in the formulation the biocidal products are not irritating to the respiratory tract. Details on the corresponding toxicity of the individual components can be found in the Confidential Annex.
Classification of the product according to CLP	Meta-SPC 1, 2 and 3: Classification for respiratory tract irritation is not required.

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, "other endpoints"
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product family has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal products do not contain components classified for respiratory irritation in relevant concentrations.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Meta-SPC 1, 2 and 3: Not sensitising to the skin. Biocidal products contain sensitising substances.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation the biocidal products are not skin-sensitising. Details on the corresponding toxicity of the individual components can be found in the Confidential Annex.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin-sensitising properties of the biocidal products are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.3 Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components

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

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal products or their components with the corresponding concentration are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

Data waiving	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal products or their components are not available.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acute toxicity via the oral route.
Justification for the selected value	Based on the acute oral toxicity properties of all components, the oral LD_{50} of the biocidal products is estimated as > 2000 mg/kg bw. Details on the toxicity of the co-formulants (classification, LD_{50}) can be found in the Confidential Annex.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

Data waiving	
Information requirement	8.5.1. By oral route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components

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

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No acute toxicity via the inhalation route. May cause drowsiness and dizziness.
Justification for the selected value	Based on the acute inhalation toxicity properties of all components, the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L (aerosol). Details on the toxicity of the co-formulants (classification, LC_{50}) can be found in the Confidential Annex.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required. However, based on the classification of the active substance propan-2-ol the biocidal products are classified as STOT SE 3, H336 (May cause drowsiness or dizziness.)

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No acute toxicity via the dermal route.

Justification for the selected value	Based on the acute dermal toxicity properties of all components, the dermal LD_{50} of the biocidal products is estimated as > 2000 mg/kg bw. Details on the toxicity of the co-formulants (classification, LD_{50}) can be found in the Confidential Annex.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Propan-2-ol (Meta-SPC 1 and 3), all scenarios with dermal exposure	Propan-2-ol (Meta-SPC 2) , all scenarios with dermal exposure
Value(s)*	Flux rate: 0.85 mg/cm^2/h	Flux rate: 0.85 mg/cm^2/h
Justification for the selected value(s)	The dermal absorption value derived in the CAR is based on the publication of Boatman et al. (1998). This study was also submitted for the 3rd party dossier. Hence, conclusions from the CAR are also valid for this dossier. From the publication of Boatman et al. (1998) a dermal flux rate of 0.85 mg/cm^2/h was derived for a 70 % aqueous dilution on rat skin. The composition of the test formulation and biocidal product are considered comparable. The active substance concentration of the test substance and the biocidal products is almost identical. In contrast to the test substance, the biocidal products of Meta-SPC 1 and 3 contain	The dermal absorption value derived in the CAR is based on the publication of Boatman et al. (1998). This study was also submitted for the 3rd party dossier. Hence, conclusions from the CAR are also valid for this dossier. From the publication of Boatman et al. (1998) a dermal flux rate of 0.85 mg/cm^2/h was derived for a 70 % aqueous dilution on rat skin. However, the composition of test substance and the biocidal product are not comparable. In contrast to the test substance, the biocidal products of the Meta-SPC contain perfumes, a dye, a chelating agent, a moisturiser and emulsifiers. With respect to the perfumes, the dye

	perfumes, dyes, pH-regulators, moisturiser, and thickening agents. Based on their low concentration and their physicochemical properties it is not expected that perfumes, dyes and pH-regulators affect dermal absorption significantly. It is known that moisturisers can improve the absorption of some substances into the skin by skin hydration. On the other hand the inverse effect promoted by propan-2-ol (skin cracking, skin dryness) also increase skin absorption. Thus, the addition of the moisturiser may reduce the skin cracking properties of propan-2-ol. Hence, in this special case it is expected that this co-formulant does not affect dermal absorption significantly. Due to their molecule size, it is not expected that thickener penetrate the skin and leads to an increase in dermal absorption. In conclusion, the dermal flux rate derived from the publication of Boatman et al. (1998) can be used for exposure and risk assessment.	and the moisturiser the differences in the composition are expected to have no significant outcome on dermal absorption (refer to the argumentation for Meta-SPC 1 and 3, left). Also the chelating agent has no impact. This substance binds to metal ions in the product or on surfaces but not to organic molecules or the active substance, at least not at this low concentration. In conclusion, the dermal absorption value derived with a simple aqueous dilution of propan-2-ol can also be used for this biocidal product Meta-SPC.

Data waiving	
Information requirement	8.6. Information on dermal absorption
Justification	Meta-SPC 1, 2 and 3: Dermal absorption is adopted from a study submitted for the 3rd party dossier of the active substance. The test substance of this study is considered comparable to the biocidal product family. For details refer to the table above.

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

Not relevant.

Available toxicological data relating to a mixture

Not available.

Other

According to regulation (EC) No 1272/2008 Annex VI, Table 3.1 the active substance is classified with STOT SE 3 (H336, May cause drowsiness or dizziness). Based on the high active substance concentration in the biocidal product (> 60 %) and the recommended generic concentration limit of 20 % for substances classified as STOT SE 3, this classification is also required for the biocidal product.

2.2.6.3 Exposure assessment

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

Table 11

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	Yes	n.a	Yes	Yes	n.a.
Dermal	n.a.	Yes	Yes	n.a	not expected	no	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	no	no

List of scenarios in meta SPC 1+2+3

Table 12

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Hand disinfection - hygienic	PT1:Primary exposure of the professional user resulting from hand disinfection (hand rubbing) with an alcohol based disinfectant in form of a ready-to-use product in naturally ventilated rooms e.g. a patient room in a hospital. Secondary exposure of a professional bystander who is present in the patient room where the hand disinfection is carried out can be expected. (Applies to meta SPC 1)	Professional
2	Small surface disinfection - in between disinfection	PT2: Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in naturally ventilated rooms e.g. a patient room in a hospital. Secondary exposure of a professional bystander who is present in the patient room where the surface disinfection is carried out. (Applies to meta SPC 2)	Professional
3	Small surface disinfection in laboratory	PT2: Primary exposure of a professional user resulting from application (spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in technically ventilated rooms e.g. a work bench in a laboratory. Secondary exposure of a professional bystander who is present in the laboratory where the surface disinfection is carried out can be expected. (Applies to meta SPC 2)	Professional
4	Small surface disinfection in kitchens and canteens	PT4: Primary exposure of a professional user resulting from application (spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces in food contact areas e.g. a work bench in a kitchen. Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out can be expected. (Applies to meta SPC 2)	Professional

5	Disinfection of food processing machinery	PT4: Primary exposure of a professional user resulting from application (wiping/pouring & wiping/ spraying & wiping) of an alcohol based disinfectant in form of a ready-to-use product on food processing machinery and its parts in a technically ventilated production hall of e.g. a non-alcoholic beverage processing plant. Secondary exposure of a professional bystander who is present in the production hall where the surface disinfection is carried out can be expected. (Applies to meta SPC 2)	Professional
6	Refilling	PT1, 2, 4: Decanting/Refilling of disinfectant from canisters (up to 10 L), drums (200 L), or IBC (1000 L) into handy sized packages (manually or with hand pumps, connecting lines). Secondary exposure is not expected. (Applies to meta SPCs 1 and 2)	Professional
7.	Application	PT1: Primary exposure, hand disinfection in private and public areas, adult, children, 1, 5 and 25 applications per day. (Applies to meta SPC 3)	Non-professional users
8	Post-application	PT1: Secondary exposure from hand disinfection in the private area, inhalation, adults, children, toddlers. (Applies to meta SPC 3)	General public, Bystanders
9	Post-application	PT1: Secondary exposure from hand disinfection in the public area, inhalation, adults, children, toddlers. (Applies to meta SPC 3)	General public, bystanders
10	Post-application	PT2: Secondary exposure after spray application and wiping in the private and public area, inhalation, adults, children, toddlers. (Applies to meta SPC2)	General public, bystanders

The Brenntag GmbH Propan-2-ol Product Family is a biocidal product family (BPF) of propan-2-ol based disinfectants comprising three meta SPCs.

Within PT1 the products of meta SPC 1 are used for hygienic hand disinfection by hand rubbing for professional use.
Within PT2 the products of meta SPC 2 are used for disinfection of small surfaces in public, healthcare, industrial areas and in areas for professional activities.
Within PT4 the products of meta SPC 2 are used for disinfection of small surfaces in the food sector or food processing industries.

Within PT1 the products of meta SPC 3 are used for hygienic hand disinfection by hand rubbing for non-professional use.

All members of meta SPC 1 - 3 are ready-to-use surface disinfectant solutions containing "propan-2-ol" (CAS-No.: 63-67-0; 62.7 - 70%w/w).

Industrial exposure

No industrial applications are intended for the products covered by meta SPC 1.

Professional exposure meta SPC 1

All members of meta SPC 1 are ready-to-use hand disinfectant gels or solutions containing "propan-2-ol" (CAS-No.: 63-67-0; 62.7 - 70 %w/w).

Table 13

meta SPC	Scenario No.	Intended applications
meta SPC 1	1	Hand disinfection - hygienic
	6	Refilling

General Information on meta SPC 1
The products of meta SPC 1 are marketed in different package sizes:

- Bottles: 0.1 to 2.5 L
- Cans: 5 to 60 L
- Drums: 200 L
- Containers: 1000 L

In Annex 3.2 the details of the exposure calculations to the a.s. propan-2-ol for the professional user are laid out.

Due to local effects of the active substance propan-2-ol, a qualitative local risk assessment is performed and described in chapter2.2.6.4, Risk characterisation for human health.

Scenario 1 – Hand disinfection

Description
The exposure assessment of hand disinfection is based on the approach of recommendation no. 9 "Hand disinfection in hospitals" of the BPC Ad hoc Working Group on Human Exposure (HE Ad-hoc working group).

Brenntag disinfectant product is a ready-to-use hand disinfectant solution or gel which may be decanted from a canister into a smaller unit prior to application.

For hand disinfection, the application liquid or gel is applied onto dry hands which are rubbed intensively, then. The disinfectant is left on the skin and evaporates.
The disinfectant is used in private, public, and industrial areas and in areas for professional activities. Use occurs indoors and outdoors.

As a realistic worst-case scenario, it is assumed that a health care worker in a hospital performs 25 hand rubs per shift. As it is unrealistic that all 25 hand rubs are carried out in one room during an 8-h shift of a health care worker, a more realistic exposure scenario is calculated. It is assumed that one nurse is responsible for 8 patients. During his/her work in a patient room, 3 hand disinfections are performed. After visiting of 4 patient rooms, he/she re-enters the first room and performs 3 hand disinfections in each room again. In summary, 25 applications per shift are performed.

According to information from the applicant the ready-to-use gel and the solution are applied with a use rate of up to 3 ml per hand rub which represents a realistic worst-case scenario. Gel and liquid application can well be compared, therefore.

Dermal exposure
Exposure to skin occurs during the application phase as the biocidal product is directly applied to both hands. Dermal exposure is limited to the time the disinfectant remains on the hands and is calculated as described in the ad-hoc-working group recommendation no. 9.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (7770 Pa at 30° C skin temperature). A refined calculation of inhalation exposure for the professional user to the a.s. is carried out as described in recommendation no. 9 using the model ConsExpo Web "Exposure to vapour: Constant rate release" which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
Exposure of the eyes is not expected as application is carried out below eye height. Furthermore, the active substance evaporates rapidly and no residue for a possible hand to eye-contact is left.

Secondary exposure
Dermal exposure of a professional bystander is not expected because due to the high vapour pressure of the active substance, the active substance quickly evaporates from the skin. Inhalation exposure occurs of a professional bystander is possible and assumed to be in the same order of magnitude or lower as for the operator.

Table 14

Details of Scenario 1	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (w/w)
Density of the b.p.	0.879 g/cm³
Number of hand disinfections	25
Volume of b.p. per application	3 ml
Area of surface of both hands	820 cm²
Temperature (hands)	30 °C
ConsExpo web parameters	
Room volume	80 m^3
Ventilation rate	1.5 / h
Emission duration*	50.27 sec
Product amount for one hand disinfection (Volume b.p. x density)	2.637 g
Exposure duration per application	10 min**
Vapour pressure of a.s. (at 30° C)	7770 Pa
Mode of release	Constant rate

* calculated evaporation time at 30°C according to HEAdhoc-Recommendation No. 9
** according to HEAdhoc-Recommendation No. 9

Calculations

The results of the calculation for potential/actual inhalation exposure are summarised in Table 16 and Table 17. Results of the calculation for a combined scenario which includes refilling of application bottles prior to hand disinfection are given in Table 18.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.4**.**

Further information and considerations

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required.

The classification of the b.p requires additional assessment of local risks (see chapter: Risk characterisation for human health). Local risk assessment has indicated a risk for eye irritation. For hand disinfection by professional users, the product is usually applied onto the hands from a short distance in downward direction as well as rubbed over them below eye height so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.
For refilling of application bottles from larger storage containers, please refer to scenario 6.

Scenario 6 – Refilling

Description

The refilling scenario is applicable for both meta-SPCs of the Brenntag GmbH Propan-2-ol Product Family.
The refilling scenario covers manual filling of application bottles with the ready-to-use solution from up to 10-L storage canisters as a realistic worst case scenario. It is assumed that a maintenance person lifts the canister with both hands which requires the use of an adequate funnel. After refilling the person closes the bottles with a screw cap and lifts the bottle to put it aside which results in dermal exposure of 1 palm.

Dermal exposure
Exposure of the palm of one hand is expected during replacement of refilled bottles, due to spilled quantities on the outside.
Dermal exposure for the meta-SPC 1 products is calculated via the dermal flux, for details please refer to chapter 2.2.6.4
In contrast to this, dermal exposure for the meta-SPC 2 products is calculated based on dermal absorption, for details please refer to chapter 2.2.6.4

Inhalation exposure
Calculation of inhalation exposure is applicable for meta-SPC 1 and meta-SPC 2. Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the active substance during manual pouring of the b.p. from a bigger vessel into e.g. a trigger spray bottle.
It is assumed that the procedure in general is carried out in a small room. The modelled scenario includes a 10 min exposure phase for the loading activity and a 470 min non-exposure period. Calculation of inhalation exposure to the a.s. is carried out using the near field model of the Advanced REACH Tool 1.5 (ART) which assesses inhalation exposure to vapour during decanting procedure. It is further assumed that the relatively small size of the canister opening and the bottle opening reduces the contact between the b.p. and adjacent air.

Exposure of the eyes
Accidental splashes to the eyes cannot be excluded during manual decanting.
This applicable for meta-SPC 1 and meta-SPC 2.

Secondary exposure
For a professional bystander, exposure via inhalation arising from evaporation of spills during refilling of disinfectant is possible and assumed to be in the same order of magnitude or lower as for the operator. Dermal exposure of a professional bystander to the spills is not expected due to the high vapour pressure of the a.s.
This applies for meta-SPC 1 and meta-SPC 2.

Table 15

Details of Scenario 6	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70.0 % (w/w)
Density of the b.p.	0.879 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ART 1.5 parameters	
Room volume	Small workroom only
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air.
Loading type	Splash loading

Calculations

The results of the calculation for potential/actual inhalation exposure are summarised in Table 16 and Table 17.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.2.6.4

Further information and considerations

Risk characterisation for human health). Local risk assessment indicated a risk for eye irritation. Accidental splashes to the eyes cannot be excluded during manual decanting, thus, eye protection is recommended.

It is assumed that refilling from canisters larger than 10 L, drums or IBCs is carried out by the help of dosing pumps or connecting lines leading to less exposure as manual decanting.

- **Summary of professional exposure**

The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are exposure values of all phases.

Table 16

Exposure scenario	Use no. (Product type)	Tier/PPE	Estimated external inhalation exposure [mg/m³]
Scenario 1 Hand disinfection - hygienic	1 (PT01)	Tier 1	10.391
Scenario 6 Refilling	1, 2, 3 (PT01, PT02, PT04)	Tier 1	0.840

Table 17

Summary table: Exposed skin area and application time for dermal exposure.						
Scenario	**Product type**	**Contact time* [min]**	**Application frequency/ day**	**exposed skin area [cm²]**	**hand (palm) surfaces**	**exposure time/day [min]**
Scenario 1 Hand disinfection - hygienic	PT01	0.84	25	820	4 (i.e. both hands)	20.95
Scenario 6 Refilling	PTs 01, 02, 04	0.75	1	205	1	0.75

- **Combined scenarios**

If refilling of small application bottles is carried out by the same staff members as the disinfection itself, exposure from both scenarios has to be combined.

Table 18

Exposure scenarios – numbers	Exposure scenarios - names	Tier/PPE	Estimated external inhalation exposure [mg/m³]
6 + 1	Refilling + Hand disinfection - hygienic	Tier 1	11.231

Non-professional exposure

The exposure assessments for non-professional users and the general public according to the CAR are based on the TNsG models/defaults and Consexpo 4.1. Although the CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal products of the BPF that new agreements on some parameters such as HEEG opinions and HEADhoc recommendations are applicable. Therefore, the exposure assessments for non-professional users and the general public are amended accordingly.

Scenario [7]
Hand disinfection in the private area (PT 1)

Description of Scenario [7]		
PT 1 (Meta-SPC1), primary exposure, hand disinfection in the private area: Non-professionals (consumers) may be exposed to propan-2-ol when using ready-to-use alcoholic hand sanitising products to disinfect their hands in the private area. This scenario is adopted from the CAR (patients performing home dialysis) and is considered applicable also for any other hand disinfection in the private area. It represents also the worst case for hand disinfection in other areas (e.g. public areas; hand disinfection in hospitals). According to the RIVM Cosmetics Products Factsheet, p. 34, the default value for consumers washing hands with hard or liquid soap is 5 times per day (based on 1825 use events per year derived from survey data). Based on these data the applicant proposed a maximum application rate of 5 per day. However, in the description of use the applicant proposed an application frequency of 25 times per day. Hence, exposure assessment is performed also with this frequency. It must be assumed that persons using the biocidal product in the private area are daily and therefore chronically exposed to the active substance. In accordance to Consexpo General Factsheet (2014) the volume for an unspecified room of 20 m^3 is assumed. For the air exchange rate in private houses and the exposure duration 0.6 h^{-1} and 10 h, respectively are used for the assessment. The scenario was calculated in line with the active substance CAR with some amendments regarding default parameters. The inhalation rates for long-term exposure were selected according to the HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products (2017). For inhalation exposure duration the applicant proposed 1 min. This is considered not realistic since it must be assumed that the user will stay in the room for a longer time interval. According to the CAR the exposure duration of 10 h is assumed. It is expected that the worst exposure duration of 10 h represents also the worst case for 25-fold application. The biocidal product may be used by adults and children but not by toddlers. A risk was identified for children if the biocidal product is applied more than three times per day. In Tier 2 for inhalation exposure, it is assumed that rooms are ventilated after application. Thus, the aerial concentration is reduced to non-relevant levels in a relatively short time interval. For the ventilation rate the value of 2.5 h^{-1} for bedroom, open window of the Consexpo General Fact Sheet (2014) was chosen.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g mol^{-1}
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 d^{-1} / 5 d^{-1} / 25 d^{-1}

	Body weight, adult (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Body weight, child, 6 – 11 y (HEEG opinion No. 14 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Weight fraction compound (applicant)	70 % (w/w)
	Inhalation model: Exposure to vapour – instantaneous release	
	Exposure duration (CAR, propan-2-ol, 2014)	5 x 2 h (10 h)
	Room volume (Consexpo General Factsheet, 2014)	20 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	0.6 hr^{-1}
	Applied amount (applicant, assuming a density of 0.879 g/cm^3 and an active substance concentration of 70 %))	2.64 g (3 mL) biocidal product equivalent to 1846 mg propan-2-ol
	Inhalation rate, adult (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.67 m^3/h (16 m^3/d)
	Inhalation rate, child, 6 – 11 y (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.5 m^3/h (12 m^3/d)
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003), it is assumed that this value can also be used for children	51 sec per application/event
	Exposed area, adult (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	820 cm^2 (two hands)
	Exposed area, child, 6 – 11 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	427.8 cm^2 (two hands)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 mg cm^{-2} h^{-1}
Tier 2	Ventilation rate, bed room, window open (Consexpo General Fact Sheet, 2014)	2.5 hr^{-1}

Calculations for Scenario [7]

Inhalation exposure
Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to section 3.2.

Tier 1
1a. Adults

Inhalation systemic exposure = 1.72 mg/kg bw/d (1 application)
= 8.58 mg/kg bw/d (5 applications)
= 42.9 mg/kg bw/d (25 applications)

1b. Children
Inhalation systemic exposure = 3.21 mg/kg bw/d (1 application)
= 16.1 mg/kg bw/d (5 applications)
= 80.3 mg/kg bw/d (25 applications)

Tier 2
1a. Adults
Inhalation systemic exposure = 0.413 mg/kg bw/d (1 application)
= 2.06 mg/kg bw/d (5 applications)
= 10.3 mg/kg bw/d (25 applications)

1b. Children
Inhalation systemic exposure = 0.773 mg/kg bw/d (1 application)
= 3.87 mg/kg bw/d (5 applications)
= 19.3 mg/kg bw/d (25 applications)

Dermal exposure
For dermal exposure the evaporation time (see table above) is calculated according to the following equation (the density of the biocidal product is 0.879 g/cm^3):

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 51 s (= 0.01417 h)

t: time [s]
m: mass of propan-2-ol on surface: 1846 mg (= appl. rate x density x conc. a.s)
R: gas constant: 8.314 J K^{-1} mol^{-1}
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g mol^{-1}
β: mass transfer coefficient, for calculation see TGD: 8.7 m h^{-1}
p: vapour pressure of the pure substance: 7600 Pa (30 °C)
A: surface area (hands): 820 cm^2
K: conversion factor: 36000

With the parameters in the table above the dermal exposure is calculated:

Tier 1 and 2
1a. Adults
Dermal systemic exposure = dermal flux rate x evaporation time x hand surface x application frequency n / body weight
= 0.85 mg cm^{-2} h^{-1} x 0.01417 h x 820 cm^2 x n / 60 kg
= 0.165 mg/kg bw/d (1 application)
= 0.823 mg/kg bw/d (5 applications)
= 4.114 mg/kg bw/d (25 applications)

1b. Children
Dermal systemic exposure = 0.85 mg cm^{-2} h^{-1} x 0.01417 h x 427.8 cm^2 x n / 23.9 kg
= 0.216 mg/kg bw/d (1 application)
= 1.078 mg/kg bw/d (5 applications)
= 5.389 mg/kg bw/d (25 applications)

Total systemic exposure
Tier 1

Adults:

Total systemic exposure	=	0.165 mg/kg bw/d	+ 1.72 mg/kg bw/d	
	=	1.89 mg/kg bw/d	(1 application))	
Total systemic exposure	=	0.823 mg/kg bw/d	+ 8.58 mg/kg bw/d	
	=	9.40 mg/kg bw/d	(5 applications)	
Total systemic exposure	=	4.114 mg/kg bw/d	+ 42.9 mg/kg bw/d	
	=	47.0 mg/kg bw/d	(25 applications)	

Children

Total systemic exposure	=	0.216 mg/kg bw/d	+ 3.21 mg/kg bw/d	
	=	3.43 mg/kg bw/d	(1 application)	
Total systemic exposure	=	1.078 mg/kg bw/d	+ 16.1 mg/kg bw/d	
	=	17.2 mg/kg bw/d	(5 applications)	
Total systemic exposure	=	5.389 mg/kg bw/d	+ 80.3 mg/kg bw/d	
	=	85.7 mg/kg bw/d	(25 applications)	

Tier 2

Adults:

Total systemic exposure	=	0.165 mg/kg bw/d	+ 0.413 mg/kg bw/d	
	=	0.578 mg/kg bw/d	(1 application)	
Total systemic exposure	=	0.823 mg/kg bw/d	+ 2.06 mg/kg bw/d	
	=	2.88 mg/kg bw/d	(5 applications)	
Total systemic exposure	=	4.11 mg/kg bw/d	+ 10.3 mg/kg bw/d	
	=	14.4 mg/kg bw/d	(25 applications)	

Children

Total systemic exposure	=	0.216 mg/kg bw/d	+ 0.773 mg/kg bw/d	
	=	0.989 mg/kg bw/d	(1 application)	
Total systemic exposure	=	1.08 mg/kg bw/d	+ 3.87 mg/kg bw/d	
	=	4.95 mg/kg bw/d	(5 applications)	
Total systemic exposure	=	5.39 mg/kg bw/d	+ 19.3 mg/kg bw/d	
	=	24.69 mg/kg bw/d	(25 applications)	

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier	Estimated inhalation uptake [mg/kg bw/d]	Estimated dermal uptake [mg/kg bw/d]	Estimated oral uptake [mg/kg bw/d]	Estimated total uptake [mg/kg bw/d]
Scenario [7a] PT 1; Applications in the private area, adult, 1 application per day	1	1.72	0.165	-	1.89
	2	0.413	0.165	-	0.578
Scenario [7a] PT 1; Applications in the private area, adult, 5 applications per day	1	8.58	0.823	-	9.40
	2	2.06	0.823	-	2.88

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier	Estimated inhalation uptake [mg/kg bw/d]	Estimated dermal uptake [mg/kg bw/d]	Estimated oral uptake [mg/kg bw/d]	Estimated total uptake [mg/kg bw/d]
Scenario [7a] PT 1; Applications in the private area, adult, 1 application per day	1	1.72	0.165	-	1.89
Scenario [7a] PT 1; Applications in the private area, adult, 25 applications per day	1	42.9	4.11	-	47.0
	2	10.3	4.11	-	14.4
Scenario [7b] PT 1; Applications in the private area, child, 1 applications per day	1	3.21	0.216	-	3.43
	2	0.773	0.216	-	0.989
Scenario [7b] PT 1; Applications in the private area, child, 5 application per day	1	16.1	1.08	-	17.2
	2	3.87	1.08	-	4.95
Scenario [7b] PT 1; Applications in the private area, child, 25 applications per day	1	80.3	5.39	-	85.7
	2	19.3	5.39	-	24.7

Combined scenarios

Combination of primary exposure scenarios for non-professional users is not considered relevant.

Exposure of the general public

The exposure assessments for non-professional users and the general public according to the CAR are based on the TNsG models/defaults and Consexpo 4.1. Although the CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal products of the BPF that new agreements on some parameters such as HEEG opinions and HEADhoc recommendations are applicable. Therefore, the exposure assessments for non-professional users and the general public are amended accordingly.

Scenario [8]

Secondary exposure of the general public after hand disinfection in the private area (PT 1)

Description of Scenario [8]		
PT 1 (Meta-SPC 1 and 3), secondary exposure of the general public after hand disinfection in private areas Secondary inhalation exposure may occur to bystanders (general public) in rooms where hand disinfection is performed during and after application. Highest exposure for the general public is assumed during application in private areas with low ventilation rates, relatively small rooms, frequent application and long stay in areas, where application takes place. Therefore, inhalation exposure as assessed in Scenario 7 for primary exposure also represents the worst case for secondary inhalation exposure. Hence, inhalation exposure as assessed in scenario 7 covers also secondary exposure of the general public. However, an exposure assessment for younger children (toddlers) is required in this case. It is assumed that this assessment for the private area after non-professional use also represents the worst case for secondary exposure after professional use (e.g. use in patient rooms or medical treatment rooms) since this exposure is based on low ventilation rates, relatively small rooms, frequent application and long stay in areas, where application takes place. Dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated hands is considered not relevant due to rapid evaporation. Secondary exposure by inhalation should be in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons may stay in the same room as the person applying the biocidal product. It is expected that secondary exposure resulting from professional use is also covered by this scenario. A risk was identified for children and toddlers if the biocidal product is applied more than three or two times, respectively. In Tier 2, it is assumed that rooms are ventilated after application. Thus, the aerial concentration is reduced to non-relevant levels in a relatively short time interval. For the ventilation rate the value of 2.5 h^{-1} for bedroom, open window of the Consexpo General Fact Sheet (2014) was chosen.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g mol^{-1}
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 d^{-1} / 5 d^{-1} /25 d^{-1}
	Body weight, adult (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler, 1 – 2 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	70 % (w/w)

	Inhalation model: Exposure to vapour – instantaneous release	
	Exposure duration (CAR, propan-2-ol, 2014)	5 x 2 h (10 h)
	Room volume (CAR, propan-2-ol, 2014)	20 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	0.6 hr^{-1}
	Applied amount (applicant, assuming a density of 0.879 g/cm^3 and a active substance concentration of 70 %)	2.64 g (3 mL) biocidal product equivalent to 1846 mg propan-2-ol
	Inhalation rate, adult (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.67 m^3/h (16 m^3/d)
	Inhalation rate, child, 6 – 11 y (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.5 m^3/h (12 m^3/d)
	Inhalation rate, toddler, 1 – 2 y (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.33 m^3/h (8 m^3/d)
	Uptake fraction (inhalation absorption)	100 %
Tier 2	Ventilation rate, bed room, window open (Consexpo General Fact Sheet, 2014)	2.5 hr^{-1}

Calculations for Scenario [8]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to section 3.2

8a. Adults

Inhalation systemic exposure	=	1.72	mg/kg bw/d	(1 application)
	=	8.58	mg/kg bw/d	(5 applications)
	=	42.9	mg/kg bw/d	(25 applications)

8b. Children

Inhalation systemic exposure	=	3.21	mg/kg bw/d	(1 application)
	=	16.1	mg/kg bw/d	(5 applications)
	=	80.3	mg/kg bw/d	(25 applications)

8c. Toddlers

Inhalation systemic exposure	=	5.07	mg/kg bw/d	(1 application)
	=	25.3	mg/kg bw/d	(5 applications)
	=	127	mg/kg bw/d	(25 applications)

Tier 2

8a. Adults

Inhalation systemic exposure	=	0.413	mg/kg bw/d	(1 application)
	=	2.06	mg/kg bw/d	(5 applications)
	=	10.3	mg/kg bw/d	(25 applications)

8b. Children

Inhalation systemic exposure	=	0.773	mg/kg bw/d	(1 application)
	=	3.87	mg/kg bw/d	(5 applications)
	=	19.3	mg/kg bw/d	(25 applications)

8c. Toddlers

Inhalation systemic exposure	=	1.22	mg/kg bw/d	(1 application)
	=	6.10	mg/kg bw/d	(5 applications)
	=	30.5	mg/kg bw/d	(25 applications)

Scenario [9]

Secondary exposure of the general public after hand disinfection in the public area (PT 1)

Description of Scenario [9]		
PT 1 (Meta-SPC 1), secondary exposure of the general public after hand disinfection in the public area (e.g. hospitals) An unacceptable risk has been identified for children if they stay in private areas where the biocidal product is applied regularly without ventilation (scenario 8, Tier 1). Therefore, a risk assessment is also performed for the use in public areas like hospitals. Room volumes and the ventilation rates in such areas are higher. It is expected that this scenario for hospitals also covers other public areas.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g mol^{-1}
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014, applicant)	1 d^{-1} / 5 d^{-1} /25 d^{-1}
	Body weight, adult (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler, 1 – 2 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	70 % (w/w)
	Inhalation model: Exposure to vapour – instantaneous release	
	Exposure duration (CAR, propan-2-ol, 2014)	5 x 2 h (10 h)
	Room volume (HEAdhoc recommendation No. 9 Hand disinfection in hospitals, 2017)	80 m^3

	Ventilation rate (HEAdhoc recommendation No. 9 Hand disinfection in hospitals, 2017)	1.5 hr^{-1}
	Applied amount (applicant, assuming a density of 0.879 g/cm^3 and a active substance concentration of 70 %))	2.64 g (3 mL) biocidal product equivalent to 1846 mg propan-2-ol
	Inhalation rate, adult (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.67 m^3/h (16 m^3/d)
	Inhalation rate, child, 6 – 11 y (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.5 m^3/h (12 m^3/d)
	Inhalation rate, toddler, 1 – 2 y (long-term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	0.33 m^3/h (8 m^3/d)
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [9]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to section 3.2.

9a. Adults

Inhalation systemic exposure	=	0.172	mg/kg bw/d	(1 application)
	=	0.860	mg/kg bw/d	(5 applications)
	=	4.30	mg/kg bw/d	(25 applications)

9b. Children

Inhalation systemic exposure	=	0.322	mg/kg bw/d	(1 application)
	=	1.61	mg/kg bw/d	(5 applications)
	=	8.05	mg/kg bw/d	(25 applications)

9c. Toddlers

Inhalation systemic exposure	=	0.508	mg/kg bw/d	(1 application)
	=	2.54	mg/kg bw/d	(5 applications)
	=	12.7	mg/kg bw/d	(25 applications)

Scenario [10]

Secondary exposure of the general public after small surface application (spraying and wiping) in the private area (PT 2 and 4)

Description of Scenario [10]		
PT 2 and 4 (Meta-SPC 2), secondary exposure of the general public after spray application and wiping in the private area Secondary inhalation exposure may occur to bystanders (general public) in rooms where surface disinfection is performed. Highest exposure for the general public is expected in areas with low ventilation rates, relatively small rooms, frequent application and long stay in areas application occurs. Hence, exposure is assessed for small bathrooms in private areas. The exposure assessment includes adults, children and toddlers. It is assumed that these bystanders do not stay permanently in rooms, where such a treatment takes place. Hence, application duration and exposure duration are relatively short (5 and 10 min). In accordance to the CAR (2014) it is assumed that exposure is limited to one application per day. Exposure by dermal contact to treated surfaces is considered not relevant due to rapid evaporation.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1 d^{-1}
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child, 6 – 11 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler, 1 – 2 y (HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	70 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	10 min
	Room volume (CAR, propan-2-ol, 2014 Consexpo General Fact Sheet, 2014)	10 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.0 hr^{-1}
	Applied amount (applicant), based on a density of 0.882 g/cm^3	17.6 g (20 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2 (1 m^2)
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Molecular weight matrix (water)	18 g mol
	Mass transfer rate (Consexpo, Thibodeaux)	0.335 m/min

	Inhalation rate, adult (short- term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.25 m³/h (0.021 m³/min)
	Inhalation rate, child, 6 – 11 y (short- term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.32 m³/h (0.022 m³/min)
	Inhalation rate, toddler, 1 – 2 y (short- term, HEAdhoc recommendation No. 14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m³/h (0.021 m³/min)
	Uptake fraction (inhalation absorption)	100 %

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 3.2.

10a. Adults
Inhalation systemic exposure = 3.44 mg/kg bw/d (1 application)

10b. Children
Inhalation systemic exposure = 9.12 mg/kg bw/d (1 application)

10b. Toddlers
Inhalation systemic exposure = 20.8 mg/kg bw/d (1 application)

According to the Consexpo model the aerial concentration of propan-2-ol after 30 min is about 450 mg/m^3. If a toddler is exposed to this concentration for 10 min, this would result in a systemic exposure of approximately 10 mg/kg bw/d (Tier 2 for toddlers).

Summary table: systemic exposure of the general public					
Exposure scenario	Tier	Estimated inhalation uptake [mg/kg bw/d]	Estimated dermal uptake [mg/kg bw/d]	Estimated oral uptake [mg/kg bw/d]	Estimated total uptake [mg/kg bw/d]
Scenario [8a] Adults 1 application 5 applications 25 applications	1	 1.72 8.58 42.9	 - - -	 - - -	 1.72 8.58 42.9
1 application 5 applications 25 applications	2	0.413 2.06 10.3	- - -	- - -	0.413 2.06 10.3
Scenario [8b] Children 1 application 5 applications 25 applications	1	 3.21 16.1 80.3	 - - -	 - - -	 3.21 16.1 80.3
1 application 5 applications 25 applications	2	0.773 3.87 19.3	- - -	- - -	0.773 3.87 19.3

Summary table: systemic exposure of the general public					
Exposure scenario	Tier	Estimated inhalation uptake [mg/kg bw/d]	Estimated dermal uptake [mg/kg bw/d]	Estimated oral uptake [mg/kg bw/d]	Estimated total uptake [mg/kg bw/d]
Scenario [8c] Toddlers 1 application 5 applications 25 applications	1	 5.07 25.3 127	 - - -	 - - -	 5.07 25.3 127
1 application 5 applications 25 applications	2	1.22 6.10 30.5	- - -	- - -	1.22 6.10 30.5
Scenario [9a] Adults 1 application 5 applications 25 applications	1	 0.172 0.860 4.30	 - - -	 - - -	 0.172 0.860 4.30
Scenario [9b] Children 1 application 5 applications 25 applications	1	 0.322 1.61 8.05	 - - -	 - - -	 0.322 1.61 8.05
Scenario [9c] Toddlers 1 application 5 applications 25 applications	1	 0.508 2.54 12.7	 - - -	 - - -	 0.508 2.54 12.7
Scenario [10a] Adults	1	3.44	-	-	3.44
Scenario [10b] Children	1	9.12	-	-	9.12
Scenario [10c] Toddlers	1	20.8	-	-	20.8
Scenario [10c] Toddlers	2	10	-	-	10

Combined scenarios

Not relevant.

Dietary exposure

The intended use descriptions of the propan-2-ol-containing biocidal products of meta-SPC 1 and 2 for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The products are to be used as hand or surface disinfectants that do not come into direct contact with food, feedstuff or livestock. Even so, use as non-professional hand disinfectants or as surface disinfectants in food/feed processing areas could potentially lead to transfer of residues onto food. However, due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal products, so that no transfer from treated hands or surfaces

to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-2-ol as a biocide of PT1, PT 2 or PT4 can be excluded.

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

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

Aggregated exposure

[Template structure to be further developed once the methodology has been developed.]

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
Hand desinfection	Professionals	Tier 1	5.79
Refilling	Professionals	Tier 1	0.18
Combined Hand desinfection + Refilling	Professionals	Tier 1	5.96

2.2.6.4 Risk characterisation for human health

Reference values have been derived during assessment of the active substance(s) for the purpose of approval see Section 2.2.6.1.

Maximum residue limits or equivalent

No MRLs are required.

Endocrine disrupting properties

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance.

Actually, no co-formulant of the biocidal product family was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. Two co-formulants are undergoing an ED assessment. However, no suggestions are available yet. Therefore, the co-formulants of the biocidal product family are not considered to have endocrine disrupting properties.

The full composition of the products of the BPF as well as the results of the ED-assessment of the co-formulants are summarised in the Confidential Annex.

Risk for industrial users

No industrial applications are intended for the products covered by meta SPC 1.

Risk characterisation for human health

The biocidal product family Brenntag GmbH Propan-2-ol Product Family comprises two meta SPCs concerning the professional user and a third concerning the non-professional user. An overview of the applications applied for the two meta SPCs is given in **Table 12** in chapter 2.2.6.3. All members of the biocidal product family Brenntag GmbH Propan-2-ol Product Family contain propan-2-ol (CAS No.: 67-63-0) as active substance.

The products of meta SPC 1 are ready-to-use hand disinfectant gels and ready-to-use hand disinfectant solutions.

The occupational risk assessment for biocidal products covered by meta SPC 1 takes into account systemic effects on the active substance propan-2-ol and and local effects of thebiocidal products.

Systemic effects

The primary toxic effect of the active substance propan-2-ol is acute central nervous system (CNS) depression and results in the classification of the biocidal products covered by meta SPC 1 with H336 (May cause drowsiness or dizziness). The risk characterisation for systemic effects of propan-2-ol is performed with the AEL approach. In this approach total internal body burden (total uptake) is compared to the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the biocidal products covered by meta SPC 1.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{acute/medium-/long-term}$ of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and exposure-to-AEL ratio (%)

For inhalation route 100 % is assumed as default absorption for propan-2-ol.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Due to the rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm^2/h) instead of data on the percentage of dermal absorption is used for the calculation of the dermal uptake. Application time/day and exposed skin area are shown in Table 17 (chapter 2.2.6.3). The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal products covered by meta SPC 1 are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m^3) x 10 m^3 / 60 kg x %-inhalation absorption / 100 %.
>
> Dermal uptake (mg/kg bw/d) = dermal flux of propan-2-ol (mg/cm^2/h) x exposed skin area (cm^2) x application time/day (h) / 60 kg.

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A Risk characterisation for human health referring to the active substance propan-2-ol resulting from the use of the biocidal products covered by meta SPC 1 is acceptable if the

exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 19 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 19. However, the underlying calculations are based on unrounded exposure values. As shown in Table 19, the scenarios 'hand disinfection - hygienic' as well as 'refilling' yield an exposure-to-AEL ratio of less than 100 % already in TIER 1.

Table 19: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1

Scenario	$AEL_{acute/medium-/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
Hand disinfection - hygienic Tier 1	17.9	1.73	4.06	5.79	32.33	**yes**
Refilling Tier 1	17.9	0.14	0.04	0.18	0.99	**yes**

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for human health resulting from the intended uses 'hand disinfection – hygienic' and 'refilling' is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A risk for human health referring to the active substance propan-2-ol resulting from the combined uses of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. Table 20 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 20. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 20, the combined scenario considered ('refilling + hand disinfection – hygienic') yields exposure-to-AEL ratio of less than 100 % already in TIER 1. This means that after TIER 1 consideration no risk for human health is identified.

Table 20: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenario for the biocidal products covered by meta SPC 1

combined scenario		$AEL_{acute/medium-/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
Refilling + hand disinfection - hygienic	Tier 1	17.9	1.87	4.09	5.96	33.32	**yes**

Tier 1: no PPE

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for human health resulting from the combined scenario 'refilling + hand disinfection – hygienic' is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Local effects

The local toxicity profile of the active substance propan-2-ol is also considered. The active substance propan-2-ol has eye irritating properties and therefore leads to classification of the biocidal products covered by meta SPC 1 with H319 (Causes serious eye irritation). In addition, the biocidal products covered by meta SPC 1 have to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking). Therefore, a qualitative risk assessment for local effects regarding skin and eye contact is necessary. The allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) is "low".

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) Table 21 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of biocidal products covered by meta SPC 1 for the intended uses 'hand disinfection – hygienic' and 'refilling'. With the proposed risk mitigation measures the reduction of dermal and eye contact minimizes the anticipated health risk to an acceptable level for the intended uses.

Table 21: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 1

PT	Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure [per day]	Potential degree of exposure of mucosa membranes (e.g. eyes)	Relevant RMM & PPE	Acceptability
01	Hand disinfection - hygienic	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	25 tasks per day; duration of dermal exposure: 1 min per task	eye contact not expected, dermal exposure (hands) intended	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	**Acceptable**
01 02 04	Refilling	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	1 task per day, dermal exposure, contact time: 0.5 min	Incidental eye contact, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene. The use of eye protection during handling of the product is recommended.	**Acceptable**

Conclusion

Concerning the local eye and skin effects of biocidal products covered by meta SPC 1, the intended uses 'hand disinfection – hygienic' and 'refilling' do not lead to concern for professional users.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [7a] Adults	1	68.5	10.7			
1 application				1.89	18	Yes
5 applications				9.40	88	Yes
25 applications				47.0	439	No
1 application	2	68.5	10.7	0.578	5.4	Yes
5 applications				2.88	27	Yes
25 applications				14.4	135	No
Scenario [7b] Children	1	68.5	10.7			
1 application				3.43	32	Yes
5 applications				17.2	161	No
25 applications				85.7	801	No
1 application	2	68.5	10.7	0.989	9.2	Yes
5 applications				4.95	46	Yes
25 applications				24.69	231	No

Local effects

Local reference values for non-professional users are not available. However, the biocidal products of this family relevant for non-professional use are classified as Eye Irrit. 2 (H319) and STOT SE 3 (H336). A human health risk from these hazards is not expected if the precautionary statements as given in section 2.3.6.3 are followed.

For eye-irritating formulations eye protection (P280) is normally required to avoid eye damage by splashes. The biocidal products of PT 1 are gels or liquids, which are applied directly to the hands. Splashes, which may reach the eyes, are normally not expected if the biocidal product is used as intended. Only if the user touches the eyes with the hands directly after application, irritation may occur. Hence, use is considered safe in relation to eye irritation if an appropriate labelling recommending to avoid eye contact is included. In addition, the precautionary statements for first aid instructions and emergency measures for H319 will minimise hazards from eye contact.

Conclusion

It must be expected that the biocidal products of Meta-SPC 3 (PT 1) are used by both adults and children for hand disinfection. For children it cannot be assumed that they will read and understand the instructions for use on the label. Based on the systemic and local risk assessment additional risk mitigation measures are required for a safe use (see below). Hence, adults have to supervise the children when the biocidal products are applied.

A human health risk has been identified for children if the biocidal products of Meta-SPC 3 (PT 1) are used more than 3 times per day in small, not ventilated rooms and the person stays there for a longer time interval. However, in Tier 2 safe use is demonstrated, if the room is well-ventilated. Also based on the classification with STOT SE 3, H336 use is limited to well-ventilated areas.

The biocidal product is classified as eye irritant. Hence, in addition to the corresponding first aid precautionary statements an advice to avoid contact with eyes is required. Eye protection is considered not appropriate for non-professional users.
The maximum application frequency for non-professional users is 5 d^{-1}.

A quantitative cumulative risk assessment is not required since only for the active substance a quantitative risk assessment is performed.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [8a] Adults	1	68.5	10.7			
1 application				1.72	16	Yes
5 applications				8.58	80	Yes
25 applications				42.9	401	No
1 application	2	68.5	10.7	0.413	3.9	Yes
5 applications				2.05	19	Yes
25 applications				10.3	96	Yes
Scenario [2b] Children	1	68.5	10.7			
1 application				3.21	30	Yes
5 applications				16.1	150	No
25 applications				80.3	750	No
1 application	2	68.5	10.7	0.773	7.2	Yes
5 applications				3.87	36	Yes
25 applications				19.3	180	No
Scenario [8c] Toddlers	1	68.5	10.7			
1 application				5.07	60	Yes
5 applications				25.3	236	No
25 applications				127	1187	No
1 application	2	68.5	10.7	1.22	11	Yes
5 applications				6.10	57	Yes
25 applications				30.5	285	No
Scenario [9a] Adults	1	68.5	10.7			
1 application				0.172	1.6	Yes
5 applications				0.860	8.0	Yes
25 applications				4.30	40	Yes
Scenario [9b] Children	1	68.5	10.7			
1 application				0.322	3.0	Yes
5 applications				1.61	15	Yes
25 applications				8.05	75	Yes
Scenario [9c] Toddlers	1	68.5	10.7			
1 application				0.508	4.7	Yes
5 applications				2.54	24	Yes
25 applications				12.7	119	No
Scenario [10a] Adults	1	68.5	10.7	3.44	32	Yes
Scenario [10b] Children	1	68.5	10.7	9.12	85	Yes
Scenario [10c] Toddlers	1	68.5	10.7	20.8	194	No
Scenario [10c]	2	68.5	10.7	10	93	Yes

Toddlers						

Combined scenarios

Not relevant.

Local effects

The biocidal products are classified with STOT SE 3, H336 and may cause drowsiness and dizziness. This effect is also relevant for bystanders near the application site. However, the precautionary statement (P271; Use only outdoors or in a well-ventilated area.) is also appropriate to protect the general public from higher exposure levels.
Other local effects (e.g. eye irritation and skin dryness) are considered not relevant for secondary exposure of the general public if the biocidal product is used as intended.

Conclusion
If biocidal products of Meta-SPC 1 and 3 (PT 1) are used as intended (5 per day in the private area, sufficient ventilation) no human health risks are expected (scenario 8). For use in public areas (scenario 9) even use frequencies up to 5 per day are considered safe for adults and children if they are used as intended and sufficient ventilation is ensured. The slight exceedance for toddlers is considered not relevant since it is based on the very conservative assumptions regarding the use frequency.
If biocidal products of Meta-SPC 2 (PT2 and 4, scenario 10) are used as intended, no human health risk is expected for adults and children exposed as bystanders. Based on the exposure assessment scenario 10 a human health risk for younger children (e.g. toddlers) can only be excluded if access to treated rooms is avoided for 30 minutes after application. The scenario is based on a ventilation rate of 2 h^{-1}. Under many circumstances even higher ventilation rates are possible (e.g. if windows are fully opened, hospitals with air condition systems) Hence, an advice is needed that adequate ventilation has to be ensured before re-entry of children.
Based on the classification and labelling with STOT SE 3, H336 the biocidal products of this family have to be used only in well-ventilated areas.

A quantitative cumulative risk assessment is not required since only for the active substance a quantitative risk assessment is performed.

Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Meta SPC 1 – professional user

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product family Brenntag GmbH Propan-2-ol Product Family is not required as meta SPC 1 of the biocidal product family contains only the active substance propan-2-ol and no substances of concern.

Summary of risk characterisation

Summary of risk characterisation for industrial user

No industrial applications are intended for the products covered by meta SPC 1.

Summary of risk characterisation for professional user

In summary, a risk for human health resulting from the intended use of the biocidal products covered by meta SPC 1 is unlikely. Risk mitigation measures described in chapter 2.1.4.5.2 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 1.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

For summary tables please refer to:

Table 19: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC **1**

Table 20: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenario for the biocidal products covered by meta SPC 1

Table 21: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 1

Summary of risk characterisation for non-professional user

Table 22

Scenario, Tier	**Relevant reference value** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
Scenario [7a] Adults, Tier 1 1 application 5 applications 25 applications	10.7	 1.89 9.40 47.0	 18 88 439	 Yes Yes No
Tier 2 1 application 5 applications 25 applications	10.7	 0.578 2.88 14.4	 5.4 27 135	 Yes Yes No
Scenario [7b] Children, Tier 1 1 application 5 applications 25 applications	10.7	 3.43 17.2 85.7	 32 161 801	 Yes No No
Tier 2 1 application 5 applications 25 applications	10.7	 0.989 4.95 24.69	 9.2 46 231	 Yes Yes No

Summary of risk characterisation for indirect exposure

Table 23

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
Scenario [8a] Adults, Tier 1	10.7			
1 application		1.72	16	Yes
5 applications		8.58	80	Yes
25 applications		42.9	401	No
Tier 2	10.7	0.413	3.9	Yes
1 application		2.05	19	Yes
5 applications		10.3	96	Yes
25 applications				
Scenario [8b] Children, Tier 1	10.7			
1 application		3.21	30	Yes
5 applications		16.1	150	No
25 applications		80.3	750	No
Tier 2	10.7	0.773	7.2	Yes
1 application		3.87	36	Yes
5 applications		19.3	180	No
25 applications				
Scenario [8c] Toddlers, Tier 1	10.7			
1 application		5.07	60	Yes
5 applications		25.3	236	No
25 applications		127	1187	No
Tier 2	10.7	1.22	11	Yes
1 application		6.10	57	Yes
5 applications		30.5	285	No
25 applications				
Scenario [9a] Adults	10.7			
1 application		0.172	1.6	Yes
5 applications		0.860	8.0	Yes
25 applications		4.30	40	Yes
Scenario [9b] Children	10.7			
1 application		0.322	3.0	Yes
5 applications		1.61	15	Yes
25 applications		8.05	75	Yes
Scenario [9c] Toddlers	10.7			
1 application		0.508	4.7	Yes
5 applications		2.54	24	Yes
25 applications		12.7	119	No
Scenario [10a] Adults	10.7	3.44	32	Yes
Scenario [10b] Children	10.7	9.12	85	Yes
Scenario [10c] Toddlers	10.7	20.8	194	No
Tier 2 Scenario [10c] Toddlers	10.7	10	93	Yes

2.2.7 Risk assessment for animal health

There is no toxicological information available implying that pets or domestic animals are more susceptible to the active substance or the biocidal product than humans. Thus, it is assumed that secondary exposure and risk assessment for the general public can be adopted to these animals. Hence, no animal-specific risk is identified and no specific risk mitigation measures are required. Risk mitigation measures resulting from the human exposure and risk assessment are also applicable for pets if adapted accordingly (e. g. pets have to be kept away from rooms where disinfection is taking place and adequate ventilation before re-entering has to be ensured; biocidal product has to be kept out of reach of pets).

2.2.8 Risk assessment for the environment

For meta SPC 1 the user categories "professional user" and "non-professional user" were applied for and assessed. As a result of the assessment (differences in C&L for both user categories) and due to the agreed SPC structure, the "non-professional user" had to be removed from meta SPC 1 and a new meta SPC 3 had to be generated for non-professional use only. However, the assessment of meta SPC 1 in this PAR still includes the non-professional use as applied for. Therefore the assessment of meta SPC 1 presented in this PAR covers the use of meta SPC 3.

The products of the biocidal products family (BPF) "Brenntag GmbH Propan-2-ol Family" contain Isopropanol/ Propan-2-ol as active substance (a.s.). They are intended to be used in product type 1 for the disinfection of hands by professional and non-professional users.

2.2.8.1 Effects assessment on the environment

As the products of the BPF contain no substances of concern for the environment, the environmental risk assessment is solely based on the a.s..

No additional studies on the ecotoxicity of the active substance propan-2-ol or the products of the BPF were provided by the applicant. Hence, the environmental effects assessment is based on the information given in the CAR and the AR of the a.s. prepared by the eCA Germany (2014, eCA DE).

Aquatic compartment (including sediment and STP)

- **Aquatic toxicity (incl. sediment)**

According to the CAR, acute and chronic data on effects of propan-2-ol on aquatic organisms are available:

Table 24: Summary table for acute aquatic toxicity.

Summary table for acute aquatic toxicity						
Guideline/ Test method/GLP status/reliability	Species	End point	Exposure		Results	Reference[1]
			Design	Duration	LC/EC_{50}	
Fish						
OECD 203	*Pimephales promelas*	mortality	Flow-through	96 h	8692 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Invertebrates						
Dutch standard method NEN 6501	*Daphnia magna*	immobility	static	48 h	2285 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Algae (growth inhibition)					E_rC_{50}	
BOD bottle test technique	*Pseudokirchneriella subspicata*	Growth inhibition	static	48 h	10500 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)

Table 25: **Summary table for chronic aquatic toxicity.**

Summary table for chronic aquatic toxicity						
Guideline/ Test method / GLP status/ reliability	Species	End point	Exposure		Results	Reference[1]
			Design	Dura-tion	NOEC/ EC_{10}	
Invertebrates						
Dutch standard method NEN 6502	*Daphnia magna*	growth	Semist atic	16 d	141 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Algae						
Cell multiplicati on Inhibition test	*Selenas trum capricor nutum*	Growth rate	Static	96 h	3154 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)

Based on the lowest available chronic effect value for *Daphnia magna*, a $PNEC_{water}$ of 2.82 mg a.s./L was derived by applying an assessment factor of 50.

Table 26: **Conclusion used in Risk Assessment- Aquatic toxicity.**

Conclusion used in Risk Assessment- Aquatic toxicity	
Value/conclusion	$PNEC_{water}$: 2.82 mg/L
Justification for the value/conclusion	The lowest effect value (NOEC = 141 mg a.s./L) for the aquatic compartment was derived from a long-term study with *Daphnia magna.* Based on the available acute and chronic data for the aquatic compartment an assessment factor of 50 has to be used for the derivation of $PNEC_{water}$.

Studies on sediment dwelling organisms are not available and are not necessarily required for the intended uses of the BPF. Therefore, the equilibrium partitioning method (EPM) was applied to estimate a $PNEC_{sediment}$ of 2.41 mg a.s./kg ww using the $PNEC_{water}$ (Eq. 89; Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

Table 27: **Conclusion used in Risk Assessment- Sediment toxicity.**

Conclusion used in Risk Assessment- Sediment toxicity	
Value/conclusion	$PNEC_{sediment}$: 2.41 mg/kg ww
Justification for the value/conclusion	Using the equilibrium partitioning method (EPM) $PNEC_{sediment}$ was calculated based on $PNEC_{water}$ according to equation 89 (Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

- **Inhibition of microbial activity (STP)**

The effect of propan-2-ol on aerobic biological sewage treatment processes was assessed by determining respiration inhibition of the microorganisms present in activated sludge (according to OECD 209). The EC_{50} was calculated to be >1000 mg a.s./L nominal. Applying an assessment factor of 100 to the EC_{50} of the respiration inhibition test a **$PNEC_{STP}$ = 10 mg/L** was concluded.

Table 28: **Conclusion used in Risk Assessment- STP.**

Conclusion used in Risk Assessment- STP

Value/conclusion	$PNEC_{STP}$: 10 mg/L
Justification for the value/conclusion	Using a respiration inhibition test (OECD 209) $PNEC_{STP}$ was calculated from the EC_{50} applying an AF of 100 (Guidance on BPR Vol. IV Part B, Chapter 3.4)

Terrestrial compartment (including groundwater)

Since a direct exposure of the terrestrial compartment and adsorption of the a.s. to soil is not expected from the use of the products of the BPF, the provision of experimentally derived data on the toxicity of the propan-2-ol to terrestrial organisms is not required. Thus, $PNEC_{soil}$ was derived by applying the equilibrium partitioning method as described in equation 91 of the Guidance on the BPR: Volume IV Part B Risk Assessment (EU, 2017). Thus, a $PNEC_{soil}$ of 0.496 mg a.s./kg ww was determined.

Table 29: Conclusion used in Risk Assessment –Terrestrial compartment.

Conclusion used in Risk Assessment –Terrestrial compartment.	
Value/conclusion	$PNEC_{soil}$: 0.496 mg/kg ww
Justification for the value/conclusion	Using the equilibrium partitioning method (EPM) $PNEC_{soil}$ was calculated based on $PNEC_{water}$ according to equation 91 (Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

Atmosphere

For the air compartment no ecotoxicological data are available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

Aquatic bioconcentration

No studies on aquatic bioconcentration were provided by the applicant. In the CAR for propan-2-ol, bioconcentration factors (BCFs) were estimated according to the procedures described in Eq. 93 and 104d of the Guidance on the BPR: Volume IV Part B Risk Assessment (2017). By applying the experimentally derived $logK_{OW}$ of 0.05 a BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww were determined. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-2-ol can be considered low. Propan-2-ol is not expected to accumulate in the environment.

Table 30: **Summary table – Estimated aquatic bioconcentration.**

Summary table – Estimated aquatic bioconcentration				
Basis for estimation	**Log K_{ow} (measured)**	**Estimated BCF for fish**	**Estimated BCF for earthworms**	**Reference**[1]
$LogK_{ow}$	0.05	0.22	0.85	Final CAR Propan-2-ol eCA: DE (2014)

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

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

Further Ecotoxicological studies

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

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

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

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

This aspect is not relevant for the BPF as the products are not applied in form of baits or granules.

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

This aspect is not relevant for the BPF as the products are not applied in form of baits or granules.

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

This aspect is not relevant for the BPF as the products are not applied in large quantities outdoors.

Environmental fate and behaviour

Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290nm and 750nm takes place. Therefore, propan-2-ol is not accessible for direct photodegradation in sunlight. Propan-2-ol is classified as readily biodegradable. Propan-2-ol has a relatively high vapour pressure at 5780 Pa at 25°C, therefore, direct evaporation is expected. The Henry's Law constant for propan-2-ol is 0.80 Pa m^3/ mol at 25°C. This indicates that propan-2-ol is moderately volatile. Propan-2-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. Based on a reaction rate constant of $5.1x10^{-12}$ cm^3/mol sec by Atkinson et al. (2006) a half-life of 3.1 days can be estimated. Based on a log K_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} was estimated as 3.3 L/kg. Therefore, propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-2-ol in soil and a very low geo-accumulation potential.

For a more detailed assessment of the environmental fate and behavior of the active substance propan-2-ol please refer to the Assessment Report of propan-2-ol of the BPD.

Biodegradation / Metabolites

Propan-2-ol is classified as readily biodegradable. No data on biodegradation in soil, water/sediment or sewage treatment plants are available as in light of the screening test result no further studies were deemed necessary. For risk refinement purposes default half-lives of 15 days for biodegradation in surface water and 300 days in sediment can be assumed. For the soil compartment a default half-life of 30 days should be applied. For elimination estimations in sewage treatment plants a rate constant of 1 h^{-1} was used.

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)

This aspect is not relevant for the BPF under consideration as the products are used indoors.

2.2.8.2 Exposure assessment

General information
In meta SPC 1 "Brenntag GmbH Propan-2-ol Product Family" contains products that are used in PT 1 for disinfection by professional and non-professional users. The ready-to-use products of the BPF contain up to 70% w/w of the active substance propan-2-ol and are available as gels or solutions. They may be applied by pouring 3mL of product in the palms of the hands. The following exposure scenarios were assessed:

Table 31: Intended use in PT 1.

Assessed PT	PT 1
Assessed scenarios	Meta SPC 1, Use 1a: hand disinfection by professional users Meta SPC 1, Use 1b: hand disinfection by non-professional users
ESD(s) used	Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004)
Approach	Use 1a und b: Average consumption/ tonnage approach
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017)
Groundwater simulation	YES: FOCUS PEARL (v.4.4.4) refinement
Confidential Annexes	YES: In the confidential Annex the tonnage based approach is provided.
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-/-

Fate and distribution in exposed environmental compartments

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the active substance (a.s.) is released to air and 10% of the a.s. is released to water. According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In case of the ready-to-use (RTU) products of the BPF "Brenntag GmbH Propan-2-ol Product Family" containing 70% w/w propan-2-ol, the disinfection is finished when the treated surface

completely dried, and the product has evaporated completely. This is facilitated by the relatively high vapour pressure of propan-2-ol. Nearly the whole amount of substance applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to waste water – via leakages or rinse off – cannot be excluded for liquid products. Therefore, for the environmental risk assessment of the BPF "Brenntag GmbH Propan-2-ol Product Family", the distribution used during the assessment of the active substance is maintained since it is plausible that the main emission path will be via air.

According to CG-17 document No. AP 13.1-CG-17-2016-13 "Evaluation of alternative dossiers during product authorisation" the LoEP values in the CAR of respective a.s. (in this case: Propan-2-ol) have to be used for the environmental exposure and risk assessment:

- No hydrolysis under environmental conditions.
- Photolysis in water is not applicable, no absorption maximum >290 nm.
- Tropospheric half-life of propan-2-ol: 3.1 d (according to Atkinson et al. (2006), reaction with OH radicals (global 24-hours mean), concentration: 5 x 10^5 OH/cm^3).
- K_{OC} was estimated by QSAR-model for alcohols described in EU TGD (2003): K_{OC} = 3.3 L/kg, no pH dependence

The vapour pressure of propan-2-ol is 5780 Pa at 25°C and direct evaporation is expected, consequently. The Henry's constant is 0.80 Pa m^3 mol^{-1} at 25°C. According to a suggested classification scheme after Lyman et al. (1983) the Henry's law constant indicates moderate volatility from water.

Table 32: Input parameters for calculating the fate and distribution in the environment

Input	Value	Unit	Remarks
Molecular weight	60.09	g/Mol	
Vapour pressure (at 12°C)	2304	Pa	
Water solubility (at 25°C)	1	kg/L	complete miscible with water
Organic carbon/water partition coefficient (K_{OC})	3.3	L/kg	
Henry's Law Constant (at 12°C)	0.383	Pa m^3 mol^{-1}	Temperature corrected from measured Henry's Law constant of 0.80 Pa m^3 mol^{-1} at 25°C
Biodegradability			a.s. is readily biodegradable
Rate constant for STP	1	h^{-1}	
DT_{50} for degradation in soil	30	d	
Degradation rate constant with OH-radicals (K_{OH})	$5.1x10^{-12}$	cm^3/mol sec	From Atkinson et al. 2006 with 5 x 10^5 OH/cm^3 and 24 hour

The distribution in the sewage treatment plant is calculated using SimpleTreat v.3.1. This results in release fractions to air of 0.3 %, water 12.5 %, sludge < 0.1 % and degraded fraction 87.1 %. For further exposure calculations, the fraction released to the environment via sludge is considered as negligible, considering the low share of propan-2-ol in sludge (<0.1 %) as well the ready biodegradability of propan-2-ol and the potential volatilisation from soil.

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

The application of the BPF "Brenntag GmbH Propan-2-ol Product Family" used for disinfection results in indirect exposure of the environment via the air (wet and dry deposition) and to a lesser extent via STP. Following environmental compartments might be exposed by application of products of meta SPC 1:

Table 33: Identification of relevant receiving compartments based on the exposure pathway

Meta SPC	Use	PT	**Wastewater (STP)**	**Surface water and Sediment**	**Soil and Groundwater**	**Air**
1	1	1	yes	yes (indirect)	yes (indirect)	yes

Local emission estimation for relevant environmental compartment

Meta SPC 1 (PT1)

Use 1: PT1 – Hand disinfection

The emission scenario for disinfectants used for skin and hand application is described in detail in chapter 4 of the Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004); for input and output values see following tables. Two approaches are calculated: (1) consumption based approach and (2) tonnage based approach. Emission scenarios differ between use by professionals and non-professionals.

a) Professional user

Consumption based approach

Table 34: Input parameters and emission rates to the environment for PT1, use 1, according to the consumption-based approach

Determinants of the emission scenario according to chapter 4, table 4.5; Environmental Emission Scenarios for PT 1 (Royal Haskoning, 2004)	**Value**
Number of beds in model hospital (D)	400
Occupancy rate (D)	0.75
Fraction released to waste water (CAR)	0.1
Fraction released to air (CAR)	0.9
Consumption of a.s. per bed (D)	15 g/d
Emission rates according to equation A+C, Royal Haskoning (2004)	**Value**
Local emission rate to waste water during the use of the hand and skin disinfectant	0.6 kg/d
Local emission rate to air during the use of the hand and skin disinfectant	5.4 kg/d

(D) – Default for Alcohols (Royal Haskoning, 2004); (CAR) – CAR Propan-2-ol (2014)
(CAR) – CAR Propan-2-ol (2014)

Tonnage based approach

The resulting local emission of propan-2-ol to waste water and air from the application of products of meta SPC1 of the biocidal product family "Brenntag GmbH Propan-2-ol Product Family" based on tonnage is given in the Confidential Annex.

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

b) Non-professional user

Please note: The assessment below is based on the use of the product by non-professional users, as applied for by the applicant (s. ch. 2.2.1). Originally, up to 25 applications per day has been requested by the applicant. The number of applications per day by non-professional users was reduced to 5 applications per day due to concerns for human health (s. ch. 2.1.5.4.1).
However, the assessment of 25 applications per day also covers a lower number of applications per day.

Consumption based approach

Table 35: Emission scenario for disinfectants used in human hygiene biocidal products (private use), calculations based on consumption

Determinants of the emission scenario according to chapter 4, table 4.2; Environmental Emission Scenarios for PT 1 (Royal Haskoning, 2004)	**Value**
Number of inhabitants feeding one STP (D)	10000
Fraction released to waste water (CAR)	0.1
Fraction released to air (CAR)	0.9
Active substance in product (S)	700 g/kg
Consumption per application (S)	3 mL
Number of applications (S)	25 d^{-1}
Fraction of inhabitants using product N (TAB ENV 42)	0.5
Market share of disinfectant (D)	0.5
Specific density of product (S)	0.879 kg/L
Emission rates according to equation B+D1; Royal Haskoning (2004)	**Value**
Local emission rate to waste water during the use of the hand and skin disinfectant	11.53 kg/d
Local emission rate to air during the use of the hand and skin disinfectant	103.78 kg/d

(D) – Default (Royal Haskoning, 2004)
(TAB) – Technical Agreements for Biocides (Version 2.0, 2018)
(CAR) – CAR Propan-2-ol (2014)
(S) – Provided by applicant

Tonnage based approach

The resulting local emission of propan-2-ol to waste water and air from the application of products of meta SPC 1 of the biocidal product "Brenntag GmbH Propan-2-ol Product Family" based on tonnage is given in the Confidential Annex.

Conclusion

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

Calculated PEC values

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). In addition, based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in a negligible concentration of propan-2-ol in sewage sludge. Therefore, no PECsoil and PECGW values were calculated for "Brenntag GmbH Propan-2-ol Product Family".

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{eff}$) according to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B+C (2017)

  According to the proposed use of the BPF, the interval between two releases to the STP is shorter than one month and therefore, the effluent concentration is representative for the exposure of microorganisms in STP.
- $PEC_{local\_surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR IV ENV B+C (2017);
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR IV ENV B+C (2017).

The local PEC values for meta SPC 1, based on the consumption approach, are presented in the following table and are used for the environmental risk assessment.

Table 36: Summary table of calculated PEClocal values from intended uses of "Brenntag GmbH Propan-2-ol Product Family"

Summary table on calculated PEC values										
Meta SPC	**Use**	**PT**	**user**	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**			**PEC_{air}**	
				µg/L	µg/L	µg/kg_{wwt}			mg/m^3	
1	1	1	professional	37.5	3.75	3.2			$1.501x10^{-3}$	
1	1	1	non-professional	720.63	72.06	61.53			0.029	

Primary and secondary poisoning

According to the CAR of propan-2-ol (2014), secondary poisoning is not relevant for propan-2-ol. Due to its physical properties propan-2-ol has only a low potential for bioaccumulation in the terrestrial and in the aquatic food chain (see chapter 2.2.8.1).

2.2.8.3 Risk characterisation

Atmosphere

As stated in section 2.2.8.1, ecotoxicological data for the air compartment are not available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance and no risk assessment for the air compartment is possible.

Sewage treatment plant (STP)

Table 37: *PEC/PNEC ratios for the STP related to use 1.*

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Professional user	0.00375
Non-professional user	0.072

Conclusion: The calculated PEC/PNEC-values are below 1 indicating an acceptable risk for the STP from the use of the product of the BPF in PT 1.

Aquatic compartment

Table 38: PEC/PNEC ratios for surface water and sediment related to use 1.

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Professional user	0.00133	0.00133	Not relevant	Not relevant
Non-professional user	0.025	0.025	Not relevant	Not relevant

Conclusion: The calculated PEC/PNEC-values are below 1 indicating an acceptable risk for the aquatic compartment from the use of the products of the BPF in PT 1.

Terrestrial compartment

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). Because it was not relevant to calculate a PEC_{soil} (see TAB ENV-A5), the $PEC_{soil}/PNEC_{soil}$ was not determined.

The fraction of propan-2-ol released to soil via sludge is considered as negligible, therefore no PEC_{soil} and no $PEC_{soil}/PNEC_{soil}$ were derived.

Groundwater

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). Additionally, as the fraction of propan-2-ol released to the soil via sludge is considered as negligible, the subsequent leaching to groundwater can be considered as negligible, too.
Therefore, no PEC_{GW} values were calculated for "Brenntag GmbH Propan-2-ol Product Family".

Mixture toxicity

The products of the biocidal product family "Brenntag GmbH Propan-2-ol Product Family" contain no substances of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance propan-2-ol.

Aggregated exposure (combined for relevant emission sources)

Biocidal active substances are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentration of active substance to be found in the environment.

Article 19(2) of the Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." This is further elaborated in Annex VI (common principles for the evaluation of biocidal products), which states that the risks associated with the relevant individual components of the biocidal product shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs.

According to the "Decision tree on the need for estimation of aggregated exposure" (refer to Guidance BPR IV ENV Part B+C (2017)) shown in Figure 1, an aggregated exposure assessment is not required for the biocidal product "Brenntag GmbH Propan-2-ol Product Family" containing propan-2-ol as active substance.

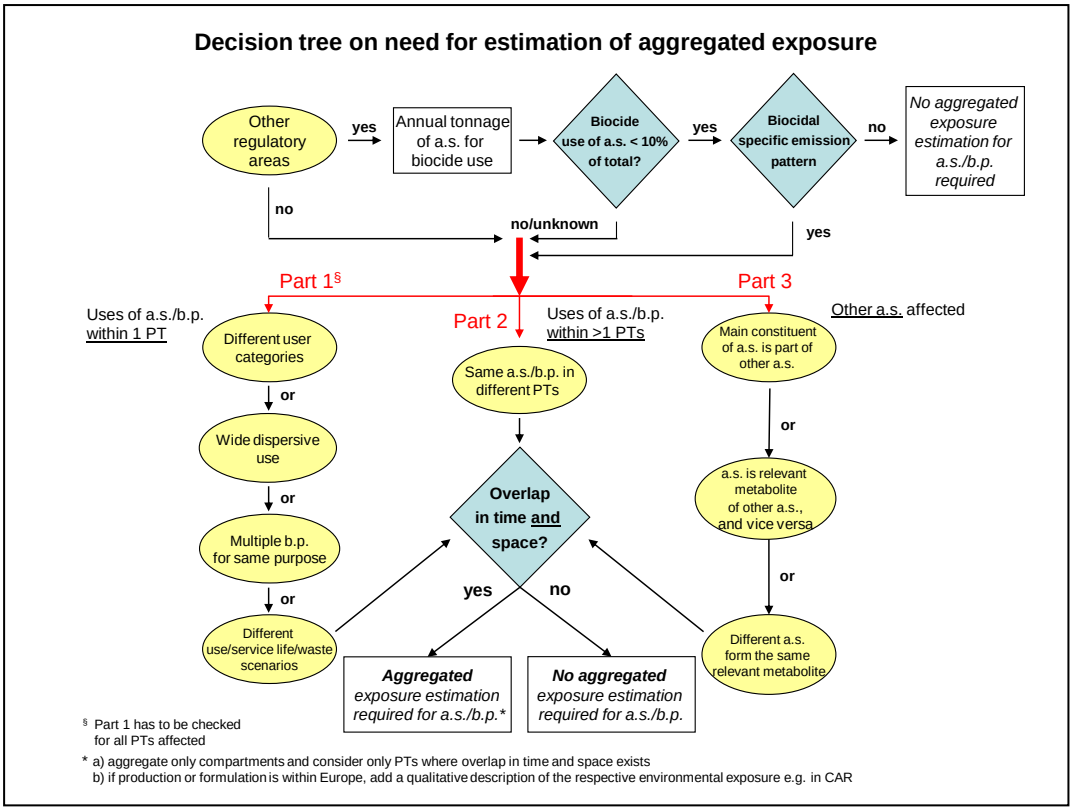


Figure 1: Decision tree on the need for estimation of aggregated exposure

The active substance propan-2-ol is notified for the list of approved substances in three products types (PT1, 2 and 4). Propan-2-ol is also evaluated in the frame of other regulatory areas (e.g. REACH). According to OECD SIDS Dossier of the HPV chemical Isopropanol (1997) most propan-2-ol goes into the solvent market either directly or via conversion to acetone or one of acetone's derivates. Small percentages are used for esters and as rubbing alcohol. The total European production volume of propan-2-ol in 1995 was reported to be 619000 tons (OECD 1997). According to the provided tonnage information only a small fraction (< 10 %) of the total tonnage produced is used as biocidal active substance. A specific emission pattern for propan-2-ol due to the use of products of "Brenntag GmbH Propan-2-ol Product Family" cannot be identified. The occurring emissions in PT1, PT2 and PT4 have been described as diffuse atmospheric emissions. This is comparable to other, non-biocidal, propan-2-ol emission sources, like e.g. solvents in inks, coatings, cosmetics and pharmaceuticals. Consequently, no aggregated exposure is required for propan-2-ol released due to the use of biocidal product "Brenntag GmbH Propan-2-ol Product Family".

PBT-Assessment

No new data were provided by the applicant. Thus, the conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substance propan-2-ol. Accordingly, propan-2-ol thus neither fulfils the PBT- nor the vP/vB-criteria.

Endocrine disrupting properties

According to the CAR for propan-2-ol, there are no indications for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance according to Regulation 2017/2100 and the EFSA/ECHA guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the products of the BPF as well as the results of the ED-assessment of the co-formulants are summarised in the „Confidential Annex.doc".

Overall conclusion on the risk assessment for the environment of the product
No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal products in meta-SPC 1 of the BPF.

2.2.9 Measures to protect man, animals and the environment

Please see the relevant chapters of the product family evaluation and the Summary of Product Characteristics (SPC).

2.2.10 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

2.2.11 Comparative assessment

No candidate for substitution was identified, hence a comparative assessment is not necessary.

2.3 Assessment of the biocidal product family Meta-SPC 02

Meta SPC identifier: Meta SPC 02

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

Intended use # 2 – Liquid Spray– General surface disinfection

Product Type(s)	2
Where relevant, an exact description of the authorised use	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Vegetative bacteria, yeast
Field of use	For use in public, healthcare, industrial areas and in areas for professional activities.
Application method(s)	Spraying on surfaces
Application rate(s) and frequency	For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces and let to dry (10-15 minutes) at room temperature. Application according to requirements, one application per use, duration 10-15 minutes, 4 times per day.
Category(ies) of user(s)	professional user
Pack sizes and packaging material	bottle HD-PE: 0,1L - 2,5L; can HD-PE: 5L - 60L; drum HD-PE: 200L; IBC container HD-PE: 1000L

Intended use # 3 – Liquid Spray - Disinfection for food contact surfaces

Product Type(s)	4
Where relevant, an exact description of the authorised use	Surface disinfection in food sector or food processing industries (including food contact)
Target organism (including development stage)	Vegetative bacteria, yeast
Field of use	Food sector or food processing industries.
Application method(s)	Spraying on surfaces
Application rate(s) and frequency	For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces and let to dry (10-15 minutes) at room temperature. Application according to requirements, one application per use, duration 10-15 minutes, 4 times per day.
Category(ies) of user(s)	professional user
Pack sizes and packaging material	bottle HD-PE: 0,1L - 2,5L; can HD-PE: 5L - 60L drum HD-PE: 200L; IBC container HD-PE: 1000L

2.3.2 Physical, chemical and technical properties

The physico-chemical data of meta SPC 1 and 2 are stated in different sections (2.2.2 and 2.3.2). In Meta SPC 2 a product was tested comprising the least amount of ingredients. In Meta SPC 1 the product "IPA-Co-Formulants-Stability-Test-Formulation" was generated only to test physico-chemical data with the highest amount of all "functions" like dye, thickener, and so on. The composition of this "artificial" product is stated in the confidential annex. By this the whole frame of compositions is covered.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual	"70:30 IPA:Water RTU", Batch No. 15014, AS (active substance) content: 63.5%	liquid	M Casco Palau, 2016, Report no. RJ74NG;
Colour at 20 °C and 101.3 kPa	visual	"70:30 IPA:Water RTU", Batch No. 15014, AS content: 63.5%	Product without dye: colourless Product with dye: blue	M Casco Palau, 2016, Report no. RJ74NG;
Odour at 20 °C and 101.3 kPa			For products comprising perfume, the odour is characteristic perfume-like. For products that do not comprise perfume, the odour is characteristic alcohol-like (deriving from >62% propan-2-ol.	
Acidity / alkalinity	pH value determined according to CIPAC MT 75.3	*"70:30 IPA:Water RTU", Batch No. 15014,* *AS content: 63.5%*	*pH = 7.81*	70:30 IPA:Water RTU M Casco Palau, 2016, Report no. RJ74NG;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Acidity determined according to CIPAC MT 191			
Relative density / bulk density	OECD Method 109 / EC Method A.3	"70:30 IPA:Water RTU", Batch No. 15014, AS content: 63.5%	$D^{20}_4 = 0.871$	M Casco Palau, 2016, Report no. RJ74NG;
Storage stability test – **accelerated storage**	CIPAC MT 46.3	"70:30 IPA:Water RTU", Batch No. 15014	70:30 IPA:Water RTU, 18 weeks at 30°C in commercial 1L PE containers; AS content: 63.5% w/w before, 62.8% w/w after storage, loss of 1.1 % Appearance: Colourless, transparent, homogenous liquid. No signs of precipitation or sedimentation observed. No change in packaging observed, packaging remained integrity after storage. Weight loss: 0.07% after 4 weeks, 0.32% after 18 weeks pH: before storage: 7.8, after storage 7.3 Please also refer to the data for MetaSPC1 in which the product "IPA-Co-Formulants-Stability-Test-Formulation" was tested that covers the BPF for storage stability tests. .	M Casco Palau, 2016, Report no. RJ74NG;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**		"70:30 IPA:Water RTU", Batch No. 15014	Storage over 24 months at 25 ± 2 °C in 1L PE bottles. AS content: T0 = 63.5% T6 months = 63.5% T12 months = 63.1%, T18months = 63.5%, T24months = 63.4% Decrease of AS content of 0.2% after 24 months. Appearance of the formulation or packaging did not change during storage of 24 months. Weight loss of 1.08% after 24 months pH: T0 = 7.81 T6 = 7.15 T12 = 7.14 T18 = 7.22 T24 = 7.15 Discharge Rate T0 = 0.999 g/stroke T24 = 1.18 g/stroke Mean Spray diameter T0 = 280 mm T24 = 270 mm Please also consider the data for MetaSPC1 in which the product "IPA-Co-Formulants-Stability-Test-Formulation" was tested to cover altogether the BPF for storage stability tests.	O'Connor, 2018, Report no. WP93TH;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			A storage stability of 24 months can be granted.	
Storage stability test – **low temperature stability test for liquids**			Waiving acceptable. A water/propan-2-ol mixture (60-70% IPA) has a freezing and melting point significantly below 0°C. Therefore a test at 0°C for 7 days would not lead to a freezing of the solutions. Effects that could result from freezing and defrosting cannot happen. Hence, a test is not deemed necessary.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver		Propan-2-ol does not absorb ultraviolet radiation (No absorption > 290 nm). Consequently photolysis could not be a route of degradation of propan-2-ol, i.e. the stability of a binary propan-2-ol/water mixture will not be affected by luminous intensity. Additionally, many of the products being registered are contained within opaque containers. Data on the dyes within the formulations has been provided by the manufacturer that states they have very good light fastness in aqueous solutions. Manufactures of the dyes and perfumes featured within formulations in this product family have confirmed the dyes and perfumes should be stable to light so would not be expected to be significantly impacted by natural light. All products should be stored within UV protected HDPE and in cardboard boxes prior to use. Only indoor use is supported by this product family which should further reduce the likelihood of exposure to intense light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			According to label claim: Keep cool and in a well-ventilated place. Furthermore the products of the BPF contain water. Thus effects of humidity can be excluded.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The Data about the packaging material is sufficient. Not reactive towards container material after ambient storage.	Dangerous Goods Database http://www.dgg.bam.de/en/ Number: 734
Wettability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Suspensibility, spontaneity and dispersion stability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Wet sieve analysis and dry sieve test	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Disintegration time	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187, Laser Diffraction	Curacid HD-sept, Batch No. 18007	Dv (10%) ≤22.8µm Dv (50%) ≤50.0µm Dv (90%) ≤116.4µm MMAD equal with Dv50% = 50µm	Manka, S., 2018, Report No. Mo6283
	SOP-PR-051 analogous to CIPAC MT 187	"70:30 IPA:Water RTU", Trigger heads: Chrystel gold Batch number: WO46276	D_{10}: 52 µm D_{50}: 162 µm D_{90}: 445 µm	Mack, L., 2019, Report No.: AQ121-19; Mack, L., 2019, Report No.: AQ122-19; Mack, L., 2019, Report No.: AQ123-19;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Chrystel gold Batch number: WO46140 Easydes IPA Batch number: 2019-07-24 HD9 Quick germs (same as HD10 Fast Germs) and TS5 Batch number: 2019-07-29	D_{10}: 45 µm D_{50}: 127 µm D_{90}: 384 µm D_{10}: 91 µm D_{50}: 365 µm D_{90}: 725 µm D_{10}: 33 µm D_{50}: 86 µm D_{90}: 217 µm	Mack, L., 2019, Report No.: AQ125-19
Persistent foaming	Waiver		Not applicable. The products are not intended to be diluted.	
Flowability/Pourability/Dustability	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Burning rate — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Burning completeness — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Composition of smoke — smoke generators	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Spraying pattern — aerosols	Waiver		Not applicable. Test need not be conducted for the type of formulation.	
Physical compatibility	Waiver		The product is not intended to be used in direct combination with any other product.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Chemical compatibility	Waiver		The product is not intended to be used in direct combination with any other product.	
Degree of dissolution and dilution stability	Waiver		Not applicable. The products are not intended to be diluted.	
Surface tension	OECD Method 115 / EC Method A.5 (ring method)	"70:30 IPA:Water RTU"; Batch No. 15014	26.0 mN/m at 20°C (undiluted BP); 71.3 mN/m at 20°C (1g/L solution in purified water)	RTU M Casco Palau, 2016, Report no. JS24WB
Viscosity	OECD Test Guideline 114 (capillary viscometer (static))	"70:30 IPA:Water RTU", Batch No. 15014, AS content: 63.5%	4.19 mm²/s at 20°C; 2.13 mm²/s at 40°C	M Casco Palau, 2016, Report no. XD38JQ

Conclusion on the physical, chemical and technical properties of the product
The products in this meta SPC without dye are colourless and with blue dye. For products comprising perfume, the odour is characteristic

perfume-like. For products that do not comprise perfume, the odour is characteristic alcohol-like. The pH of a representative product within the meta SPC is 7.8, the relative density is 0.871.
The products (ready-to-use liquids) have a shelf life of 24 months based on the results of the accelerated storage studies as well as on the long term storage studies at ambient temperature. Yet, an instruction for use "Products must be shaken before use" shall be used because of a reversible phase separation after storage. The MMAD of the different trigger heads ranges from 86µm – 365 µm.

The surface tension ofa representative product within the meta SPC is 71.3 mN/m as 1 g/L solutions in water at 20°C, and 26.0 mN/m for the undiluted BP at 20 °C. The kinematic viscosity is around 79.2 mm²/s at 20°C and 29.5 mm²/s at 40°C.

2.3.3 Physical hazards and respective characteristics

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in propan-2-ol, water and the other non-active substances which are associated with explosive properties.	IUCLID[4]
Flammable gases	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Flammable aerosols	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Oxidising gases	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID

[4] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Flammable liquids	ASTM D93 Guideline 440/2008(EC) Annex A.9	Desmila HSI D (Batch No. 25082020-01), 63% w/w 2-Propanol Isopropanol 70 Biozid (Batch No. 0000991071) 70% w/w 2-Propanol	Flash point: Desmila HSI D: 12.5 °C Isopropanol 70 Biozid: 14.5 °C Boiling point: 80.6 °C of azeotropic mixture	Flammable liquid, Category 2 based on GHS/CLP Criteria	Mack, L., 2020 (Report No. Mo6859) Mack, L., 2020 (Report No. Mo6860)
Flammable solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in propan-2-ol, water and the other non-active substances which are associated with explosive or self-reactive properties.	IUCLID
Pyrophoric liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the products are known to be stable in contact with air at room temperature for prolonged periods of time (days).	IUCLID
Pyrophoric solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-heating substances and mixtures	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the substances are known to be soluble in water to form a stable mixture.	IUCLID
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the products are classified as Flam. Liq. 2; H225: Highly flammable liquid and vapour. Actual testing of oxidising properties with highly flammable substances and mixtures according to UN Test O.2 is very difficult due to burning of the flammable liquid. Correct interpretation of the test results and application of the classification criteria are not possible. Additionally, none of the organic substances in the BPF are expected to have oxidising properties based on the fact that the contained oxygen or halogens are only bound to carbon or hydrogen.	IUCLID
Oxidising solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the products do not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Corrosive to metals	UN Guideline C.1, Section 37.4	Isopropanol 70 Biozid (Batch No. 0000991071), 70% (w/w) 2-Propanol	Maximum weight loss 0.01% after 7 d No localized corrosion observed.	The product is not considered corrosive to metals in the sense of the guideline.	Mack, L., 2020 (Report No. Mo6862)
Auto-ignition temperature (liquids and gases)	study scientifically not necessary		Auto-ignition temperature: 425 °C (for pure propan-2-ol)	Waiver: Assuming the lowest available auto-ignition temperature of propan-2-ol (425 °C) as worst case is considered to be sufficiently protective for the usage of the product.	Chemsafe (2017)
Relative self-ignition temperature for solids	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID
Dust explosion hazard	study scientifically unjustified			Not applicable The study does not need to be conducted because products are liquids	IUCLID

Conclusion on the physical hazards and respective characteristics of the product
The data provided by the applicant was acceptable. The measured flashpoints of representative samples are < 23 °C. The boiling point of propan-2-ol is >35 °C according to CAR. Therefore, all liquid products of the BPF should be considered as flammable liquids, category 2. Propan-2-ol has an upper explosion limit of 12% (V) and a lower explosion limit of 2% (V). The auto-ignition temperature of propan-2-ol is 425 °C and can also be used for the products of the BPF "Brenntag GmbH Propan-2-ol Product Family" as a worst case. The products of the BPF are not expected to have any explosive or oxidising properties. A study on a representative sample led to the conclusion that the products of the BPF are not corrosive to metals. Based on experience in production and handling it can be concluded that the products of the BPF are not pyrophoric and do not evolve any flammable gases in contact with water or humid air. According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified as follows:

Flam. Liq. 2; (Flammable liquids, category 2) H225: Highly flammable liquid and vapour

2.3.4 Methods for detection and identification

Table 39

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance *Isopropanol* *(Test product:* *70:30 IPA:Water RTU and Wofasept AHA (only repeatybility)*	SANCO/3030/99 GC- FID/MS	Given,Test conducted with blank, standard and sample solution, no interference	R^2=0.9997	1500 mg/L (n=2), 2000 mg/L (n=2), 2500 mg/L (n=3)	97,8% – 103%	100%	1.69%	Not relevant;	M Casco Palau, 2016, Report no. TH36LB
Active substance *Isopropanol* *(Test product:* *IPA-Co-Formulants-Stability-Test-Formulation; Please refer to*	SANCO/3030/99 GC- FID	Specificity is given, test conducted with blank, standard and sample solution, no interference	R^2 = 1	1400 mg/L (n=3), 2000 mg/L (n=3) and 2600 mg/mL (n=3)	98.5 - 100.4%	99.4%	0.6%	Not relevant;	Matyssek, F, 2018, Report No. Mo6079

confidential annex for composition)									

Table 40

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (01/2015)
Drinking water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (01/2015)
Surface water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (01/2015)
Air	propan-2-ol	3.2 mg/m³	$AEL_{acute/medium\text{-}term/long\text{-}term}$:10.7 mg/kg bw/d (general population) AR for PT1, PT2, PT4; LoEP (01/2015)
Animal and human body fluids and tissues	no relevant residues		not classified as toxic or very toxic
Food of plant origin	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (01/2015)
Food of animal origin	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (01/2015)

Table 41:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

propan-2-ol	GC-FID, DB-5MS column	confirmation by GC-MS possible	Calibration in solvent: 0.34 – 3.4 µg/mL R^2=0.9983 matrix-matched calibration: 0.50 – 12.56 mg/mL R^2=0.9998	Air 21 °C, 80 % rel humidity (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6 Dry air (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6	99.2-101 102-103.6 102.7-104.9 102.1-104.8 103.2-104.3 102.6-104.6 101.1-103.4 102.3-104.5 102.5-104.4 104-106.1 103.3-105.3 103.1-107.3	100.2 102.9 103.6 103.2 103.7 103.8 102.5 103.3 103.4 104.8 104.5 105.4	0.8 0.8 1.0 1.1 0.3 0.7 1.0 0.9 0.7 0.8 0.7 1.7	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit 0.05 x OSHA target concentration of 983 mg/m³)	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997

				1966 mg/m³ / 6					
propan-2-ol	GC-MS using DB-5 column, m/z 59 as quantifier and m/z 45 as qualifier	confirmation not included, since for second fragment ion no validation data presented	0.025 – 7.4 mg/mL R^2=0.995 – 1.000	Air (considering maximum sample volume of 23.8 L of OSHA-method 9.4 mg/m³ / 5 93.8 mg/m³ / 5 250 mg/m³ / 4 750 mg/m³ / 5	97.3-103 106-115 105-110 104-110	99.2 111 107 107	2.6 3.1 2.1 2.3	LOQ of the method is dependent on sampling volume: The lowest concentration of 0.025 mg/mL corresponds to 3.1 mg/m³ 2-propanol in air at the maximum sampling volume of 23.8 L in the OSHA method (9.4 mg/m³ - it refers to the validated QC-standard of 0.075 mg/mL and the supposed maximum sample volume of 23.8 L of OSHA-method)	DocIIIA, 4.1; 11/2015 Alcohol Task Force, 2015

Table 42

Data waiving was acceptable for the following information requirements	
Information requirement	1. Air: For analytical methods for air; the applicant refers to the 3rd party active substance dossier for propan-2-ol, which was submitted by the ASD Consortium Alcohol for Inclusion into the List of Active Substances and Suppliers according to Article 95 (1) of the BPR. 2. Soil: Data waving is accepted. 3. Water (including drinking water) and sediment: Data waving is accepted. 4. Animal and human body fluids and tissues: Data waving is accepted. 5. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waving is accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Conclusion on the methods for detection and identification of the product
The method(s) provided regarding the active substance(s) was acceptable. The information provided regarding the residues was acceptable. Methods regarding substances of concern were not necessary.

2.3.5 Efficacy against target organisms

See Chapter 2.2.5

2.3.6 Risk assessment for human health

2.3.6.1 Assessment of effects of the active substance on human health

Reference values have been derived during assessment of the active substance(s) for the purpose of approval see Section 2.2.6.1.

2.3.6.2 Assessment of effects on Human Health

This assessment is valid for all Meta-SPC, see Section 2.2.6.2.

2.3.6.3 Exposure assessment

For **non-professional user** the assessment is valid for all Meta-SPC, see Section 2.2.6.3.

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

For an overview please refer to section 2.2.6.3, Table 11**.**

List of scenarios for meta SPC 2

For an overview please refer to section **2.2.6.3** Table 11

Industrial exposure

No industrial applications are intended for the products covered by meta SPC 2.

Professional exposure

All members of meta SPC 2 are ready-to-use surface disinfectant solutions for professional users containing "propan-2-ol" (CAS-No.: 63-67-0; 70%w/w).

Scenario No.	**Intended applications**
2.1	Small surface disinfection - in-between disinfection
3	Small surface disinfection in laboratory
4	Small surface disinfection in kitchens and canteens
5	Disinfection of food processing machinery
6	Refilling

General Information on meta SPC 2

The products of meta SPC 2 are marketed in different package sizes:

- Bottles:0.1 to 2.5 L
- Cans: 5 to 60 L
- Drums: 200 L
- Containers: 1000 L

In Annex 3.2 the details of the exposure calculations to the a.s. propan-2-ol for the professional user are laid out.

Due to local effects of the active substance propan-2-ol, a qualitative local risk assessment is performed (see chapter **2.3.6.4**, Risk characterisation for human health).

Scenario 2.1 - Small surface disinfection – in-between disinfection

Description

The following scenario covers disinfection of small surfaces with an alcohol based disinfectant in a naturally ventilated room. This scenario is introduced because in the CAR for the active substance propan-2-ol, the scenarios consider disinfection in technically ventilated rooms, only. The assessment is based on the Recommendation no. 15 of the BPC Ad hoc Working Group on Human Exposure "Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer".

The eCA assessed two different types of professional users according to the decision in Working Group Human Health VII 2018:

- Scenario 2.1: Small surface disinfection – in-between disinfection
- Scenario 2.2: Small surface disinfection – in patient rooms

The complete exposure assessments for both types of users are available in Annex 3.2. Based on the results, scenario 2.1 is the worst case. Therefore, scenario 2.1 is described in more detail in the following section and in the risk characterisation section.

Brenntag disinfectant product is a ready-to-use surface disinfectant solution which may be decanted from a storage canister into a smaller unit prior to application.

For disinfection of small surfaces

- the liquid is poured or sprayed onto the surface or onto a wipe. Finally, the surface is wiped off. Or
- the application liquid is sprayed onto the surface which is left to dry, then.

To get the alcoholic disinfectant on the surface effectively, spraying is carried out directly from a short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

Based on HEAdhoc recommendation 15, during the working day a nurse/carer is expected to stay 20 minutes in every room to perform the duties. After visiting 4 rooms they are expected to repeat the process revisiting each room in turn (2 visits per room per day).

Dermal exposure

Exposure to skin occurs during the application phase when the biocidal product is distributed by wiping with e.g. a single use paper towel in one hand. Exposure of the area of one palm during application is assumed. Dermal exposure is calculated based on the 75th percentile value of the model BEAT - small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures during Mixing, Spraying and Wiping Activities.

Annals of Occupational Hygiene (48) 245-256). Dermal internal exposure is calculated via dermal absorption, for details please refer to 2.2.6.4.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature (5780 Pa at 25° C). Calculation of inhalation exposure for the professional user to the a.s. is carried out according to recommendation 15 (hospital scenario) using the model ConsExpo Web "Inhalation exposure to vapour - evaporation model" which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
For treatment of small surfaces the application liquid is directly applied to the surface from a short distance so that exposure to the eyes is not expected. Moreover, the application liquid evaporates quickly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure
Secondary dermal exposure of a professional bystander in the same room is not expected because due to the high vapour pressure of the active substance the product evaporates from the treated surface quickly. It is possible that inhalation exposure occurs to a professional bystander who is present in the room where the disinfection is carried out. Inhalation exposure will be in the same order of magnitude or lower as for the operator.

Details of Scenario 2.1	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70.0 % (w/w)
Density of the b.p.	0.879 g/cm³
Number of surface disinfections per day	8
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	20 ml/m²
ConsExpo web parameters	
Room volume	80 m³
Ventilation rate	1.5 / h
Treated surface area	0.5 m²
Product amount per application	8.79 g
Frequency of use	4 rooms visited (2 visits per room per day)
Exposure duration (in one room)	20 min
Mode of release	Evaporation

Calculations
The results of the calculation for potential inhalation and dermal exposure are summarised in Table 46 and Table 47. Results of the calculation for a combined scenario which includes

refilling of the application bottles prior to the surface disinfection are given in Table 48 and Table 49.
For details of the calculation of exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.3.6.4.

Further information and considerations
Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

Classification of the b.p. requires additional assessment of local risks (see chapter 2.3.6.4: Risk characterisation for human health). For disinfection of small surfaces by professional users the product is usually applied from a short distance onto the surface in downward direction so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

Scenario 2.1 "Small surface disinfection – in-between disinfection by nurses or health care workers" represents a realistic worst case scenario and also covers scenario 2.2 "Small surface disinfection in patient rooms" performed by specialised cleaning personal. This scenario describes disinfection of small surfaces in hospital rooms where one disinfection of 0.5 m² is carried out by e.g. a specialised cleaning personal that visits 8 hospital rooms during the shift and stays 20 minutes in each room to perform routine cleaning tasks.
For further details please refer to the Annex 3.2.

For refilling of the application bottles from larger storage containers, please refer to scenario 6.

Scenario 3 – Small surface disinfection in laboratory

Description
The exposure assessment of small surface disinfection in technically ventilated rooms (e.g. laboratory) is based on the approach described in the assessment report (CAR) for propan-2-ol. Alcohol based ready to use (RTU) products are applied for rapid in-between disinfection of small surfaces, e.g. prior to a new task to remove potential contamination e.g. of biomaterial from the previous task.

The products of meta SPC 2 are ready-to-use surface disinfectant solutions which may be decanted from a canister into a smaller unit prior to application (refilling).

For disinfection of small surfaces the application liquid is either sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface to be disinfected is wiped off or let to dry.
To get the alcoholic disinfectant onto the surface by spraying effectively, it is carried out directly from a short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface, not the spraying (aerosol formation) and wiping.

The disinfectant is used in public, healthcare, industrial areas and in areas for other professional activities.

It is assumed that a staff person in a laboratory carries out 10 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 0.5 m² is commonly performed in laboratories prior to every new task to remove potential contamination e.g. of biomaterial from a previous task. As a realistic worst case scenario, it is assumed that one person disinfects its working bench every 45 minutes in

a small room and that the person does not leave the room in-between (according art.19, para.2, lit.a, Reg. (EU) No. 528/2012).

Dermal exposure
During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with a wipe e.g. a single use paper towel in one hand. So it can be expected that the area of one palm is exposed to the biocidal product during the application procedure.
Dermal exposure is calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
The internal dermal exposure is calculated via dermal absorption, for details please refer to 2.3.6.4.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (5780, 25 °C). Calculation of inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web "Inhalation-exposure to vapour - evaporation model" which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
The products of meta SPC 2 are ready-to-use surface disinfectant solutions and sprays. For the treatment of small surfaces e. g. work benches, a small amount of the application liquid is directly applied to the surface from a short distance, so that exposure to the eyes is not expected. Moreover, the application liquid evaporates quickly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure
Dermal exposure of a professional bystander in the same room is not expected because due to the high vapour pressure of the active substance the product evaporates quickly from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the laboratory where the disinfection is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 43

Details of Scenario 3: **Small surface disinfection in laboratory**	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (w/w)
Density of the b.p.	0.879 g/cm³
Number of surface disinfections per day	10
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	20 ml / m^2
Temperature (room)	25° C
ConsExpo Web parameters	
Room volume	25 m^3
Ventilation rate	8 / h
Surface area	0.5 m²
Product amount per application	8,79 g (10 ml)
Exposure duration per application	45 min
Vapour pressure of the a.s.	5780 Pa (25 °C)
Mode of release	Evaporation

Calculations
The results of the calculation for potential inhalation and dermal exposure are summarised in Table 46 and Table 47. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 48 and Table 49.
For details of the calculation of exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.3.6.4.

Further information and considerations
The used paper towels have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

Classification of the b.p. requires additional assessment of local risks (see chapter 2.3.6.4: Risk characterisation for human health). Local risk assessment indicated a risk for eye irritation. For disinfection of small surfaces by professional users the product is usually applied from a short distance onto the surface in downward direction, so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

For refilling of application bottles from larger storage containers, please refer to scenario 6.

Scenario 4 – Small surface disinfection in kitchens and canteens

Description
The exposure assessment of small surface disinfection in kitchens and canteens is based on the approach described in the assessment report (CAR) for propan-2-ol. Alcohol based

ready to use (RTU) products are applied for rapid in-between disinfection of small surfaces, e.g. prior to a new task.

The products of meta SPC 2 are ready-to-use surface disinfectant solutions and sprays which may be decanted from a canister into a smaller unit prior to application (refilling).

For disinfection of small surfaces the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface to be disinfected is wiped off.
To get the alcoholic disinfectant effectively onto the surface by spraying, it is carried out directly from a short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface, not the spraying (aerosol formation) and wiping.

The disinfectant is used in the food sector or food processing industries.

It is assumed that a staff person in a kitchen or canteen carries out 4 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 1 m² is commonly performed in kitchens and canteens after the finish of special tasks (e.g. working with eggs or egg-containing substances). As a realistic worst case scenario, it is assumed that one person disinfects its working bench every 120 minutes in a small room and that the person does not leave the room in-between (realistic worst-case assumption).

Dermal exposure
During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with e.g. a single use paper towel in one hand. So it can be expected that the area of one palm is exposed to the biocidal product during the application procedure.
Dermal exposure is calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
Internal dermal exposure is calculated via dermal absorption, for details please refer to 2.3.6.4.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (5780 Pa, 25 °C). Calculation of inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web "Inhalation exposure to vapour - evaporation model" which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
The products of meta SPC 2 are ready-to-use surface disinfectant solutions and sprays. For treatment of small surfaces e. g. work benches a small amount of the application liquid is applied directly to the surface from a short distance so that exposure to the eyes is not expected. Moreover, the application liquid evaporates quickly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure
Secondary dermal exposure of a professional bystander in the same room is not expected because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the laboratory where the disinfection of a small surface is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 44

Details of Scenario 4	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (w/w)
Density of the b.p.	0.879 g/cm³
Number of surface disinfections per day	4
Area of one palm	205 cm²
Application duration	2 min
Application rate	20 ml / m^2
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	25 m^3
Ventilation rate	15 / h
Surface area	1 m²
Product amount per application	17.6 g (20 ml)
Exposure duration	120 min
Vapour pressure (a.s.)	5780 Pa (25 °C)
Mode of release	Evaporation

Calculations

The results of the calculation for potential inhalation and dermal exposure are summarised in Table 46 and Table 47. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 48 and Table 49.

For details of the calculation of exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.3.6.4 .

Further information and considerations

The used paper towels have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

Classification of the b.p. requires additional assessment of local risks (see chapter:2.3.6.4 Risk characterisation for human health). Local risk assessment indicated a risk for eye irritation. For disinfection of small surfaces by professional users the product is usually applied from a short distance onto the surface in downward direction, so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

This scenario also covers the application of propan-2-ol based disinfectants for disinfection of small surfaces in e.g. canteens or supermarkets which have a larger room volume but a lower air exchange rate.

For refilling of the application bottles from larger storage containers, please refer to scenario 6.

Scenario 5 – Disinfection of food processing machinery

Description

The exposure assessment for disinfection in food contact areas and of food processing machinery is based on the approach described in the assessment report (CAR) for propan-2-ol.

The products of meta SPC 2 are ready-to-use surface disinfectant solutions and sprays which have to be decanted from a canister into a smaller unit prior to application.

For disinfection of small surfaces the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface is wiped off.
To get the alcoholic disinfectant effectively onto the surface by spraying, it is carried out directly from a short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface, not the spraying (aerosol formation) and wiping.

The scenario covers disinfection of food processing machinery. It is assumed that a staff person in a production hall of e.g. a non-alcoholic beverage processing plant carries out 4 disinfections of food processing machinery per day, e.g. after the finishing of special tasks. According to the CAR for propan-2-ol, alcoholic disinfection of a cutting machine and a packaging machine and thus of a total surface of approx. 4.6 m² is a representative task for disinfection of food processing machinery.

Dermal exposure
During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping. It is expected that both hands are used for wiping of the food processing machinery as its parts may not be easily accessible. Thus, the palms of both hands are exposed to the product.
Dermal exposure was calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256). Dermal internal exposure is calculated via the dermal absorption, for details please refer to chapter 2.3.6.4.

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (4260 Pa at 20° C). A calculation of inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web "Inhalation exposure to vapour - evaporation model" which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
Disinfection of the food processing machinery by spraying from a hand-held bottle and wiping with a wetted wipe may include the treatment of not easily accessible parts of the machinery which also may be in the height of the operator's face. Thus, incidental exposure of eyes to the biocidal product is possible to occur. Even if local effects for eye irritation are taken into account via the AEL approach according to the CAR of propan-2-ol, it is assumed that possible eye irritation on a daily basis should be avoided and therefore wearing of eye protection for this task is recommended.

Secondary exposure
Dermal exposure of a professional bystander in the same production hall is not expected because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the production hall or canteen where the surface

disinfection is carried out. Inhalation exposure will be in the same order of magnitude or lower as for the operator.

Details of Scenario 5	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (w/w)
Density of the b.p.	0.879 g/cm³
Number of surface disinfections per day	4
Area of two palms	410 cm²
Application duration	5 min
Temperature (room)	20 °C
ConsExpo Web parameters	
Room volume production hall	1584 m^3
Room volume around the machine	300 m^3
Ventilation rate	20 / h
Surface area	4.6 m²
Product amount	80.87 g (92 ml)
Exposure duration	120 min
Vapour pressure of a.s.	4260 Pa (20° C)
Mode of release	Evaporation

Calculations

The results of the calculation for potential/ inhalation and dermal exposure are summarised in Table 46 and Table 47. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to surface disinfection are given in Table 48 and Table 49.

For details of the calculation of exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.3.6.4.

Further information and considerations

The used paper towels have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels.

Classification of the b.p requires additional assessment of local risks (see chapter 2.3.6.4: Risk characterisation for human health). Local risk assessment has indicated a risk for eye irritation. For disinfection of food processing machinery the product is applied on vertical surfaces and also in eye height. Since eye contact can occur, the use of eye protection is recommended.

For refilling of the application bottles from larger storage containers, please refer to scenario 6.

Scenario 6 – Refilling

Description

This scenario is applicable for meta-SPC 1 and 2. For a detailed description please refer to chapter 2.2.6.3.

Dermal exposure
Exposure of the palm of one hand is expected during replacement of refilled bottles, due to spilled quantities on the outside.
The calculation is based on "Mixing and loading model 4" (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG).
Internal dermal exposure is calculated via the dermal absorption, for details please refer to chapter 2.3.6.4.

Table 45

Details of Scenario 6	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	70.0 % (w/w)
Density of the b.p.	0.879 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ART 1.5 parameters	
Room volume	Small workroom only
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air.
Loading type	Splash loading

Calculations
The results of the calculation for potentialdermal and inhalation exposure are summarised in Table 46 and Table 47. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to surface disinfection are given in Table 48 and Table 49.
For details of the calculation of exposure, please refer to Annex 3.2 of this PAR. For risk characterisation, see chapter 2.3.6.4**.**

Further information and considerations
Classification of the b.p requires additional assessment of local risks (see chapter 2.3.6.4: Risk characterisation for human health). Local risk assessment indicated a risk for eye

irritation. Accidental splashes to the eyes cannot be excluded during manual decanting, thus, eye protection is recommended.
It is assumed that refilling from canisters larger than 10 L, drums or IBCs is carried out by the help of dosing pumps or connecting lines leading to less exposure as manual decanting.

Summary of professional exposure

Table 46 Summary of inhalation exposure

Exposure scenario	**Use no. (Product type)**	**Tier**	**Estimated external inhalation exposure [mg/m³]**
Scenario 2.1 Small surface disinfection in-between disinfection	2 (PT02)	Tier 1	18.900
Scenario 3 Small surface disinfection in laboratory	2 (PT02)	Tier 1	37.969
Scenario 4 Small surface disinfection in kitchens and canteens	3 (PT04)	Tier 1	16.300
Scenario 5 Disinfection of food processing machinery	3 (PT04)	Tier 1	4.670
Scenario 6 Refilling	1,2 and 3 (PT01,PT02, PT04)	Tier 1	0.840

Table 47 Summary dermal exposure

Exposure scenario	**Use no. (Product type)**	**Tier**	**Estimated external dermal exposure [mg/d]**
Scenario 2.1 Small surface disinfection - in-between disinfection	2 (PT02)	Tier 1	1053.39
Scenario 3 Small surface disinfection in laboratory	2 (PT02)	Tier 1	1316.74
Scenario 4 Small surface disinfection in kitchens and canteens	3 (PT04)	Tier 1	1053.39
Scenario 5 Disinfection of food processing machinery	3 (PT04)	Tier 1	2633.48
Scenario 6 Refilling	1,2 and 3 (PT01,PT02, PT04)	Tier 1	307.65

Combined scenarios

If refilling of small application bottles is carried out by the same staff members as the disinfection itself, exposure from both scenarios has to be combined.

Table 48 Summary inhalation exposure

Exposure scenarios – numbers	**Exposure scenarios - names**	**Tier**	**Estimated external inhalation exposure [mg/m³]**
6 + 2.1	Refilling + Small surface disinfection in-between disinfection	Tier 1	19.740
6 + 3	Refilling + Small surface disinfection in laboratory	Tier 1	38.809
6 + 4	Refilling + Small surface disinfection in kitchens and canteens	Tier 1	17.140
6 + 5	Refilling + Disinfection of food processing machinery	Tier 1	5.510

Table 49 Summary dermal exposure

Exposure scenarios – numbers	**Exposure scenarios - names**	**Tier**	**Estimated external dermal exposure [mg/d]**
6 + 2.1	Refilling + Small surface disinfection in-between disinfection	Tier 1	1361.04
6 + 3	Refilling + Small surface disinfection in laboratory	Tier 1	1624.39
6 + 4	Refilling + Small surface disinfection in kitchens and canteens	Tier 1	1361.04
6 + 5	Refilling + Disinfection of food processing machinery	Tier 1	2941.13

Non-professional exposure

The biocidal products of Meta-SPC 2 are for professional use only.

Exposure of the general public

See chapter 2.2.6.3, scenario 10.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
Small surface disinfection - in between disinfection (PT02)	Professional user	Tier 1	7.54
Small surface disinfection in laboratory (PT02)	Professional user	Tier 1	11.81
Small surface disinfection in kitchens and canteens	Professional user	Tier 1	7.11
Disinfection of food processing machinery	Professional user	Tier 1	11.75
Refilling	Professional user	Tier 1	1.42
Refilling + Small surface disinfection in-between disinfection	Professional user	Tier 1	8.96
Refilling + Small surface disinfection in laboratory	Professional user	Tier 1	13.24
Refilling + Small surface disinfection in kitchens and canteens	Professional user	Tier 1	8.54
Refilling + Disinfection of food processing machinery	Professional user	Tier 1	13.17

2.3.6.4 Risk characterisation for human health

Reference values have been derived during assessment of the active substance(s) for the purpose of approval see Section 2.2.6.1

Endocrine disrupting properties
According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance.
Actually, no co-formulant of the biocidal product family was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. Two co-formulants are undergoing an ED assessment. However, no suggestions are available yet. Therefore, the co-formulants of the biocidal product family are not considered to have endocrine disrupting properties.
The full composition of the products of the BPF as well as the results of the ED-assessment of the co-formulants are summarised in the Confidential Annex.

General considerations

The biocidal product family Brenntag GmbH Propan-2-ol Product Family comprises two meta SPCs concerning the professional user and a third concerning the non-professional user. An overview of the applications applied for the two meta SPCs relevant for the professional user is given in Table 12. All members of the biocidal product family Brenntag GmbH Propan-2-ol Product Family contain propan-2-ol (CAS No.: 67-63-0) as active substance.

The products of meta SPC 2 are ready-to-use surface disinfectant solutions.

The occupational risk assessment for biocidal products covered by meta SPC 2 takes into account systemic and local effects of the biocidal product.

Risk for industrial users

No industrial applications are intended for the products covered by meta SPC 2.

Risk characterisation for human health

Systemic effects

The primary toxic effect of the active substance propan-2-ol is acute central nervous system (CNS) depression and results in the classification of the biocidal products covered by meta SPC 2 with H336 (May cause drowsiness or dizziness). The risk characterisation for systemic effects of propan-2-ol is performed with the AEL approach. In this approach total internal body burden (total uptake) is compared to the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the biocidal products covered by meta SPC 2.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{acute/medium-/long-term}$ of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and exposure-to-AEL ratio (%)

For inhalation route 100 % is assumed as default absorption for the active substance propan-2-ol.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Due to the rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm^2/h) instead of data on the percentage of dermal absorption should be used for the calculation of the dermal uptake. The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal products covered by meta SPC 2 are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m^3) x 10 m^3 / 60 kg x %-inhalation absorption / 100 %.
>
> Dermal uptake (mg/kg bw/d) = dermal flux of propan-2-ol (mg/cm^2/h) x exposed skin area (cm^2) x application time/day (h) / 60 kg.

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A Risk characterisation for human health referring to the active substance propan-2-ol resulting from the use of the biocidal products covered by meta SPC 2 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 50 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 2. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 50. However, the underlying calculations are based on unrounded exposure values. As shown in Table 50, the scenarios 'small surface disinfection – in between disinfection', 'small surface disinfection in laboratory', 'small surface disinfection in kitchens and canteens', 'disinfection of food processing machinery' and 'refilling' yield an exposure-to-AEL ratio (%) of less than 100 % already in TIER 1. This means that after TIER 1 consideration no risk for human health is identified.

Table 50: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 2

Scenario		$AEL_{acute/medium-/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
Small surface disinfection - in between disinfection	Tier 1	17.9	3.15	0.39	3.54	19.76	**yes**
Small surface disinfection in laboratory	Tier 1	17.9	6.33	0.48	6.81	28.06	**yes**
Small surface disinfection in kitchens and canteens	Tier 1	17.9	2.72	0.39	3.10	17.34	**yes**
Disinfection of food processing machinery	Tier 1	17.9	0.78	0.94	2.71	15.16	**yes**
Refilling	Tier 1	17.9	0.14	0.04	0.18	0.99	**yes**

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for human health resulting from the intended scenarios 'small surface disinfection – in between disinfection', 'small surface disinfection in laboratory', 'small surface disinfection in kitchens and canteens', 'disinfection of food processing machinery' and 'refilling' with the biocidal products covered by meta SPC 2 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A Risk characterisation for human health referring to the active substance propan-2-ol resulting from the combined uses of the biocidal products covered by meta SPC 2 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 51 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 2. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 51. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 51, the combined scenarios considered ('refilling + small surface disinfection – in between disinfection', 'refilling + small surface disinfection in laboratory', 'refilling + small surface disinfection in kitchens and canteens' and 'refilling + disinfection of food processing machinery') yields exposure-to-AEL ratio of less than 100 % already in TIER 1. This means that after TIER 1 consideration no risk for human health is identified.

Table 51: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenario for the biocidal products covered by meta SPC 2

combined scenario		$AEL_{acute/medium-/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
Refilling + small surface disinfection - in between disinfection	Tier 1	17.9	3.29	0.42	3.71	20.75	**yes**
Refilling + small surface disinfection in laboratory	Tier 1	17.9	6.47	0.52	6.99	39.04	**yes**
Refilling + small surface disinfection in kitchens and canteens	Tier 1	17.9	2.87	0.42	3.28	18.33	**yes**
Refilling + disinfection of food processing machinery	Tier 1	17.9	0.92	2.01	2.93	16.35	**yes**

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for human health resulting from the combined scenarios 'refilling + small surface disinfection – in between disinfection', 'refilling + small surface disinfection in laboratory and medical practice', 'refilling + small surface disinfection in kitchens and canteens' and 'refilling + disinfection of food processing machinery' is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Local effects

The local toxicity profile of the biocidal product family is considered. The active substance propan-2-ol has eye irritating properties and therefore leads to classification of the biocidal products covered by meta SPC 2 with H319 (Causes serious eye irritation). Therefore a qualitative risk assessment for local effects is necessary. The allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) is "low".

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) Table 52 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of biocidal products covered by meta SPC 2 for the intended uses 'small surface disinfection – in between disinfection', small surface disinfection in laboratory', 'small surface disinfection in kitchens and canteens', 'disinfection of food processing machinery' and 'refilling'. With the proposed risk mitigation measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses.

Table 52: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 2

PT	Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure [per day]	Potential degree of exposure of mucosa membranes (e.g. eyes)	Relevant RMM & PPE	Acceptability
02	Small surface disinfection - in between disinfection	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	8 tasks per day; duration of dermal exposure: 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	**Acceptable**
02	Small surface disinfection in laboratory	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	10 tasks per day; duration of dermal exposure: 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	**Acceptable**
04	Small surface disinfection in kitchens and canteens	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	4 tasks per day; duration of dermal exposure: 2 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	**Acceptable**
04	Disinfection of food processing machinery	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	4 tasks per day; duration of dermal exposure 5 min per task	Incidental eye contact, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene. The use of eye protection during handling of the product is recommended.	**Acceptable**

01 02 04	Refilling	RTU (70 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	low	1 task per day, dermal exposure, contact time: 0.5 min	Incidental eye contact, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene. The use of eye protection during handling of the product is recommended.	**Acceptable**

Conclusion

Concerning the local eye and skin effects of biocidal products covered by meta SPC 2, the intended uses 'small surface disinfection – in between disinfection', small surface disinfection in laboratory', 'small surface disinfection in kitchens and canteens', 'disinfection of food processing machinery' and 'refilling' do not lead to concern for professional users.

Risk for non-professional users

The products of the biocidal product family (BPF) "Brenntag GmbH Propan-2-ol Product Family" in meta SPC 2 are intended to be used in product types 2 and 4 by professional users only.

Risk for the general public

Please see chapter 2.2.6.4, scenario 10)

Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Meta SPC 2 – professional user

A quantitative cumulative risk assessment for the active substance and the substances of concerns was not performed. A quantitative assessment is only required for the active substance.

Summary of risk characterisation

Summary of risk characterisation for industrial user

No industrial applications are intended for the products covered by meta SPC 2.

Summary of risk characterisation for professional user

In summary, a risk for human health resulting from the intended use of the biocidal products covered by meta SPC 2 is unlikely. Risk mitigation measures described in chapter 2.1.3.5.2 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 2.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.
For summary tables please refer to
Table 50: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 2Table 51: Overview

of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenario for the biocidal products covered by meta SPC 2
Table 52: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 2

Summary of risk characterisation for indirect exposure

Please see chapter 2.2.6.4, scenario 10.

2.3.7 Risk assessment for animal health

Please see chapter 2.2.7.

2.3.8 Risk assessment for the environment

The products of the biocidal product family (BPF) "Brenntag GmbH Propan-2-ol Product Family" contain Isopropanol/Propan-2-ol as active substance (a.s.). They are intended to be used in product types 2 and 4 for the disinfection of surfaces, materials, equipment and furniture which are not in direct contact with food and feeding stuff, but also for the disinfection in the food sector and food processing industry.

2.3.8.1 Effects assessment on the environment

As the products of the BPF contain no substances of concern for the environment, the environmental risk assessment is solely based on the a.s.

No additional studies on the ecotoxicity of the active substance propan-2-ol or the products of the BPF were provided by the applicant. Hence, the environmental effects assessment is based on the information given in the CAR and the AR of the a.s. prepared by the eCA Germany (2014, eCA DE).

Aquatic compartment (including sediment and STP)

- **Aquatic toxicity (incl. sediment)**

According to the CAR, acute and chronic data on effects of propan-2-ol on aquatic organisms are available:

Table 53:**Summary table for acute aquatic toxicity.**

Summary table for acute aquatic toxicity						
Guideline/ Test method/GLP status/reliability	Species	End point	Exposure		Results	Reference[1]
			Design	Duration	LC/EC_{50}	
Fish						
OECD 203	*Pimephales promelas*	mortality	Flow-through	96 h	8692 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Invertebrates						
Dutch standard method NEN 6501	*Daphnia magna*	immobility	static	48 h	2285 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Algae (growth inhibition)					E_rC_{50}	
BOD bottle test technique	*Pseudokirchneriella subspicata*	Growth inhibition	static	48 h	10500 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)

Table 54: **Summary table for chronic aquatic toxicity.**

Summary table for chronic aquatic toxicity						
Guideline/ Test method / GLP status/ reliability	Species	End point	Exposure		Results	Reference[1]
			Design	Dura-tion	NOEC/ EC_{10}	
Invertebrates						
Dutch standard method NEN 6502	*Daphnia magna*	growth	semistatic	16 d	141 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)
Algae						
Cell multiplication Inhibition test	*Selenastrum capricornutum*	Growth rate	static	96 h	3154 mg/L	Final CAR Propan-2-ol, eCA: DE (2014)

Based on the lowest available chronic effect value in *Daphnia magna*, a $PNEC_{water}$ of 2.82 mg a.s./L was derived by applying an assessment factor of 50.

Table 55: **Conclusion used in Risk Assessment- Aquatic toxicity.**

Conclusion used in Risk Assessment- Aquatic toxicity	
Value/conclusion	$PNEC_{water}$: 2.82 mg/L
Justification for the value/conclusion	The lowest effect value (NOEC = 141 mg a.s./L) for the aquatic compartment was derived from a long-term study with *Daphnia magna.* Based on the available acute and chronic data for the aquatic compartment an assessment factor of 50 has to be used for the derivation of $PNEC_{water}$.

Studies on sediment dwelling organisms are not available and are not necessarily required for the intended uses of the BPF. Therefore, the equilibrium partitioning method (EPM) was applied to estimate a $PNEC_{sediment}$ of 2.41 mg a.s./kg ww using the $PNEC_{water}$ (Eq. 89; Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

Table 56: **Conclusion used in Risk Assessment- Sediment toxicity.**

Conclusion used in Risk Assessment- Sediment toxicity	
Value/conclusion	$PNEC_{sediment}$: 2.41 mg/kg ww

Justification for the value/conclusion	Using the equilibrium partitioning method (EPM) $PNEC_{sediment}$ was calculated based on $PNEC_{water}$ according to equation 89 (Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

- **Inhibition of microbial activity (STP)**

The effect of propan-2-ol on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge. The EC_{50} was calculated to be >1000 mg a.s./L nominal. Applying an assessment factor of 100 to the EC_{50} of the respiration inhibition test a **$PNEC_{STP}$ = 10 mg/L** was concluded.

Table 57: **Conclusion used in Risk Assessment- STP.**

Conclusion used in Risk Assessment- STP	
Value/conclusion	$PNEC_{STP}$: 10 mg/L
Justification for the value/conclusion	Using a respiration inhibition test (OECD 209) $PNEC_{STP}$ was calculated from the EC_{50} (Guidance on BPR Vol. IV Part B, Chapter 3.4)

Terrestrial compartment (including groundwater)

Since a direct exposure of the terrestrial compartment and adsorption of the a.s. to soil is not expected from the use of the products of the BPF, the provision of experimentally derived data on the toxicity of the propan-2-ol to terrestrial organisms is not required. Thus, $PNEC_{soil}$ was derived by applying the equilibrium partitioning method as described in equation 91 of the Guidance on the BPR: Volume IV Part B Risk Assessment (EU, 2017). Thus, a $PNEC_{soil}$ of 0.496 mg a.s./kg ww was determined.

Table 58: **Conclusion used in Risk Assessment –Terrestrial compartment**.

Conclusion used in Risk Assessment –Terrestrial compartment	
Value/conclusion	$PNEC_{soil}$: 0.496 mg/kg ww
Justification for the value/conclusion	Using the equilibrium partitioning method (EPM) $PNEC_{soil}$ was calculated based on $PNEC_{water}$ according to equation 91 (Guidance on the BPR: Volume IV Part B Risk Assessment, 2017).

Atmosphere

For the air compartment no ecotoxicological data are available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

Aquatic bioconcentration

No studies on aquatic bioconcentration were provided by the applicant. In the CAR for propan-2-ol, bioconcentration factors (BCFs) were estimated according to the procedures described in Eq. 93 and 104d of the Guidance on the BPR: Volume IV Part B Risk Assessment (2017). By applying the experimentally derived $logK_{OW}$ of 0.05 a BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww were determined. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-2-ol can be considered negligible. Propan-2-ol is not expected to accumulate in the environment.

Table 59: **Summary table – Estimated aquatic bioconcentration**.

Summary table – Estimated aquatic bioconcentration				
Basis for estimation	**Log K_{ow} (measured)**	**Estimated BCF for fish**	**Estimated BCF for earthworms**	**Reference**[1]
LogK_{ow}	0.05	0.22	0.85	Final CAR Propan-2-ol eCA: DE (2014)

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

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

Further Ecotoxicological studies

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

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

As indicated above, no new studies on the product were provided by the applicant. As the products contain no substances of concern for the environment, the risk assessment is based on the data provided for active substance.

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

This aspect is not relevant for the BPF as the products are not applied in form of baits or granules.

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

This aspect is not relevant for the BPF as the products are not applied in form of baits or granules.

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

This aspect is not relevant for the BPF as the products are not applied in large quantities outdoors.

Environmental fate and behaviour

Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290nm and 750nm takes place. Therefore, propan-2-ol is not accessible for direct photodegradation in sunlight. Propan-2-ol is classified as readily biodegradable. Propan-2-ol has a relatively high vapour pressure at 5780 Pa at 25°C, therefore, direct evaporation is expected. The Henry's Law constant for propan-2-ol is 0.80 Pa m^3/ mol at 25°C. This indicates that propan-2-ol is moderately volatile. Propan-2-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. Based on a reaction rate constant of $5.1x10^{-12}$ cm^3/mol sec by Atkinson et al. (2006) a half-life of 3.1 days can be estimated. Based on a log K_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} was estimated as 3.3 L/kg. Therefore, propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-2-ol in soil and a very low geo-accumulation potential.

For a more detailed assessment of the environmental fate and behavior of the active substance propan-2-ol please refer to the Assessment Report of propan-2-ol of the BPD.

Biodegradation / Metabolites

Propan-2-ol is classified as readily biodegradable. No data on biodegradation in soil, water/sediment or sewage treatment plants are available as in light of the screening test result no further studies were deemed necessary. For risk refinement purposes default half-lives of 15 days for biodegradation in surface water and 300 days in sediment can be assumed. For the soil compartment a default half-life of 30 days should be applied. For elimination estimations in sewage treatment plants a rate constant of 1 h^{-1} was used.

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)

This aspect is not relevant for the BPF under consideration as the products are used indoors.

2.3.8.2 Exposure assessment

Products of meta SPC 2 of the biocidal product family (BPF) "Brenntag GmbH Propan-2-ol Product Family" are used in product type 2 and 4 for disinfection by professional users. The ready-to-use products of the BPF contain up to 70% v/v (62.8-70 % w/w equivalent) of the active substance propan-2-ol and are available as trigger sprays.

The products are applied by spraying. The surfaces are then let to dry. Excess product in PT2 and 4 may be soaked with wipes, after. The following exposure scenarios are assessed:

Table 60: **Intended use in PT 2**

Assessed PT	PT 2
Assessed scenarios	Meta SPC 2, Use 2a: disinfection of small surfaces in industrial areas – professional user Meta SPC 2, Use 2b: disinfection of small surfaces for sanitary purposes in institutional areas – professional user

ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC, 2011.
Approach	Use 2a: Average consumption Use 2b: Average consumption/tonnage
Distribution in the environment	Calculated based on Guidance BPR IV ENV B+C (2017)
Groundwater simulation	-
Confidential Annexes	Yes: In the confidential Annex the tonnage based approach is provided
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-/-

Table 61: **Intended use in PT 4**

Assessed PT	PT 4
Assessed scenarios	Meta SPC 2, Use 3: disinfection of food contact surfaces by professional users
ESD(s) used	Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas, JRC 2011
Approach	Use 3: average consumption
Distribution in the environment	Calculated based on Guidance BPR IV ENV B+C (2017)
Groundwater simulation	-
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-/-

Fate and distribution in exposed environmental compartments

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the active substance (a.s.) is released to air and 10% of the a.s. is released to water. According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In case of the ready-to-use (RTU) products of the BPF "Brenntag GmbH Propan-2-ol Product Family"

containing 62.8-70% w/w propan-2-ol, the disinfection is finished when the treated surface completely dried, and the product has evaporated completely. This is facilitated by the relatively high vapour pressure of propan-2-ol. Nearly the whole amount of substance applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to waste water – via leakages or rinse off – cannot be excluded for liquid products. Therefore, for the environmental risk assessment of the BPF "Brenntag GmbH Propan-2-ol Product Family", the distribution used during the assessment of the active substance is maintained since it is plausible that the main emission path will be via air.

According to CG-17 document No. AP 13.1-CG-17-2016-13 "Evaluation of alternative dossiers during product authorisation" the LoEP values in the CAR of respective a.s. (in this case: Propan-2-ol) have to be used for the environmental exposure and risk assessment:

- No hydrolysis under environmental conditions.
- Photolysis in water is not applicable, no absorption maximum >290 nm.
- Tropospheric half-life of propan-2-ol: 3.1 d (according to Atkinson et al. (2006), reaction with OH radicals (global 24-hours mean), concentration: 5 x 10^5 OH/cm^3).
- K_{OC} was estimated by QSAR-model for alcohols described in EU TGD (2003): K_{OC} = 3.3 L/kg, no pH dependence

The vapour pressure of propan-2-ol is 5780 Pa at 25°C and direct evaporation is expected, consequently. The Henry's constant is 0.80 Pa m^3/mol^{-1} at 25°C. According to a suggested classification scheme after Lyman et al. (1983) the Henry's law constant indicates moderate volatility from water.

Table 62: **Input parameters for calculating the fate and distribution in the environment**

Input	Value	Unit	Remarks
Molecular weight	60.09	g/Mol	
Vapour pressure (at 12°C)	2304	Pa	
Water solubility (at 25°C)	1	kg/L	Complete miscible with water
Organic carbon/water partition coefficient (K_{OC})	3.3	L/kg	
Henry's Law Constant (at 12°C)	0.383	Pam^3 mol^{-1}	Temperature corrected from measured Henry's Law constant of 0.80 Pa m3 mol-1 at 25°C
Biodegradability			a.s. is readily biodegradable
Rate constant for STP	1	h^{-1}	
DT_{50} for degradation in soil	30	d	

Input	Value	Unit	Remarks
Degradation rate constant with OH-radicals (K_{OH})	$5.1x10^{-12}$	cm^3/mol sec	From Atkinson et al. 2006 reaction with OH radicals (global 24-hours mean), concentration: 5×10^5 OH/cm^3

The distribution in the sewage treatment plant is calculated using SimpleTreat v.3.1. This results in release fractions to air of 0.3%, water 12.5 %, sludge <0.1% and degraded fraction 87.1%. For further exposure calculations, the fraction released to the environment via sludge is considered as negligible, considering the low share of propan-2-ol in sludge (<0.1 %) as well the ready biodegradability of propan-2-ol and the potential volatilisation from soil.

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

The application of the BPF "Brenntag GmbH Propan-2-ol Product Family" used for disinfection results in indirect exposure of the environment via the air (wet and dry deposition) and to a lesser extent via STP. Following environmental compartments might be exposed by application of products of meta SPC 2.

Table 63: **Identification of relevant receiving compartments based on the exposure pathway**

Meta SPC	Use	PT	**Waste-water (STP)**	**Surface water and Sediment**	**Soil and Groundwater**	**Air**
2	2	2	yes	yes (indirect)	yes (indirect)	yes
	3	4	yes	yes (indirect)	yes (indirect)	yes

Emission estimation

Meta SPC 2 (PT2 and PT4)

Use 2a: PT2 – Disinfection of small surface in industrial areas – professional user

Consumption based approach

The emission scenario for disinfectants used in industrial areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). The scenario provided in the ESD PT2 (JRC, 2011) for use in industrial areas is based on application rate, a scenario based on annual tonnage is not provided for this use in the ESD. The application rate of 30 mL/m^2 provided by the applicant represents a worst-case application of the RTU solutions. According to the applicant max. 4 times per day an application is foreseen. Since the surface area of 25m^2 in industrial areas for RTU products in PT2 (TAB v1.3 2017, ENV38) in combination with the default application frequency of 1 (ESD PT2 2001, 2011) already covers multiple applications, the RefMS considered this application frequency as covered by the default value of 1. The resulting local emission of propan-2-ol to the waste water and air from the application of the BPF "Brenntag GmbH Propan-2-ol Product Family" is given in Table 64.

Table 64: **Emission scenario for surface disinfection in industrial areas**

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2011)	**Value**
Application rate of b.p.(S)	30 mL/m^2
Concentration of a.s in b.p(S)	609.7 g/L
Surface area treated(WG ENV I 2017)	25 m^2
Number of applications per day(D)	1
Fraction of a.s. disintegration(D)	0
Fraction released to wastewater(CAR)	0.1
Fraction released to air(CAR)	0.9
Calculation Results	**Value**
Local emission rate to waste water	0.05 kg/d
Local emission rate to air	0.412 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

Use 2b: PT2 – Disinfection of small surfaces for sanitary purposes in institutional areas – professional user

The emission can be calculated based on the tonnage or on the specific consumption. According to the EU Workshop PT 1-6 Report (European Commission – Directorate General

Environment, 2008), both approaches will be presented. For the environmental exposure and risk assessment, the worst-case emission estimations are chosen to be relevant.

Tonnage based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas based on tonnage is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). It can be assumed that in institutional and private health care areas disinfection takes place only during the working week. The amount of emission days (Temission) was adapted accordingly to 260 days. The resulting local emission of propan-2-ol to the waste water and air from the application of the BPF "Brenntag GmbH Propan-2-ol Product Family" based on tonnage is given in the Confidential Annex.

Consumption based approach

The emission scenario for disinfectants used for sanitary purposes in institutional areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). The default consumption per capita of the b.p for general purpose is 5 mL/d. The resulting local emission of propan-2-ol to the waste water and air from the application of the BPF "Brenntag GmbH Propan-2-ol Product Family" is given in Table 65.

Table 65: **Emission scenario for surface disinfection in institutional areas (professional users) based on consumption**

Determinants of the local emission according to Chapter 2.1, Table 4; Environmental Emission Scenarios for PT 2 (JRC, 2011)	**Value**
Number of inhabitants feeding one STP (D)	10000
Active substance in product (S)	0.610 kg/L
Consumption per capita (D)	0.005 L/d
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9
Penetration factor (CAR)	0.3
Calculation Results	**Value**
Local release to waste water	0.92 kg/d
Local release to air	8.24 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

It can be assumed that in institutional and private health care areas disinfection takes place only during the working week (260 days per year). 260 emission days per year were considered for the exposure of the air compartment.

Break-even point

Based on the local emission from the consumption based approach a regional tonnage equivalent (break-even point) can be calculated. If the consumption based break-even point is larger than the regional tonnage, then the local emission from the consumption based approach should be used for further environmental exposure and risk assessment.

In case of the BPF "Brenntag GmbH Propan-2-ol Product Family" for the environmental exposure and risk assessment the emission based on consumption is used.

Use 3: PT4 – Disinfection of food contact surfaces

The emission scenario for surface disinfection in food and feed areas is described in detail in chapter 2.2.4 of the Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (JRC, 2011); for input and output values see following table.

The surface area to be disinfected by small-scale RTU products was defined at WG ENV I 2017 (see also TAB v2.0 2018, ENV67). It is assumed that 50 m^2 of a large scale catering kitchen are treated. For slaughterhouses a smaller treated surface area (10m²) was defined. Therefore, use in slaughterhouses is covered by assessment of large scale kitchens and is not further considered.

According to the background document attached to this TAB item, a disinfected surface area of 50 m² considers 2-3 treatments per day. However, the applicant applied for up to 4 treatment per day. Therefore, the disinfected surface area is adapted as follows: 50 m² treated surface area for 2.5 treatments per day results in 20m² per treatment. 4 treatments of 20m² per day result in a total treated surface area of 80m². 80m² treated surface area per day are implemented in the following assessment.

Table 66: **Emission scenario for surface disinfection in institutional areas (professional users) based on consumption**

Determinants of the emission scenario according to chapter 2.2.4, table 10; Environmental Emission Scenarios for PT 4 (JRC, 2011)	**Value**
Application rate of the a.s. (S) (resulting from: 30mL product per m², 70% w/w propanol, density product: 0.871 g/cm²)	18.29 g/m^2
Surface area to be disinfected (TAB v2.0, ENV 67, adapted (see above)) Large scale catering kitchens	 80 m^2
Number of applications per day(D)	1
Fraction of substance disintegrated during or after application (before release to the sewer system)(D)	0
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water(D)	0
Calculation Results	**Value**
Local release to waste water	0.146 kg/d

Determinants of the emission scenario according to chapter 2.2.4, table 10; Environmental Emission Scenarios for PT 4 (JRC, 2011)	Value
Local release to air	1.317 kg/d

(D) – Default (Royal Haskoning, 2004)

(TAB) – Technical Agreements for Biocides (Version 2.0, 2018)

(CAR) – CAR Propan-2-ol (2014)

(S) – Provided by applicant

It can be assumed that in professional food and feed producing/processing areas disinfection takes place only during the working week (260 days per year). 260 emission days per year were considered for the exposure of the air compartment.

Calculated PEC values

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). In addition, based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in a negligible concentration of propan-2-ol in sewage sludge. Therefore, no PEC_{soil} and PEC_{GW} values were calculated for "Brenntag GmbH Propan-2-ol Product Family".

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{eff}$) according to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B+C (2017)

According to the proposed use of the BPF, the interval between two releases to the STP is shorter than one month and therefore, the effluent concentration is representative for the exposure of microorganisms in STP.

- $PEC_{local\_surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR IV ENV B+C (2017);
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR IV ENV B+C (2017).

The local PEC values for meta SPC 2, based on the consumption approach, are presented in the following table and are used for the environmental risk assessment.

Meta SPC	Use	PT	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{air}	
			[µg/L]	[µg/L]	[µg/kg_{wwt}]	[mg/m^3]	
2	2a	2	2.88	0.29	0.25	$1.15x10^{-4}$	
	2b	2	57.2	5.72	4.88	$1.63x10^{-3}$	
	3	4	9.13	0.91	0.78	$2.61x10^{-4}$	

Primary and secondary poisoning

According to the CAR of propan-2-ol (2014), secondary poisoning is not relevant for propan-2-ol. Due to its physical properties propan-2-ol has only a low potential for bioaccumulation in the terrestrial and in the aquatic food chain (see chapter 2.2.8.1).

2.3.8.3 Risk characterisation

Atmosphere

As stated in section 2.3.8.1, ecotoxicological data for the air compartment are not available. Therefore, no quantitative estimation of PNECair for the active substance and no risk assessment for the air compartment is possible.

Sewage treatment plant (STP)

Table 67: **PEC/PNEC ratios for the STP related to uses 2 and 3.**

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Use 2a	0.00029
Use 2b	0.0057
Use 3	0.00091

Conclusion: The calculated PEC/PNEC-values are below 1 indicating an acceptable risk for the STP from the use of the product of the BPF in PT 2 and 4.

Aquatic compartment

Table 68: PEC/PNEC ratios for surface water and sediment related to uses 2 and 3.

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Use 2a	$1.018x10^{-4}$	$1.021x10^{-4}$	Not relevant	Not relevant
Use 2b	0.0020	0.0020	Not relevant	Not relevant
Use 3	$3.227x10^{-4}$	$3.237x10^{-4}$	Not relevant	Not relevant

Conclusion: The calculated PEC/PNEC-values are below 1 indicating an acceptable risk for the aquatic compartment from the use of the products of the BPF in PT 2 and 4.

Terrestrial compartment

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). Because it was not relevant to calculate a PEC_{soil} (see TAB ENV-A5), the $PEC_{soil}/PNEC_{soil}$ was not determined.

The fraction of propan-2-ol released to soil via sludge is considered as negligible, therefore no PEC_{soil} and no $PEC_{soil}/PNEC_{soil}$ were derived.

Groundwater

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols being used in small-scale applications, there is no need to conduct a risk assessment of the subsequent environmental compartments following the release path via air (terrestrial compartment) (see also TAB ENV-A5). Additionally, as the fraction of propan-2-ol released to the soil via sludge is considered as negligible, the subsequent leaching to groundwater can be considered as negligible, too. Therefore, no PEC_{GW} values were calculated for "Brenntag GmbH Propan-2-ol Product Family".

Mixture toxicity

The products of the biocidal product family "Brenntag GmbH Propan-2-ol Product Family" contain no substances of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance propan-2-ol.

Aggregated exposure (combined for relevant emission sources)

Biocidal active substances are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentration of active substance to be found in the environment.

Article 19(2) of the Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." This is further elaborated in Annex VI (common principles for the evaluation of biocidal products), which states that the risks associated with the relevant individual components of the biocidal product shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs.

According to the "Decision tree on the need for estimation of aggregated exposure" (refer to Guidance BPR IV ENV Part B+C (2017)) shown in Figure 2, an aggregated exposure assessment is not required for the biocidal product "Brenntag GmbH Propan-2-ol Product Family" containing propan-2-ol as active substance.

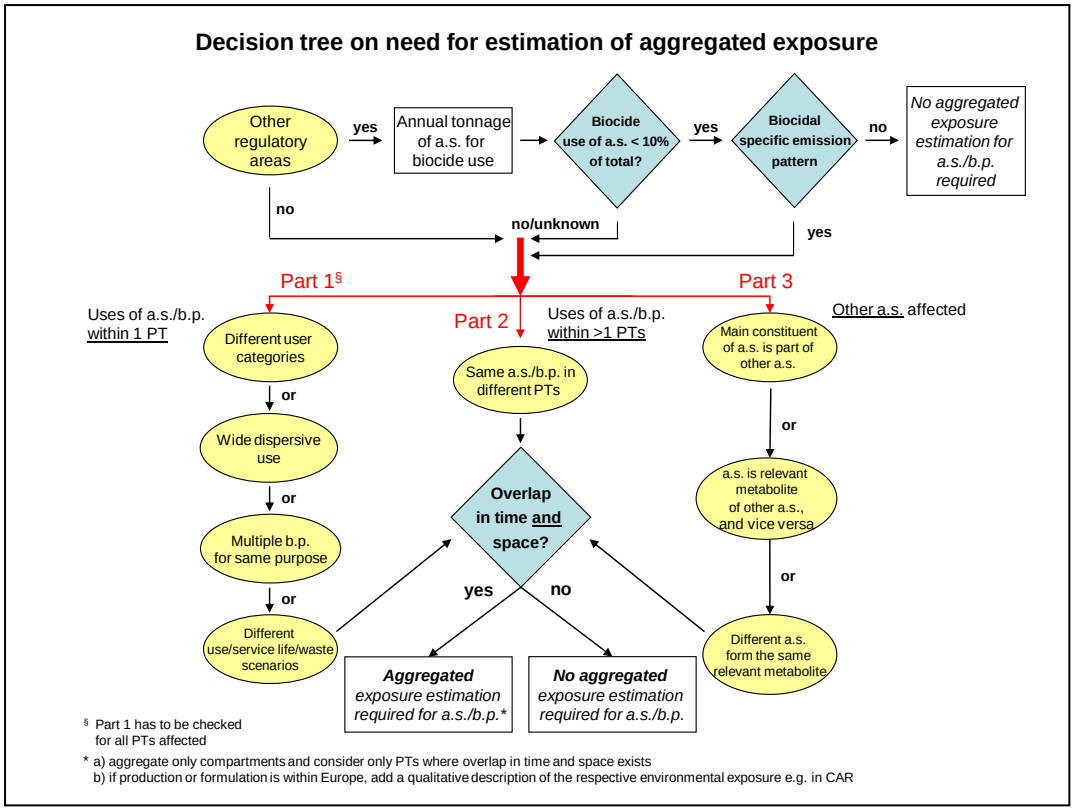


Figure 2: Decision tree on the need for estimation of aggregated exposure

The active substance propan-2-ol is notified for the list of approved substances in three products types (PT1, 2 and 4). Propan-2-ol is also evaluated in the frame of other regulatory areas (e.g. REACH). According to OECD SIDS Dossier of the HPV chemical Isopropanol (1997) most propan-2-ol goes into the solvent market either directly or via conversion to acetone or one of acetone's derivates. Small percentages are used for esters and as rubbing alcohol. The total European production volume of propan-2-ol in 1995 was reported to be 619000 tons (OECD 1997). According to the provided tonnage information only a small fraction (< 10 %) of the total tonnage produced is used as biocidal active substance. A specific emission pattern for propan-2-ol due to the use of products of "Brenntag GmbH Propan-2-ol Product Family" cannot be identified. The occurring emissions in PT1, PT2 and PT4 have been described as diffuse atmospheric emissions. This is comparable to other, non-biocidal, propan-2-ol emission sources, like e.g. solvents in inks, coatings, cosmetics and pharmaceuticals. Consequently, no aggregated exposure is required for propan-2-ol released due to the use of biocidal product "Brenntag GmbH Propan-2-ol Product Family".

PBT-Assessment

No new data were provide by the applicant. Thus, the conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substance propan-2-ol. Accordingly, propan-2-ol thus neither fulfils the PBT- nor the vP/vB-criteria.

Endocrine disrupting properties

According to the CAR for propan-2-ol, there are no indications for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance according to Regulation 2017/2100 and the EFSA/ECHA guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the products of the BPF as well as the results of the ED-assessment of the co-formulants are summarised in the „Confidential Annex.doc".

Table 69: **Overall conclusion on the risk assessment for the environment of the product.**

Overall conclusion on the risk assessment for the environment of the product
No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal products in the meta-SPC 2 of the BPF.

2.3.9 Measures to protect man, animals and the environment

Please see the relevant chapters of the product family evaluation and the Summary of Product Characteristics (SPC).

2.3.10 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

2.3.11 Comparative assessment

No candidate for substitution was identified, hence a comparative assessment is not necessary.

3 Annexes

3.1 List of studies for the biocidal product family

Table 70

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
3.1.1-01 3.1.2-01 3.1.3-01 3.2-01 3.3-01 3.4.1.1-01 3.4.2.2-01 3.9-01	Casco Palau, M.	2016a	70:30 IPA:Water RTU: Determination of Accelerated Storage Stability	Brenntag Holding GmbH
3.1.1-02 3.1.2-02 3.1.3-02 3.2-02 3.3-02 3.4.1.1-02 3.4.2.2-02 3.9-02	Casco Palau, M.	2016b	Wofasept AHA: Determination of Accelerated Storage Stability	Brenntag Holding GmbH
3.1.1-03 3.1.2-03 3.1.3-03	Mack, L.	2020	Determination of physico-chemical Properties and accelerated Storage Stability Tests for IPA-Co-Formulants-Stability-Test-Formulation	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
3.2-12 3.3-03 3.4.1.1-03 3.4.1.2-03 3.4.2.3-03 3.8-07 3.9-03				
3.2-03 3.2-04 3.2-05 3.2-06 3.2-07 3.2-08 3.2-09 3.2-10 3.2-11 3.8-02 3.8-03 3.8-05	Matyssek, F.	2018a	Determination of physico-chemical Properties for Disinfectant Products	Brenntag Holding GmbH
3.2-13 3.2-14 3.3-04 3.3-05 3.8-04 3.8-06	Matyssek, F.	2018b	Determination of physico-chemical Properties for Disinfectant Products	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
3.4.1.2-01 3.4.2.3-01	O'Connor, B. J.	2018a	70:30 IPA:Water RTU: Determination of Long-Term Storage Stability	Brenntag Holding GmbH
3.4.1.2-02 3.4.2.3-02	O'Connor, B. J.	2018a	Wofasept AHA: Determination of Long-Term Storage Stability	Brenntag Holding GmbH
3.4.2	Czornik, K.	2020	Discharge Rate of Pump Spray of Crystel GOLD, batch WO46276	Brenntag Holding GmbH
3.4.2	Czornik, K.	2020	Discharge Rate of Pump Spray of Crystel GOLD, batch WO46140	Brenntag Holding GmbH
3.4.2	Czornik, K.	2020	Discharge Rate of Pump Spray of Easydes IPA	Brenntag Holding GmbH
3.4.2	Czornik, K.	2020	Discharge Rate of Pump Spray of DH9 Quick germs	Brenntag Holding GmbH
3.5.6	Manka, S.	2018	Determination of physico-chemical Properties for Curacid HD-sept	Brenntag Holding GmbH
3.5.6	Mack, L.,	2019	Certificate of Analysis (MMAD)	Brenntag Holding GmbH
3.8-01	Casco Palau, M.	2016c	70:30 IPA:Water RTU: Determination of Surface Tension	Brenntag Holding GmbH
4.1-01 4.4-01 4.8-01 4.11-01 4.13-01	Curl, M. G.	2016	Expert Statement on the EU CLP Characteristics of Propan-2-ol Disinfectants Product Family: Explosivity, Oxidising Properties, Self-Reacting, Self-Heating and Corrosive to Metals	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
4.14-01 4.16-01 4.17.1-01				
4.6	Mack, L.	2020	Determination of the flashpoint for "Desmila HSI D"	Brenntag Holding GmbH
4.6		2020	Determination of the flashpoint for "Isopropanol 70 Biozid"	Brenntag Holding GmbH
4.6	Mack, L.	2020	Determination of the flashpoint for "Easysept"	Brenntag Holding GmbH
4.6	Mack, L.	2020	Determination of the flashpoint for "Deogel Mani"	Brenntag Holding GmbH
4.16	Mack, L.	2020	Determination of the Metal Corrosive Properties for "Desmila VSI"	Brenntag Holding GmbH
4.16	Mack, L.	2020	Determination of the Metal Corrosive Properties for "Isopropanol 70 Biozid"	Brenntag Holding GmbH
5.1-01	Casco Palau, M.	2016	Analytical Method Validation for the Determination of Propan-2-ol	Brenntag Holding GmbH
5.1-02	Matyssek, F.	2018	Validation of Method MV195: BRT:GC - Determination of 2-Propanol in IPA-Co-Formulants-Stability-Test-Formulation	Brenntag Holding GmbH
6.7-01	Werner, H.-P.	2016	Wofasept AHA EN 1276 Quantitative suspension test - bactericidal activity (Phase 2 Step 1)	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
6.7-02	Werner, H.-P.	2016	Wofasept AHA EN 1650 Quantitative Suspension Test - Yeasticidal Activity (Phase 2 Step 1)	Brenntag Holding GmbH
6.7-03	Werner, H.-P.	2016	Wofasept AHA EN 13697 - Quantitative non-porous surface test - bactericidal and yeasticidal activity (phase 2 step 2)	Brenntag Holding GmbH
6.7-04 (ver. 1)	Werner, H.-P.	2016	Virucidal Quantitative Suspension Test According EN 14476/ Murine Norovirus/Clean Conditions	Brenntag Holding GmbH
6.7-04 (ver. 2)	Werner, H.-P.	2018	Virucidal Quantitative Suspension Test According EN 14476/ Murine Norovirus/Clean Conditions	Brenntag Holding GmbH
6.7-05	Werner, H.-P.	2016	Wofasept AHA, EN 13727, Quantitative Suspension Test, Bactericidal Activity (Phase 2 Step 1)	Brenntag Holding GmbH
6.7-06	Werner, H.-P.	2016	Wofasept AHA, EN 13624, Quantitative Suspension Test - Yeasticidal Activity (Phase 2 Step 1)	Brenntag Holding GmbH
6.7-07	Werner, H.-P.	2016	Wofasept AHA, EN 1500 Hygienic Handrub (Phase 2, Step 2)	Brenntag Holding GmbH
6.7-08	Werner, H.-P.	2016	Virucidal Quantitative Suspension Test According EN 14476/ Adenovirus Type 5/Clean Conditions	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
6.7-09	Werner, H.-P.	2016	EN 14348 (2005) Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1)	Brenntag Holding GmbH
6.7-10	Werner, H.-P.	2016	Virucidal quantitative suspension test according to EN 14476 / Human Rotavirus A	Brenntag Holding GmbH
6.7-12	Werner, H.-P.	2018	Anfosan, Anfosan Forte, Curacid HD-sept, EN 13727, Quantitative Suspension Test, Bactericidal (*S. aureus*) Activity (Phase 2, Step 1)	Brenntag Holding GmbH
6.7-13	Werner, H.-P.	2018	Frend Hand Sanitiser Gel, Easysept, HD 18 Mano Germs, Wofasept AHA, Esept Gel, EN 13727, Quantitative Suspension Test, Bactericidal (*S. aureus*) Activity (Phase 2, Step 1)	Brenntag Holding GmbH
6.7-14	Werner, H.-P.	2018	Anfosan, Anfosan Forte, Curacid HD-sept, EN 13624, Quantitative Suspension Test, Yeasticidal Activity (Phase 2, Step 1)	Brenntag Holding GmbH
6.7-15	Werner, H.-P.	2018	Frend Hand Sanitiser Gel, Easysept, HD 18 Mano Germs, Wofasept AHA, Esept Gel, EN 13624, Quantitative Suspension Test, Yeasticidal Activity (Phase 2, Step 1)	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
6.7-16	Werner, H.-P.	2018	Anfosan, Anfosan forte, Wofasept AHA, Desmila VSI, Curacid HD-sept, Deogel Mani, EN 13727 Quantitative suspension test – bactericidal (S. aureus) activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-17	Werner, H.-P.	2018	Anfosan, Anfosan forte, Wofasept AHA, Desmila VSI, Curacid HD-sept, Deogel Mani, EN 13624, Quantitative Suspension Test - Yeasticidal Activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-18	Werner, H.-P.	2018	Curacid HD-sept EN 1650 Quantitative suspension test - yeasticidal (S. cerevisiae) activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-19	Werner, H.-P.	2018	Curacid HD-sept EN 13697 Quantitative non-porous surface test – Yeastical (S. cerevisiae) activity (phase 2, step 2)	Brenntag Holding GmbH
6.7-20	Werner, H.-P.	2018	Curacid HD-sept EN 1276 Quantitative suspension test – bactericidal activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-21	Werner, H.-P.	2018	Curacid HD-sept EN 1650 Quantitative suspension test – yeasticidal (*C. albicans*) activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-22	Werner, H.-P.	2018	Curacid HD-sept EN 13697 Quantitative non-porous surface test – bactericidal and yeasticidal activity (phase 2, step 2)	Brenntag Holding GmbH

Data set according to Annex III Regulation (EU) No 528/2012	Author(s)	Year	Title	Owner company
6.7-23	Werner, H.-P.	2018	Curacid HD-sept EN 1276 Quantitative suspension test – bactericidal activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-24	Werner, H.-P.	2018	Curacid HD-sept EN 1650 Quantitative suspension test – yeasticidal (C. albicans) activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-25	Werner, H.-P.	2018	Curacid HD-sept EN 13697 Quantitative non-porous surface test – bactericidal and yeasticidal activity (phase 2, step 2)	Brenntag Holding GmbH
6.7-25	Werner, S.	2018	Wofasept AHA, Esept Gel, Easysept EN 13727 Quantitative suspension test – Bactericidal activity (phase 2, step 1)	Brenntag Holding GmbH
6.7-25	Werner, S.	2018	Wofasept AHA, Esept Gel, Easysept EN 13624 Quantitative suspension test – Yeasticidal activity (phase 2, step 1)	Brenntag Holding GmbH

3.2 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools
Safety for professional users

Output_Occupational Expo.pdf

RC_professionals.pdf

BrenntagARTreport_Scenario6.pdf

Safety for non-professional users and the general public

ConsExpo 4.1 report

Scenario 7a_8a_PT1_adult_1x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	6,4	mg/m3
inhalation air concentration year average :	6,4	mg/m3/day
inhalation acute (internal) dose :	1,72	mg/kg
inhalation chronic (internal) dose :	1,72	mg/kg/day

Integrated (point estimates)

total external dose:	1,72	mg/kg
total acute dose (internal):	1,72	mg/kg
total chronic dose (internal):	1,72	mg/kg/day

ConsExpo 4.1 report

Scenario 7a_8a_PT1_adult_1x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	1,54	mg/m3

inhalation air concentration year average :	1,54	mg/m3/day
inhalation acute (internal) dose :	0,413	mg/kg
inhalation chronic (internal) dose :	0,413	mg/kg/day

Integrated (point estimates)

total external dose:	0,413	mg/kg
total acute dose (internal):	0,413	mg/kg
total chronic dose (internal):	0,413	mg/kg/day

ConsExpo 4.1 report

Scenario 7a_8a PT1_adult_5x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	32	mg/m3
inhalation air concentration year average :	32	mg/m3/day
inhalation acute (internal) dose :	1,72	mg/kg
inhalation chronic (internal) dose :	8,58	mg/kg/day

Integrated (point estimates)

total external dose:	1,72	mg/kg
total acute dose (internal):	1,72	mg/kg
total chronic dose (internal):	8,58	mg/kg/day

ConsExpo 4.1 report

Scenario 7a_8a PT1_adult_5x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	7,7	mg/m3
inhalation air concentration year average :	7,7	mg/m3/day
inhalation acute (internal) dose :	0,413	mg/kg
inhalation chronic (internal) dose :	2,06	mg/kg/day

Integrated (point estimates)

total external dose:	0,413	mg/kg
total acute dose (internal):	0,413	mg/kg
total chronic dose (internal):	2,06	mg/kg/day

ConsExpo 4.1 report

Scenario 7a_8a PT1_adult_25x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	160	mg/m3
inhalation air concentration year average :	160	mg/m3/day
inhalation acute (internal) dose :	1,72	mg/kg
inhalation chronic (internal) dose :	42,9	mg/kg/day

Integrated (point estimates)

total external dose:	1,72	mg/kg
total acute dose (internal):	1,72	mg/kg
total chronic dose (internal):	42,9	mg/kg/day

ConsExpo 4.1 report

Scenario 7a_8a PT1_adult_25x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3

ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	38,5	mg/m3
inhalation air concentration year average :	38,5	mg/m3/day
inhalation acute (internal) dose :	0,413	mg/kg
inhalation chronic (internal) dose :	10,3	mg/kg/day

Integrated (point estimates)

total external dose:	0,413	mg/kg
total acute dose (internal):	0,413	mg/kg
total chronic dose (internal):	10,3	mg/kg/day

ConsExpo 4.1 report

Scenario 7b_8b_PT1_child_1x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	6,4	mg/m3
inhalation air concentration year average :	6,4	mg/m3/day
inhalation acute (internal) dose :	3,21	mg/kg
inhalation chronic (internal) dose :	3,21	mg/kg/day

Integrated (point estimates)

total external dose:	3,21	mg/kg
total acute dose (internal):	3,21	mg/kg
total chronic dose (internal):	3,21	mg/kg/day

ConsExpo 4.1 report

Scenario 7b_8b_PT1_child_1x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	1,54	mg/m3
inhalation air concentration year average :	1,54	mg/m3/day
inhalation acute (internal) dose :	0,773	mg/kg
inhalation chronic (internal) dose :	0,773	mg/kg/day

Integrated (point estimates)

total external dose:	0,773	mg/kg
total acute dose (internal):	0,773	mg/kg
total chronic dose (internal):	0,773	mg/kg/day

ConsExpo 4.1 report

Scenario 7b_8b_PT1_child_5x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	32	mg/m3
inhalation air concentration year average :	32	mg/m3/day
inhalation acute (internal) dose :	3,21	mg/kg
inhalation chronic (internal) dose :	16,1	mg/kg/day

Integrated (point estimates)

total external dose:	3,21	mg/kg
total acute dose (internal):	3,21	mg/kg
total chronic dose (internal):	16,1	mg/kg/day

Scenario 7b_8b_PT1_child_5x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	7,7	mg/m3
inhalation air concentration year average :	7,7	mg/m3/day
inhalation acute (internal) dose :	0,773	mg/kg
inhalation chronic (internal) dose :	3,87	mg/kg/day

Integrated (point estimates)

total external dose:	0,773	mg/kg
total acute dose (internal):	0,773	mg/kg
total chronic dose (internal):	3,87	mg/kg/day

ConsExpo 4.1 report

Scenario 7b_8b_PT1_child_25x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	160	mg/m3
inhalation air concentration year average :	160	mg/m3/day
inhalation acute (internal) dose :	3,21	mg/kg
inhalation chronic (internal) dose :	80,3	mg/kg/day

Integrated (point estimates)

total external dose:	3,21	mg/kg
total acute dose (internal):	3,21	mg/kg
total chronic dose (internal):	80,3	mg/kg/day

ConsExpo 4.1 report

Scenario 7b_8b_PT1_child_25x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	38,5	mg/m3
inhalation air concentration year average :	38,5	mg/m3/day
inhalation acute (internal) dose :	0,773	mg/kg
inhalation chronic (internal) dose :	19,3	mg/kg/day

Integrated (point estimates)

total external dose:	0,773	mg/kg
total acute dose (internal):	0,773	mg/kg
total chronic dose (internal):	19,3	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_1x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	6,4	mg/m3
inhalation air concentration year average :	6,4	mg/m3/day
inhalation acute (internal) dose :	5,07	mg/kg
inhalation chronic (internal) dose :	5,07	mg/kg/day

Integrated (point estimates)

total external dose:	5,07	mg/kg
total acute dose (internal):	5,07	mg/kg
total chronic dose (internal):	5,07	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_1x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	1,54	mg/m3
inhalation air concentration year average :	1,54	mg/m3/day
inhalation acute (internal) dose :	1,22	mg/kg
inhalation chronic (internal) dose :	1,22	mg/kg/day

Integrated (point estimates)

total external dose:	1,22	mg/kg
total acute dose (internal):	1,22	mg/kg
total chronic dose (internal):	1,22	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_5x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	32	mg/m3

inhalation air concentration year average :	32	mg/m3/day
inhalation acute (internal) dose :	5,07	mg/kg
inhalation chronic (internal) dose :	25,3	mg/kg/day

Integrated (point estimates)

total external dose:	5,07	mg/kg
total acute dose (internal):	5,07	mg/kg
total chronic dose (internal):	25,3	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_5x_Tier2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	7,7	mg/m3
inhalation air concentration year average :	7,7	mg/m3/day
inhalation acute (internal) dose :	1,22	mg/kg
inhalation chronic (internal) dose :	6,1	mg/kg/day

Integrated (point estimates)

total external dose:	1,22	mg/kg
total acute dose (internal):	1,22	mg/kg
total chronic dose (internal):	6,1	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_25x_Tier 1

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	0,6	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	15,4	mg/m3
inhalation mean concentration on day of exposure:	160	mg/m3
inhalation air concentration year average :	160	mg/m3/day
inhalation acute (internal) dose :	5,07	mg/kg
inhalation chronic (internal) dose :	127	mg/kg/day

Integrated (point estimates)

total external dose:	5,07	mg/kg
total acute dose (internal):	5,07	mg/kg
total chronic dose (internal):	127	mg/kg/day

ConsExpo 4.1 report

Scenario 8c_PT1_toddler_25x_Tier 2

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	20	m3
ventilation rate	2,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	3,7	mg/m3
inhalation mean concentration on day of exposure:	38,5	mg/m3
inhalation air concentration year average :	38,5	mg/m3/day
inhalation acute (internal) dose :	1,22	mg/kg
inhalation chronic (internal) dose :	30,5	mg/kg/day

Integrated (point estimates)

total external dose:	1,22	mg/kg
total acute dose (internal):	1,22	mg/kg
total chronic dose (internal):	30,5	mg/kg/day

ConsExpo 4.1 report

Scenario 9a_PT1_adult_1x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	24	hour
room volume	80	m3

ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,642	mg/m3
inhalation mean concentration on day of exposure:	0,642	mg/m3
inhalation air concentration year average :	0,642	mg/m3/day
inhalation acute (internal) dose :	0,172	mg/kg
inhalation chronic (internal) dose :	0,172	mg/kg/day

Integrated (point estimates)

total external dose:	0,172	mg/kg
total acute dose (internal):	0,172	mg/kg
total chronic dose (internal):	0,172	mg/kg/day

ConsExpo 4.1 report

Scenario 9a_PT1_adult_5x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	24	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,642	mg/m3
inhalation mean concentration on day of exposure:	0,642	mg/m3
inhalation air concentration year average :	3,21	mg/m3/day
inhalation acute (internal) dose :	0,172	mg/kg
inhalation chronic (internal) dose :	0,86	mg/kg/day

Integrated (point estimates)

total external dose:	0,172	mg/kg
total acute dose (internal):	0,172	mg/kg
total chronic dose (internal):	0,86	mg/kg/day

ConsExpo 4.1 report

Scenario 9a_PT1_adult_25x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	24	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,67	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,642	mg/m3
inhalation mean concentration on day of exposure:	0,642	mg/m3
inhalation air concentration year average :	16	mg/m3/day
inhalation acute (internal) dose :	0,172	mg/kg
inhalation chronic (internal) dose :	4,3	mg/kg/day

Integrated (point estimates)

total external dose:	0,172	mg/kg
total acute dose (internal):	0,172	mg/kg
total chronic dose (internal):	4,3	mg/kg/day

ConsExpo 4.1 report

Scenario 9b_PT1_child_1x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	0,642	mg/m3
inhalation air concentration year average :	0,642	mg/m3/day
inhalation acute (internal) dose :	0,322	mg/kg
inhalation chronic (internal) dose :	0,322	mg/kg/day

Integrated (point estimates)

total external dose:	0,322	mg/kg
total acute dose (internal):	0,322	mg/kg
total chronic dose (internal):	0,322	mg/kg/day

ConsExpo 4.1 report

Scenario 9b_PT1_child_5x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	3,21	mg/m3
inhalation air concentration year average :	3,21	mg/m3/day
inhalation acute (internal) dose :	0,322	mg/kg
inhalation chronic (internal) dose :	1,61	mg/kg/day

Integrated (point estimates)

total external dose:	0,322	mg/kg
total acute dose (internal):	0,322	mg/kg
total chronic dose (internal):	1,61	mg/kg/day

ConsExpo 4.1 report

Scenario 9b_PT1_child_25x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,5	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	16	mg/m3
inhalation air concentration year average :	16	mg/m3/day
inhalation acute (internal) dose :	0,322	mg/kg
inhalation chronic (internal) dose :	8,05	mg/kg/day

Integrated (point estimates)

total external dose:	0,322	mg/kg
total acute dose (internal):	0,322	mg/kg

total chronic dose (internal):	8,05	mg/kg/day

ConsExpo 4.1 report

Scenario 9c_PT1_toddler_1x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	0,642	mg/m3
inhalation air concentration year average :	0,642	mg/m3/day
inhalation acute (internal) dose :	0,508	mg/kg
inhalation chronic (internal) dose :	0,508	mg/kg/day

Integrated (point estimates)

total external dose:	0,508	mg/kg
total acute dose (internal):	0,508	mg/kg
total chronic dose (internal):	0,508	mg/kg/day

ConsExpo 4.1 report

Scenario 9c_PT1_toddler_5x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	5	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	3,21	mg/m3

inhalation air concentration year average :	3,21	mg/m3/day
inhalation acute (internal) dose :	0,508	mg/kg
inhalation chronic (internal) dose :	2,54	mg/kg/day

Integrated (point estimates)

total external dose:	0,508	mg/kg
total acute dose (internal):	0,508	mg/kg
total chronic dose (internal):	2,54	mg/kg/day

ConsExpo 4.1 report

Scenario 9c_PT1_toddler_25x

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	25	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	70	%
exposure duration	10	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	2,64E3	milligram

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	0,33	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,54	mg/m3
inhalation mean concentration on day of exposure:	16	mg/m3
inhalation air concentration year average :	16	mg/m3/day
inhalation acute (internal) dose :	0,508	mg/kg
inhalation chronic (internal) dose :	12,7	mg/kg/day

Integrated (point estimates)

total external dose:	0,508	mg/kg
total acute dose (internal):	0,508	mg/kg
total chronic dose (internal):	12,7	mg/kg/day

ConsExpo 4.1 report

Scenario 10a_PT2 4_adult

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	70	%
exposure duration	10	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	17,6	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,25	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	991	mg/m3
inhalation mean concentration on day of exposure:	6,88	mg/m3
inhalation air concentration year average :	6,88	mg/m3/day
inhalation acute (internal) dose :	3,44	mg/kg
inhalation chronic (internal) dose :	3,44	mg/kg/day

Integrated (point estimates)

total external dose:	3,44	mg/kg
total acute dose (internal):	3,44	mg/kg
total chronic dose (internal):	3,44	mg/kg/day

ConsExpo 4.1 report

Scenario 10b_PT2 4_child

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23,9	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	70	%
exposure duration	10	minute

room volume	10	m3
ventilation rate	2	1/hr
applied amount	17,6	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,32	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	991	mg/m3
inhalation mean concentration on day of exposure:	6,88	mg/m3
inhalation air concentration year average :	6,88	mg/m3/day
inhalation acute (internal) dose :	9,12	mg/kg
inhalation chronic (internal) dose :	9,12	mg/kg/day

Integrated (point estimates)

total external dose:	9,12	mg/kg
total acute dose (internal):	9,12	mg/kg
total chronic dose (internal):	9,12	mg/kg/day

ConsExpo 4.1 report

Scenario 10c_PT2 4_toddler

Product

Brenntag GmbH Propan-2-ol PF

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60,1	g/mol
vapour pressure	5,78E3	Pascal
KOW	0,05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	70	%
exposure duration	10	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	17,6	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,335	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,26	m3/hour

Output

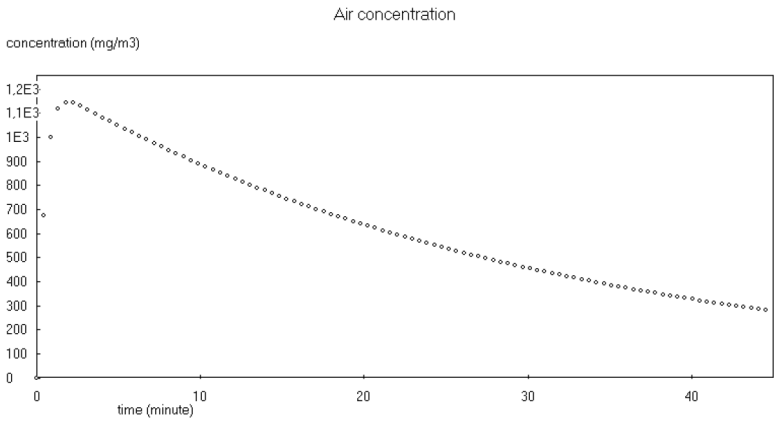
Inhalation (point estimates)

inhalation mean event concentration :	991	mg/m3
inhalation mean concentration on day of exposure:	6,88	mg/m3
inhalation air concentration year average :	6,88	mg/m3/day
inhalation acute (internal) dose :	20,8	mg/kg
inhalation chronic (internal) dose :	20,8	mg/kg/day

Integrated (point estimates)

total external dose:	20,8	mg/kg
total acute dose (internal):	20,8	mg/kg
total chronic dose (internal):	20,8	mg/kg/day

Scenario 10c, toddler, aerial concentration after 30 min



3.3 New information on the active substance

The applicant submitted no new information on the active substance "propan-2-ol".

Access to data from active substances approval

The applicant has no access to the dossier for the approval of the active substance "propan-2-ol" for use in PT1 (Human hygiene), (PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

Access to data according to for the active substance "propan-2-ol"

The applicant provided a letter of access to the dossier for the active substance "propan-2-ol recorded under the asset no. EU-0011803-0000. This dossier is satisfying the requirements set out in Annex II of Regulation (EU) No 528/2012 for use in PT1 (Human hygiene), PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area).

3.4 Residue behaviour

The information provided regarding the residues was acceptable. Please refer to chapter 2.2.4 and 2.3.4.

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

An IUCLID file is available. Please refer to the IUCLID file.

3.6 Confidential annex

Please refer to the separate document.

3.7 Other

No other information.