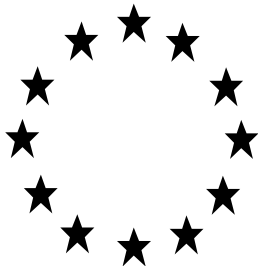
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product family identifier in R4BP	orochemie hand- and surface disinfectants
Product type(s):	PT 01 (Human hygiene) PT 02 (Disinfectants and algaecides not intended for direct application to humans or animals) PT 04 (Food and feed area)
Active ingredient(s):	Propan-2-ol
Case No. in R4BP	BC-WT071043-15
Asset No. in R4BP	DE-0015778-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/02.00004 710-05-02-00004-00-04-00-0000
Date	13.01.2023

Table of content

Overview of applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment)	Page
NA-APP	DE	BC-CP025485-33	23.09.2020	First Authorisation	See PAR under case mentioned before
NA-ADC	DE	BC-NR063832-15	26.01.2021	Adminstrative change (additional trade names and change of existing trade names in Germany)	
NA-ADC	DE	BC-WD064365-34	01.03.2021	Adminstrative change (additional trade names and change of existing trade names in Germany)	
NA-MAC	DE	BC-WT071043-15	13.01.2023	Major Change (additional „limited spectrum virucidal activity”-claim)	p. 13 ff

1 Overall conclusion

The assessment presented in this report has shown the efficacy and no unacceptable risks, if the products in meta SPC 1 to 5 of biocidal product family (BPF) “orochemie hand- and surface disinfectants” with the active substance propan-2-ol (63.1 % w/w) are used for products in product type 01 (Human hygiene), 02 (Disinfectants and algaecides not intended for direct application to humans or animals) and 04 (Food and feed area). The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled for meta SPCs 1 to 5. Please find detailed information on the uses appropriate for authorisation and directions for use in chapter 2.3.

A classification according to Regulation (EC) No 1272/2008[2] is necessary for meta SPCs 1, 2, 3, 4 and 5.

The assessment of the intended uses as applied for by the applicant (see chapter 3.1 has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance propan-2-ol including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.
2. The specific provisions from the approval decision for the active substance propan-2-ol (Commission Implementing Regulation (EU) 2015/407).

Approval of the active substance

The active substance propan-2-ol is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

For products in product type 1 and 2:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Composition and formulation

The ready-to-use liquids contain the active substance propan-2-ol. No substances of concern (SoC) were identified in all meta SPC.

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[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

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

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.
Please refer to chapter 2.2, 2.3.1.2 and chapter 5 (full composition; confidential Annex) for detailed information.

Physical, chemical and technical properties

The products within the family are colourless and have an alcoholic odour.
The products of meta SPC 1 (ready-to-use gel) have a shelf-life of 48 months The products of meta SPC 2 and 4 (ready-to-use liquids) have a shelf-life of 48 months, whereas products (ready-to-use wipes) of meta SPC 3 and 5 have a shelf-life of 24 months. (please find more information in chapter 3.2).

Physical hazards and respective characteristics

According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified with regard to physical hazards as follows.
Flam. Liq. 2; (Flammable liquids, hazard category 2)
H225: Highly flammable liquid and vapour (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The products have been shown to be efficacious for the uses appropriate for authorisation listed in chapters 2.3. Please find more information on efficacy of the products in chapter 3.5.

Risk assessment for human health

A human health risk assessment has been carried out for professional use of the products in meta SPC 1 to 5 (see chapter 3.6) for all intended uses.

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the instructions for use and risk mitigation measures according to chapters 2.3 are followed.

Risk assessment for the environment

Since no relevant SoC has been identified the risk assessment for the environment for the products in meta SPC 1 to 5 is based on the active substance. The risk assessment for the environment has been carried out for professional use of products in meta SPC 1 to 5 (see chapter 3.8) for all intended uses.
Based on the risk assessment it is unlikely that the intended uses cause any unacceptable risk for the environment if the instructions for use and risk mitigation measures according to chapters 2.3 are followed.

Comparative Assessment

Since the active substance propan-2ol has not been identified as a candidate for substitution a comparative assessment was not necessary.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

orochemie hand- and surface disinfectants

2.1.2 Product type(s)

01 (Human hygiene) 02 (Disinfectants and algaecides not intended for direct application to humans or animals) 04 (Food and feed area)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	orochemie GmbH + Co. KG
Address of manufacturer	Max-Planck-Str. 27, 70806 Kornwestheim Germany
Location of manufacturing sites	Max-Planck-Str. 27, 70806 Kornwestheim Germany

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

Active substance	Propan-2-ol
Name of manufacturer	AUG HEDNGER GmbH Co KG (supplied by Shell Nederland Chemie B.V.)
Address of manufacturer	Heiligenwissen 26, 70327 Stuttgart Germany
Location of manufacturing sites	Vondelingenweg 601, 3196 KK Rotterdam,

	The Netherlands

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

Active substance	Propan-2-ol
Name of manufacturer	STOCKMEIER Holding GmbH (supplied by INEOS Solvents Germany GmbH)
Address of manufacturer	Am Stadtholz 37 33609 Bielefeld Germany
Location of manufacturing sites	Römerstraße 733, 47443 Moers Germany

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active sub-stance	67-63-0	200-661-7	63.1	63.1

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

2.2.2 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-0014021-0000 EU-0017009-0000 and EU-0012153-0000)

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

2.2.4 Information on the substance(s) of concern

No substance of concern was identified.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type(s) of formulation

AL (any other liquid)-ready to use

2.3 Meta SPC(s) (second information level)

2.3.1 Meta SPC No. meta-01

2.3.1.1 Administrative information

2.3.1.1.1 Meta SPC identifier

Meta-SPC 01

2.3.1.1.2 Suffix to the authorisation number

01

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

01 (Human hygiene)

2.3.1.2 Composition and formulation of the products within the meta SPC

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

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	63.1	63.1

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

AL (any other liquid)-ready to use

2.3.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [3]

Human Health

This classification regarding Human Health is valid for all meta SPCs 1 to 5 of the orochemie hand- and surface disinfectants BPF.

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 propan-2-ol (CAS-No. 67-63-0) 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.

Classification of the products in all meta SPCs pursuant to the Regulation (EC) 1272/2008 is required.

In addition, the biocidal product family has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) 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.

Environment:

The composition of the BPF does not require environmental classification and labelling. The active substance needs no classification or labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) and the other components do not affect the classification of the products.

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 0 and if applicable to chapter 2.3.1.4.

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**

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

Pictograms	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	EU066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection/face 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+P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to …
Note	-	

According to Article 29(2) Regulation (EC) No 1272/2008 the hazard statements and the precautionary statements linked to the hazard category Flam. Liq. 2 may be omitted from the label elements if the contents of the package do not exceed 125 ml.

H319 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated 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 of the biocidal product this precautionary statement is not required.

2.3.1.4 Use(s) of the products in the meta SPC appropriate for authorisation[4]

2.3.1.4.1 Use 1 appropriate for authorisation – Hand disinfection gel (hand gel)

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection gel orochemie hand disinfectants is propan-2-ol based hand rub gel for the hygienic and surgical handrub disinfection
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection and surgical handrub disinfection with hand gel
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection (without long-term effect according to EN 12791): rub in 3 ml portions on hands and forearms during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	100 mL bottle (PET), closure (PP); 500 mL – 10 L bottle/canister (PE); closure (PP or PE); 220 L drum PE; 1000L Container PE

4 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.3.1.4.1.1 Use-specific instructions for use

Please refer to chapter 2.3.1.5.

2.3.1.4.1.2 Use-specific risk mitigation measures

Please refer to chapter 2.3.1.5.

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

Please refer to chapter 2.3.1.5.

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

Please refer to chapter 2.3.1.5.

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

Please refer to chapter 2.3.1.5.

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

2.3.1.5.1 Instructions for use

1. Hygienic handrub: The product is used undiluted. For hygienic hand disinfection, rub clean hands with the product and keep moist for at least 30 seconds (at least 2x 3 ml) to achieve bactericidal (incl. tuberculocidal) and levurocidal efficacy, as well as efficacy against enveloped viruses. Limited spectrum virucidal activity is achieved after rubbing clean hands for 60 seconds.
2. Surgical handrub (without long-term effect according to EN 12791): The product is used undiluted. Rub clean hands and forearms with 3 ml portions of the undiluted product. For bactericidal (incl. tuberculocidal) and levurocidal efficacy, keep the skin moist for at least 90 seconds.

2.3.1.5.2 Risk mitigation measures

1) Avoid contact with eyes.

2) The following personal risk mitigation measure can be considered for the 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. 3) For refilling, a funnel must be applied.

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

First aid IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. Call a POISON CENTER/ doctor/…/if you feel unwell. If eye irritation persists get medical advice/attention.

2.3.1.5.4 Instructions for safe disposal of the product and its packaging

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

1) Store cool (not above 30°C) 2) 48 months shelf life

2.3.1.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.2 Meta SPC No. meta-02

2.3.2.1 Administrative information

2.3.2.1.1 Meta SPC identifier

Meta-SPC 02

2.3.2.1.2 Suffix to the authorisation number

02

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

01 (Human hygiene)

2.3.2.2 Composition and formulation of the products within the meta SPC

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

Table 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	63.1	63.1

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

AL (any other liquid)-ready to use

2.3.2.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [5]

Human Health

This classification regarding Human Health is valid for all meta SPCs 1 to 5 of the orochemie hand- and surface disinfectants BPF.

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 propan-2-ol (CAS-No. 67-63-0) 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.

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

Classification of the products in all meta SPCs pursuant to the Regulation (EC) 1272/2008 is required. In addition, the biocidal product family has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) 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.

Environment:
The composition of the BPF does not require environmental classification and labelling. The active substance needs no classification or labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) and the other components do not affect the classification of the products.

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 2.3.2.5 and if applicable to chapter 2.3.2.4.

Table 5

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit. 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	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	EU066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-

Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection/face 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+P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to …
Note	-	

According to Article 29(2) Regulation (EC) No 1272/2008 the hazard statements and the precautionary statements linked to the hazard category Flam. Liq. 2 may be omitted from the label elements if the contents of the package do not exceed 125 ml.

H319 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated 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 of the biocidal product this precautionary statement is not required.

2.3.2.4 Use(s) of the products in the meta SPC appropriate for authorisation[6]

2.3.2.4.1 Use 1 appropriate for authorisation – hand solution

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection solution orochemie hand disinfectants is a propan-2-ol based hand rub solution for hygienic and surgical handrub disinfection
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection and surgical handrub disinfection with hand solution
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection (without long-term effect according to EN 12791): rub in 3 ml portions on hands and forearms during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL- 10 L bottle/canister (PE), closure (PP or PE); 220 L drum PE; 1000L Container PE

2.3.2.4.1.1 Use-specific instructions for use

Please refer to chapter 2.3.2.5.

2.3.2.4.1.2 Use-specific risk mitigation measures

Please refer to chapter 2.3.2.5.

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

Please refer to chapter 2.3.2.5.

6 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

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

Please refer to chapter 2.3.2.5

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

Please refer to chapter 2.3.2.5

2.3.2.4.2 Use 2 appropriate for authorisation –hand spray

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection solution orochemie hand disinfectants is a propan-2-ol based hand rub solution for for hygienic and surgical handrub disinfection.
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection and surgical handrub disinfection with hand spray
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection (without long-term effect according to EN 12791): rub in 3 ml portions on hands and forearms during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL – 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), pump sprayer; 220 L drum (PE); 1000L Container (PE)

2.3.2.4.2.1 Use-specific instructions for use

Please refer to chapter 2.3.2.5.

2.3.2.4.2.2 Use-specific risk mitigation measures

Please refer to chapter 2.3.2.5.

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

Please refer to chapter 2.3.2.5.

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

Please refer to chapter 2.3.2.5

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

Please refer to chapter 2.3.2.5.

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

2.3.2.5.1 Instructions for use

1. Hygienic handrub: The product is used undiluted. For hygienic hand disinfection, rub clean hands with the product and keep moist for at least 30 seconds (at least 2x 3 ml) to achieve bactericidal (incl. tuberculocidal) and levurocidal efficacy, as well as efficacy against enveloped viruses. Limited spectrum virucidal activity is achieved rubbing clean hands for 60 seconds. 2. Surgical handrub (without long-term effect according to EN 12791): The product is applied undiluted. Rub clean hands and forearms with 3 ml portions of the undiluted product. For bactericidal (incl. tuberculocidal) and levurocidal efficacy, keep the skin moist for at least 90 seconds.

2.3.2.5.2 Risk mitigation measures

1) Avoid contact with eyes. 2) The following personal risk mitigation measure can be considered for the 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. 3) For refilling a funnel must be applied.

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

First aid

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

Call a POISON CENTER/ doctor/…/if you feel unwell.

If eye irritation persists get medical advice/attention.

2.3.2.5.4 Instructions for safe disposal of the product and its packaging

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

1) Store cool (not above 30°C)
2) 48 months shelf life

2.3.2.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.3 Meta SPC No. meta-03

2.3.3.1 Administrative information

2.3.3.1.1 Meta SPC identifier

Meta-SPC 03

2.3.3.1.2 Suffix to the authorisation number

03

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

01 (Human hygiene)

2.3.3.2 Composition and formulation of the products within the meta SPC

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

Table 6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	63.1	63.1

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

AL (any other liquid)-ready to use

2.3.3.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [7]

Human Health:

This classification regarding Human Health is valid for all meta SPCs 1 to 5 of the orochemie hand- and surface disinfectants BPF.

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 propan-2-ol (CAS-No. 67-63-0) 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.

Classification of the products in all meta SPCs pursuant to the Regulation (EC) 1272/2008 is required.

In addition, the biocidal product family has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) 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.

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

Environment:

The composition of the BPF does not require environmental classification and labelling. The active substance needs no classification or labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) and the other components do not affect the classification of the products.

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 2.3.3.5 and if applicable to chapter 2.3.3.4.

Table 7

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit. 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
	GHS07	
	GHS02	
Signal word	-	Danger
	H225	Highly flammable liquid and vapour.
Hazard statements	H319	Causes serious eye irritation
	H336	May cause drowsiness and dizziness
Supplemental hazard information	EU066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P261	Avoid breathing dust/fumes/gas/mist/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+P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to …
Note	-	

H319 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated 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 of the biocidal product this precautionary statement is not required.

2.3.3.4 Use(s) of the products in the meta SPC appropriate for authorisation[8]

2.3.3.4.1 Use 1 appropriate for authorisation – disinfectant wipes for hands

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection wipes orochemie hand disinfectants is a propan-2-ol based hand rub solution for the hygienic handrub disinfection.
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection with ready-to-use wipes
Application rate(s) and frequency	2 wipes used subsequently, contact time 60 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	Box (PE) with 40 – 300 wipes (non-woven PET) in aluminium compound foils (PET/Alu/PE), 1 Wipe (non-woven PET) in aluminium compound foil (PET/Alu/PE)

8 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.3.3.4.1.1 Use-specific instructions for use

Please refer to chapter 2.3.3.5.

2.3.3.4.1.2 Use-specific risk mitigation measures

Please refer to chapter 2.3.3.5.

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

Please refer to chapter 2.3.3.5.

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

Please refer to chapter 2.3.3.5.

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

Please refer to chapter 2.3.3.5.

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

2.3.3.5.1 Instructions for use

1) Rub one wipe thoroughly over clean hands for 30 seconds, then rub a second wipe over hands for an additional 30 seconds for bactericidal (incl. tuberculocidal) and levurocidal efficacy as well as efficacy against enveloped viruses and limited spectrum virucidal activity. 2) Used wipes must be disposed in a closed container.

2.3.3.5.2 Risk mitigation measures

Avoid contact with eyes.

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

First aid IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

Call a POISON CENTER/ doctor/…/if you feel unwell. If eye irritation persists get medical advice/attention.

2.3.3.5.4 Instructions for safe disposal of the product and its packaging

-

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

1) Store cool (not above 30°C) 2) 36 months shelf life

2.3.3.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.4 Meta SPC No. meta-04

2.3.4.1 Administrative information

2.3.4.1.1 Meta SPC identifier

Meta-SPC 04

2.3.4.1.2 Suffix to the authorisation number

04

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

02 (Disinfectants and algaecides not intended for direct application to humans or animals) 04 (Food and feed area)

2.3.4.2 Composition and formulation of the products within the meta SPC

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

Table 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	63.1	63.1

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

AL (any other liquid)-ready to use

2.3.4.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [9]

Human Health:

This classification regarding Human Health is valid for all meta SPCs 1 to 5 of the orochemie hand- and surface disinfectants BPF.

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 propan-2-ol (CAS-No. 67-63-0) 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.

Classification of the products in all meta SPCs pursuant to the Regulation (EC) 1272/2008 is required.

In addition, the biocidal product family has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) 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.

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

Environment:

The composition of the BPF does not require environmental classification and labelling. The active substance needs no classification or labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) and the other components do not affect the classification of the products.

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 2.3.4.5 and if applicable to chapter 2.3.4.4.

Table 9

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit. 2	H319	
STOT SE 3	H336	
Labelling	**Code**	**Pictogram / Wording**
Pictograms		
	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	EU066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements		
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.

	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection/face 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+P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to …
Note	-	

According to Article 29(2) Regulation (EC) No 1272/2008 the hazard statements and the precautionary statements linked to the hazard category Flam. Liq. 2 may be omitted from the label elements if the contents of the package do not exceed 125 ml.

H319 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated 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 of the biocidal product this precautionary statement is not required.

2.3.4.4 Use(s) of the products in the meta SPC appropriate for authorisation[10]

2.3.4.4.1 Use 1 appropriate for authorisation – Surface disinfection by wiping

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by wiping
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)

10 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry Disinfection of non-porous surfaces
Application method(s)	Pouring and wiping
Application rate(s) and frequency	Max. 50 ml/m²
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); 220 L drum (PE); 1000L Container (PE)

2.3.4.4.1.1 Use-specific instructions for use

Spectrum of action: bactericidal (incl. tuberculocidal), levurocidal, effective against enveloped viruses and limited spectrum virucidal activity.
The product is applied undiluted. Apply the product by pouring onto the surface and wipe. Ensure complete wetting (max. 50 ml/m²) of the surface. For bactericidal (incl. tuberculocidal) and levurocidal activity and activity against enveloped viruses, the contact time is 1 minute (medical and non-medical area, each clean and dirty conditions). For limited spectrum virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions.

2.3.4.4.1.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measure can be considered for the refilling procedure unless it can be replaced by technical and / or organisational measures:
2) The use of eye protection during handling of the product is recommended.
3) The product must only be applied for disinfection of small surfaces.
4) For medical practices and small rooms, provide adequate ventilation (technical ventilation or keeping windows and doors open). The stay in the treated area should be minimised.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

2.3.4.4.2 Use 2 appropriate for authorisation – Surface disinfection by spraying and wiping

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by spraying and wiping
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry Disinfection of non-porous surfaces
Application method(s)	Spraying and Wiping
Application rate(s) and frequency	Max. 50 ml/m²
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), pumpsprayer 220 L drum (PE); 1000L Container (PE)

2.3.4.4.2.1 Use-specific instructions for use

Spectrum of efficacy: Bactericidal (incl. tuberculocidal), levurocidal, effective against enveloped viruses and limited spectrum virucidal activity. Spray and wipe: The product is applied undiluted. Apply the product by spraying from a distance of 20 - 30 cm onto the surface and wipe. Ensure complete wetting (max. 50 ml/m²) of the surface. For bactericidal (incl. tuberculocidal) and levurocidal activity and activity against enveloped viruses, the contact time is 1 minute (medical and non-medical area, each clean and dirty conditions). For limited spectrum virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions.

2.3.4.4.2.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measure can be considered for the 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) The product must only be applied for disinfection of small surfaces. 3) For medical practices and small rooms, provide adequate ventilation (technical ventilation or keeping windows and doors open). The stay in the treated area should be minimised.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

2.3.4.4.3 Use 3 appropriate for authorisation – Surface disinfection by wiping – PT4

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by wiping
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Viruses
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and – handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Pouring and wiping
Application rate(s) and frequency	Max. 50 ml/m²
Category(ies) of users	Professional user

Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); 220 L drum (PE); 1000L Container PE

2.3.4.4.3.1 Use-specific instructions for use

Spectrum of efficacy: bactericidal (incl. tuberculocidal), levurocidal, and virucidal The product is applied undiluted. Apply the product by pouring onto the surface and wipe. Ensure complete wetting (max. 50 ml/m²) of the surface. For bactericidal (incl. tuberculocidal) and levurocidal activity, the contact time is 1 minute (clean and dirty conditions). For virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions.

2.3.4.4.3.2 Use-specific risk mitigation measures

1) 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: 2) The use of eye protection during handling of the product is recommended 3) The product must only be applied for disinfection of small surfaces.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

2.3.4.4.4 Use 4 appropriate for authorisation – Surface disinfection by spraying and wiping

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by spraying and wiping
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Viruses
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and – handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Spraying and Wiping
Application rate(s) and frequency	Max. 50 ml/m²
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), Pump sprayer; 220 L drum (PE); 1000L Container (PE)

2.3.4.4.4.1 Use-specific instructions for use

Spectrum of activity: bactericidal (incl. tuberculocidal), levurocidal, virucidal.

Spraying and wiping: The product is applied undiluted. Apply the product by spraying from a distance of 20 - 30 cm onto the surface and wipe. Ensure complete wetting (max. 50 ml/m²) of the surface.
For bactericidal (incl. tuberculocidal) and levurocidal activity, the contact time is 1 minute (clean and dirty conditions). For virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions.

2.3.4.4.4.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measure can be considered for disinfection of food processing machinery and the 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) The product must only be applied for disinfection of small surfaces.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

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

Please refer to chapter 2.3.4.5.

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

2.3.4.5.1 Instructions for use

1) For use at room temperature (20±2°C).
2) Do not apply more than 50 ml/m².
3) Used wipes must be disposed in a closed container.

2.3.4.5.2 Risk mitigation measures

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

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

First aid:
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
Call a POISON CENTER/ doctor/…/if you feel unwell.
If eye irritation persists get medical advice/attention.

2.3.4.5.4 Instructions for safe disposal of the product and its packaging

-

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

1) Store cool (not above 30°C)48 month shelf life

2.3.4.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.5 Meta SPC No. meta-05

2.3.5.1 Administrative information

2.3.5.1.1 Meta SPC identifier

Meta-SPC 05

2.3.5.1.2 Suffix to the authorisation number

05

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

02 (Disinfectants and algaecides not intended for direct application to humans or animals) 04 (Food and feed area)

2.3.5.2 Composition and formulation of the products within the meta SPC

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

Table 10

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol	2-Propanol	Active substance	67-63-0	200-661-7	63.1	63.1

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

AL (any other liquid)-ready to use

2.3.5.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [11]

Human Health:

This classification is valid for all meta SPCs 1 to 5 of the orochemie hand- and surface disinfectants BPF. 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 propan-2-ol (CAS-No. 67-63-0) 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.

Classification of the products in all meta SPCs pursuant to the Regulation (EC) 1272/2008 is required.

In addition, the biocidal product family has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) 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.

Environment:

The composition of the BPF does not require environmental classification and labelling. The active substance needs no classification or labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) and the other components do not affect the classification of the products.

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 2.3.5.5 and if applicable to chapter 2.3.5.4.

Table 11

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Flam. Liq. 2	H225
Eye Irrit. 2	H319
STOT SE 3	H336
Labelling	
	Code Pictogram / Wording

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

Pictograms	GHS02	
	GHS07	
Signal word	-	Danger
	H225	Highly flammable liquid and vapour.
Hazard statements	H319	Causes serious eye irritation
	H336	May cause drowsiness and dizziness
Supplemental hazard information	EU066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
	P233	Keep container tightly closed.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P261	Avoid breathing dust/fumes/gas/mist/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+P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to …
Note	-	

According to Article 29(2) Regulation (EC) No 1272/2008 the hazard statements and the precautionary statements linked to the hazard category Flam. Liq. 2 may be omitted from the label elements if the contents of the package do not exceed 125 ml.

H319 triggers P264 (Wash … thoroughly after handling.). This precautionary statement is not required since propan-2-ol and the formulated biocidal product is very volatile and will evaporate from contaminated 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 of the biocidal product this precautionary statement is not required.

2.3.5.4 Use(s) of the products in the meta SPC appropriate for authorisation[12]

2.3.5.4.1 Use 1 appropriate for authorisation – ready-to-use wipes -PT 02

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use wipes for disinfection
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast Enveloped viruses Viruses (limited spectrum virucidal activity)
Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry Disinfection of non-porous surfaces
Application method(s)	Wiping
Application rate(s) and frequency	RTU The product must only be applied for disinfection of small surfaces.
Category(ies) of users	Professional user
Pack sizes and packaging material	Box (PE) with 40 – 300 wipes (non-woven PET) in aluminium compound foils (PET/Alu/PE), 1 Wipe (non-woven PET) in aluminium compound foil (PET/Alu/PE)

12 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.3.5.4.1.1 Use-specific instructions for use

Spectrum of efficacy: bactericidal (incl. tuberculocidal), levurocidal, effective against enveloped viruses and limited spectrum virucidal activity. Wet the surfaces and objects to be disinfected completely by wiping with the soaked wipe. For bactericidal (incl. tuberculocidal) and levurocidal activity and activity against enveloped viruses, the contact time is 1 minute (medical and non-medical area, each clean and dirty conditions). For limited spectrum virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions. Use the product only for disinfection of small surfaces.

2.3.5.4.1.2 Use-specific risk mitigation measures

1) The product must only be applied for disinfection of small surfaces. 2) For medical practices and small rooms, provide adequate ventilation (technical ventilation or keeping windows and doors open). The stay in the treated area should be minimised.

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

Please refer to chapter 2.3.5.5.

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

Please refer to chapter 2.3.5.5.

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

Please refer to chapter 2.3.5.5.

2.3.5.4.2 Use 2 appropriate for authorisation – Ready-to-use wipes – PT 4

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use wipes for disinfection
Target organism(s) (including development stage)	Bacteria Mycobacterium tuberculosis Yeast

	Viruses
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and – handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Wiping
Application rate(s) and frequency	RTU The product must only be applied for disinfection of small surfaces.
Category(ies) of users	Professional user
Pack sizes and packaging material	Box (PE) with 40 – 300 wipes (non-woven PET) in aluminium compound foils (PET/Alu/PE), 1 Wipe (non-woven PET) in aluminium compound foil (PET/Alu/PE)

2.3.5.4.2.1 Use-specific instructions for use

Spectrum of efficacy: bactericidal (incl. tuberculocidal), levurocidal, virucidal

Wet the surfaces and objects to be disinfected completely by wiping with the soaked wipe. For bactericidal (incl. tuberculocidal) and levurocidal activity, the contact time is 1 minute (clean and dirty conditions). For virucidal activity, the contact time is 1 min under clean conditions or 2 min under dirty conditions.

Use the product only for disinfection of small surfaces.

2.3.5.4.2.2 Use-specific risk mitigation measures

The product must only be applied for disinfection of small surfaces.

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

Please refer to chapter 2.3.5.5.

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

Please refer to chapter 2.3.5.5.

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

Please refer to chapter 2.3.5.5.

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

2.3.5.5.1 Instructions for use

1) For use at room temperature (20±2°C). 2) Used wipes must be disposed in a closed container.

2.3.5.5.2 Risk mitigation measures

1) Avoid contact with eyes.

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

First aid: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. Call a POISON CENTER/ doctor/…/if you feel unwell. If eye irritation persists get medical advice/attention.

2.3.5.5.4 Instructions for safe disposal of the product and its packaging

-

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

1) Store cool (not above 30°C) 2) 36 month shelf life

2.3.5.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.4 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 (chapter 5).

2.5 Packaging

Table 12

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
Wipe (non-woven PET)	1 piece	aluminium compound foil (PET/Alu/PE)	-	Professional	Yes
Wipes (non-woven PET) Secondary Packaging: Bucket;	40-300 pieces	aluminium compound foil (PET/Alu/PE) PE	-	Professional	Yes
Bottle	100 ml	PET	flip-top cap, PP	Professional	Yes
Bottle	125 ml	PE	flip-top cap, PP	Professional	Yes
Bottle	125 mL	PE	spray nozzle, PP	Professional	Yes
Bottle	500 ml, 1 L, 2,5 L	HDPE	screw cap, PP or PE	Professional	Yes
canister	5 L, 10 L	PE	PP or PE	Professional	Yes
Drum	220 L	PE	PP and PE	Professional	Yes
IBC	1000 L	PE	PP or PE	Professional	Yes

3 Assessment of meta SPC No. 01 -05 of the product family

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

3.1.1 meta SPC 1

Table 13. Intended use 1 – hand disinfection gel

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection gel orochemie hand disinfectants is fast effective propanol based hand rub gel for the hygenic and surgical purposes.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Indoor: Health care, in institutional, industrial, domestic and veterinary medical area, industry, as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection and surgical handrub disinfection with hand gel
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection: rub in 3 ml portions hands and forearm during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	100 mL bottle (PET), closure (PP); 500 mL – 10 L bottle/canister (PE); closure (PP or PE); 220 L drum (PE); 1000L Container (PE)

3.1.2 meta SPC 2

Table 14. Intended use 1 – Hand disinfection solution

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection solution orochemie hand disinfectants is a fast effective propanol based hand rub solution for the hygenic and surgical purposes,

Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Indoor: Health care, in institutional, industrial, domestic and veterinary medical area, industry as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Hygienic handrub disinfection and surgical handrub disinfection with hand solution
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection: rub in 3 ml portions during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL- 10 L bottle/canister (PE), closure (PP or PE); 220 L drum (PE); 1000L container (PE)

Table 15. Intended use 2 – Hand disinfection spray

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection solution orochemie hand disinfectants is a propanol based hand rub solution for the hygenic and surgical purposes,
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area, industry as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.)
Application method(s)	Spraying and handrub: Hygienic handrub disinfection and surgical handrub disinfection with hand spray
Application rate(s) and frequency	Hygienic handrub disinfection: 2*3 ml product, contact time 30 seconds Surgical handrub disinfection: rub in 3 ml portions during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL – 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), pump sprayer;

	220 L drum (PE); 1000L Container (PE)

3.1.3 meta SPC 3

Table 16. Intended use 1 – disinfection wipes for hands

Product Type(s)	PT 1
Where relevant, an exact description of the use	Ready to use hand disinfection wipes orochemie hand disinfectants is a fast effective propanol based hand rub solution for the hygenic and surgical purposes.
Target organism(s) (including development stage)	Bactericidal (incl. MRSA) Tuberculocidal Yeasticidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.))
Application method(s)	Hygienic handrub disinfection with ready-to-use wipes
Application rate(s) and frequency	Hygienic handrub disinfection: contact time 30 seconds Surgical handrub disinfection: rub in during contact time of 90 seconds
Category(ies) of users	Professional user
Pack sizes and packaging material	Box with 40 -300 wipes and single wipes The non-woven wipes consist of mixed fibres (cellulose/synthetic).

3.1.4 meta SPC 4

Table 17. Intended use 1 – surface disinfection by wiping- PT 2

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by wiping orochemie surface disinfectants are applied undiluted on clean or not clean non-porous surfaces. For disinfection of surfaces by wiping: Pour product on wipe until completely wetted and wipe the surface or pour product directly on the surface until complete wetting and wipe.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA)

	Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry
Application method(s)	Ready to use solution for disinfection of surfaces by wiping
Application rate(s) and frequency	As required: Apply undiluted product For disinfection of surfaces by wiping: Pour product on wipe until completely wetted and wipe the surface or pour product directly on the surface until complete wetting and wipe.
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); 220 L drum (PE); 1000L Container (PE)

Table 18. Intended use 2 – surface disinfection by spraying- PT 2

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by spraying orochemie surface disinfectants wird unverdünnt angewendet auf sauberen und belasteten nicht-poröse Oberflächen. Spraying: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm. Make sure to wet surfaces completely Spraying and Wiping: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm and wiping afterwards or by soaking a wipe by spraying and wiping the surface with the soaked wipe. Make sure to wet surfaces completely.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry
Application method(s)	Ready to use solution for disinfection of surfaces by spraying or by Spraying and Wiping
Application rate(s) and frequency	upon demand: Apply undiluted product

	Spraying: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm. Make sure to wet surfaces completely Spraying and Wiping: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm and wiping afterwards or by soaking a wipe by spraying and wiping the surface with the soaked wipe. Make sure to wet surfaces completely.
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), pumpsprayer 220 L drum (PE); 1000L Container (PE)

Table 19. Intended use 3 – surface disinfection by wiping –PT 4

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by wiping orochemie surface disinfectants are applied undiluted on clean or not clean non-porous surfaces. For disinfection of surfaces by wiping: Pour product on wipe until completely wetted and wipe the surface or pour product directly on the surface until complete wetting and wipe.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal activity Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and –handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Pouring and wiping
Application rate(s) and frequency	As required. Apply this product undiluted. For disinfection of surfaces by wiping: Pour product on wipe until completely wetted and wipe the surface or pour product directly on the surface until complete wetting and wipe.
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); 220 L drum (PE); 1000L Container PE

Table 20. Intended use 4 – surface disinfection by spraying –PT 4

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use solution for disinfection of surfaces by spraying On clean or dirty and non-porozs surfaces. Apply this orochemie surface disinfectants undiluted. Spraying: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm. Make sure to wet surfaces completely Spraying and Wiping: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm and wiping afterwards or by soaking a wipe by spraying and wiping the surface with the soaked wipe. Make sure to wet surfaces completely.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and – handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Spraying Spraying and Wiping
Application rate(s) and frequency	As required. Apply this product undiluted. Spraying: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm. Make sure to wet surfaces completely Spraying and Wiping: Apply product to the surface undiluted by spraying from a distance of 20 – 30 cm and wiping afterwards or by soaking a wipe by spraying and wiping the surface with the soaked wipe. Make sure to wet surfaces completely.
Category(ies) of users	Professional user
Pack sizes and packaging material	125 mL - 10 L bottle/canister (PE), closure (PP or PE); Spray bottle: 125 mL (PE), Pump sprayer; 220 L drum (PE); 1000L Container (PE)

3.1.5 meta SPC 5

Table 21. Intended use 1 – Ready to use wipes – PT 02

Product Type(s)	PT 2
Where relevant, an exact description of the use	Ready to use wipes for disinfection

Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries), institutional areas and healthcare industry Disinfection of non-porous surfaces
Application method(s)	Wiping
Application rate(s) and frequency	As required.
Category(ies) of users	Professional user
Pack sizes and packaging material	Box with 40 – 300 wipes, One wipe

Table 22. Intended use 2 – Ready to use wipes – PT 04

Product Type(s)	PT 4
Where relevant, an exact description of the use	Ready to use wipes for disinfection of clean or dirty and non- porous surfaces.
Target organism(s) (including development stage)	Yeasticidal Bactericidal (incl. MRSA) Tuberculocidal Limited spectrum virucidal activity incl. enveloped viruses (HBV, HCV, HIV, SARS corona virus) and non-enveloped viruses (rota virus, adenovirus, norovirus)
Field(s) of use	Use area: food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and – handling, kitchens in retirement homes Disinfection of non-porous surfaces
Application method(s)	Wiping
Application rate(s) and frequency	As required
Category(ies) of users	Professional user
Pack sizes and packaging material	Box with 40 – 300 wipes, One wipe

3.2 Physical, chemical and technical properties

Information has been provided on the physical-chemical properties of biocidal products of meta SPC 1, meta SPC 2 and meta SPC 3.
Due to the fact that the biocidal products of meta SPC 2 and 3 share the same composition as the biocidal products of meta SPC 4 and 5 the results of the physico-chemical properties are also valid for meta SPC 4 and 5. The only difference of the meta SPCs is the use in different product types.
Additionally it has to be taken into account that the spray heads are only available as accessories. Thus, during storage, neither the spray head nor the trigger spray bottle come into contact with the product. Therefore, no spray characteristics after storage were requested.

Table 23: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	C 20 Hände + Haut Des. (meta SPC 2 – 5) 10x0,125 l D; Charge: 1602726	clear liquid	Winkens, J.; 2014; Report no. C20_WA- V. 12 Prüfprotokoll 1319370
	Visual	C 25 Händedesinfektionsgel (meta SPC 1) Charge: 1522720	clear viscous liquid	Winkens, J.; 2014; Report no. C25-1_WA- V. 02 Prüfprotokoll 1318666
Colour at 20 °C and 101.3 kPa	Visual	C 20 Hände + Haut Des. (meta SPC 2 – 5) 10x0,125 l D;	colourless	Winkens, J.; 2014; Report no. C20_WA- V. 12 Prüfprotokoll 1319370

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Charge: 1602726		
	Visual	C 25 Händedesinfektionsgel (meta SPC 1) Charge: 1522720	colourless	Winkens, J.; 2014; Report no. C25-1_WA- V. 02 Prüfprotokoll 1318666
Odour at 20 °C and 101.3 kPa	Olfactory Ph. Eur. 2.3.4	C 20 Hände + Haut Des. 10x0,125 l D; (meta SPC 2 – 5) Charge: 1602726	characteristic smell of alcohol	Winkens, J.; 2014; Report no. C20_WA- V. 12 Prüfprotokoll 1319370
	Olfactory	C 25 Händedesinfektionsgel (meta SPC 1) Charge: 1522720	alcoholic	Winkens, J.; 2017; Report no. C25-1_WA- V. 05 Prüfprotokoll 1318666
Acidity / alkalinity	CIPAC MT 75.3	C 20 Hände + Haut Des. 10x0,125 l D; (meta SPC 2 – 5) Batch no.: 1705129	pH = 7.31 (undiluted product)	Trillen, J., 2017, Report no. 1401
		C 25 Händedesinfektionsgel (meta-SPC 1) Charge: 1522720	pH =5.5; ca. 9% solution in 0.5% NaCl solution	Winkens, J.; 2014; Report no. C25-1_WA- V. 02 Prüfprotokoll 1318666
Relative density / bulk density	Ph. Eur. 2.2.5 oscillating densitometer	C 20 Hände + Haut Des. 10x0,125 l D; (meta SPC 2 – 5)	rel. density: 0,877	Winkens, J.; 2016a; Report no. C20_WA- V. 12 Prüfprotokoll 1319370

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Charge: 1602726</td><td></td><td></td></tr>
<tr><td></td><td>Ph. Eur. 2.2.5
Pycnometer method</td><td>C 25 Händedesinfektionsgel (meta SPC 1)
Charge: 1709202</td><td>rel. density: 0,875</td><td>Trillen, J., 2017,
Report no. 1402</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>In accordance to CIPAC MT 46.3</td><td>C 20 solution, 1 L PE bottle with PP screw cap, Batch No. 1514217
C 20 solution, 0.125 L PE bottle with PP flip-top cap, Batch No. 1519726
C 20 solution, 0.125 L PE bottle with PP spray nozzle, Batch No. 1513717
(meta SPC 2 – 5)</td><td>Test samples stored for 4 weeks at 54 ± 2°C:
The appearance and the density of the tested samples did not change during storage.
Active substance content:
<table>
<tr><th>[%]</th><th>start</th><th>2 weeks</th><th>4 weeks</th></tr>
<tr><td>Batch 1514217</td><td>62.7</td><td>62.7</td><td>63.8</td></tr>
<tr><td>Batch 1519726</td><td>62.5</td><td>63.1</td><td>63.2</td></tr>
<tr><td>Batch 1513717</td><td>61.8</td><td>62.9</td><td>63.3</td></tr>
</table></td><td>Stability test with C20 solution
Schneider ,A. 2016
Report No. 1324
Report No. 1329
Report No. 1330</td></tr>
<tr><td></td><td>In accordance to CIPAC MT 46.3</td><td>C 25 gel, 1 L PE bottle with PP screw cap, Batch No. 1606302
C 25 gel, 0.1 L PE bottle with PP screw cap, Batch No. 1605215
(meta SPC 1)</td><td>Test samples stored for 4 weeks at 54 ± 2°C:
The appearance and the density of the tested samples did not change during storage.
Active substance content:</td><td>Stability test with C25, gel
Schneider ,A. 2016
Report No. 1326
Report No. 1328</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[%] start 2 weeks 4 weeks Batch 1606302 63.1 63.2 64.0 Batch 1606302 64.3 64.6 66.3	
	In accordance to CIPAC MT 46.3	C20 wipes hand disinfection, ready to use Batch No. 1621228 manual filling (meta SPC 3 and 5) Description of the wipes: non-woven fabrics made of 100% PET in a bag made of aluminium laminted foil	Test samples stored for 2 weeks at 54 ± 2°C: The appearance “clear, colourless liquid” and the density (0.877) did not change during storage. Active substance content: [%] start 2 weeks Batch 1621228 63.4 61.9 (-2.36%)	Stability test with C20, wipes hand disinfection Fridrich,D. 2017 Report No. 1396
Storage stability test – **long term storage at ambient temperature**			The test item C20 (batch number C20-226) was stored for 4 years at room temperature at 25 ± 2°C and 60 ± 5% RH in the 1L bottle from polyethylen. At the following storage points: before storage (time 0), 3 months, 6 months, 12	Biemel,W. 2005; Inspection data of C20 solutions

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			months, 18 months, 24 months, 36 months and 48 months the corresponding properties were measured: appearance, odour and density. The content of the active ingredient was indirectly determined through the measurement of the density(start and end value:0.876 g/mL) , following European Pharmacopoeia (Ph. Eur.), which is for this kind of the mixture (alcohol/ water) products containing more than 70% of Propan-2-ol a very good and suitable determination method. The method is acceptable.	
		C 25 gel, Batch No. 13211H15	Test samples stored for 48 month.	Long-term storage test at ambient temperature with C25

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Magenta round bottle (PET) 100mL;
Square bottle, opaque (PET): 500, 1000mL,
(meta SPC 1)</td><td>Magenta round bottle (PET) 100mL:
<table><tr><td></td><td>start</td><td>48 months</td></tr><tr><td>2 Propanol content [%]</td><td>62.5%</td><td>66.6% (+ 6.6%)</td></tr><tr><td>Weight change</td><td>100.01g</td><td>97.16g (-3.80%)</td></tr><tr><td>Viscosity [Pa*s] at 20°C</td><td>0.9</td><td>0.7</td></tr><tr><td>pH value</td><td>5.8</td><td>7.5</td></tr></table>
Square bottle, opaque (PET): 500 mL
<table><tr><td></td><td>start</td><td>48 months</td></tr><tr><td>2 Propanol content [%]</td><td>62.5%</td><td>63.1% (+ 0.9%)</td></tr><tr><td>Weight change</td><td>444.02g</td><td>445.92g (-0.42%)</td></tr><tr><td>Viscosity [Pa*s] at 20°C</td><td>0.9</td><td>1.0</td></tr><tr><td>pH value</td><td>5.8</td><td>7.5</td></tr></table></td><td>Friedrich D. 2017
Report No. 1452</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Square bottle, opaque (PET):
1000 mL

<table><tr><td></td><td>start</td><td>48 months</td></tr><tr><td>2 Propanol content [%]</td><td>62.5%</td><td>66.6%
(+ 6.6%)</td></tr><tr><td>Weight change</td><td>931.22g</td><td>934.06g
(-0.21%)</td></tr><tr><td>Viscosity [Pa*s] at 20°C</td><td>0.9</td><td>0.8</td></tr><tr><td>pH value</td><td>5.8</td><td>7.4</td></tr></table>
For all three packaging no change in the appearance of packaging was observed during storage.</td><td></td></tr>
<tr><td></td><td></td><td>C 20 wipes, Batch No. 1621228
1 roll of 100 wipes in a bag made of aluminium laminated foil.
Wipes: non-woven fabrics made of 100 % PET</td><td>The test is on-going until December 2020.
After two years of storage at 25 +- 2 °C and 60 +- 5 % relative humidity the liquid is still clear and colourless with</td><td>Schneider, A., test report No. 1614, July 2019</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(meta SPC 3 and 5)	characteristic odour like alcohol. All test results were within the defined ranges. 0 months: Relative density: 0.877 Content Propan-2-ol: 63.4 % 24 months: Relative density: 0.879 Content Propan-2-ol: 62.8 % 36 months: Relative density: 0.877 Content Propan-2-ol: 63.2	
Storage stability test – **low temperature stability test for liquids**	In accordance to CIPAC MT 39.3	C 20 solution, 2.5 L PE bottle with PP screw cap, Batch No. 1315033	The samples were stored at ≤ -20°C for 4 weeks. The appearance and the density of the tested samples did not change during storage.	Stability test with C20 solution Schneider ,A. 2016 Report No. 1335 FB_0414.001

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>C 20 solution, 0.125 L PE bottle with PP spray nozzle, Batch No. 1315035
(meta SPC 2 – 5)</td><td>Active substance content:<table><tr><td>[%]</td><td>start</td><td>4 weeks</td></tr><tr><td>Batch 1315033</td><td>62.9</td><td>62.7</td></tr><tr><td>Batch 1315035</td><td>62.9</td><td>64.5</td></tr></table></td><td></td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>In accordance to CIPAC MT 39.3</td><td>C 25 gel, 1 L PE bottle with PP screw cap, Batch No. 1606302
C 25 gel, 0.1 L PE bottle with PP screw cap, Batch No. 1605215
(meta SPC 1)</td><td>The samples were stored at ≤ -20°C for 1 weeks.
The appearance and the density of the tested samples did not change during storage.
Active substance content:<table><tr><td>[%]</td><td>start</td><td>1 weeks</td></tr><tr><td>Batch 1606302</td><td>63.1</td><td>63.5</td></tr><tr><td>Batch 1606302</td><td>64.4</td><td>64.7</td></tr></table></td><td>Stability test with C25, gel
Schneider ,A. 2016
Report No. 1333
Report No. 1334</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td>SAA_ALGA.006; Ph. Eur. 8. Ausgabe, 5. Nachtrag (Ph. Eur. 0970)</td><td>C 20 solution; Batch number: 1001909
stored in different types of packaging:
Glass bottle: 1000 mL
White bottle(PE): 500 mL, 800 mL
Opaque bottle (PE): 500 mL, 800 mL, 1000 mL
(meta SPC 2 – 5)</td><td>The experiments in the absence of light demonstrated a 2-propanol content of 61.6% - 62.8% by weight. This applied to all types of packaging analysed up to the end of the three month tests. In C20 samples exposed to light, a 2-propanol content of 61.0 -</td><td>Stability test with C20, wipes hand disinfection
Fridrich,D. 2017
Report No. 1394</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			62.8% by weight was detected including the long- term experiment of 3 months and all tested types of packaging. The absence of peroxides was confirmed as all samples were without any staining. In conclusion, no effects of light on the shelf life of the biocidal product C20 were observed under these experimental conditions.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	SAA_ALGA version 06, SAA_025 03/04	C 25 gel; Batch number: 13211H15 different types of packaging: Glass bottle: 250 mL Magenta round bottle (PET). 100 mL Square bottle, opaque (PE). 500 mL, 800 mL, 1000 mL (Meta-SPC 1)	The experiments in the absence of light demonstrated a 2-propanol content of 61.5 - 63.8% by weight. In C25 samples exposed to light, a 2-propanol content of 61.5 - 63.1% by weight was detected. This applies to all types of packaging analysed for the two and three month tests. The viscosity of samples protected from light was in the range of 0.816 - 1.0 Pa*s. In the presence of light the viscosity ranged from 0.765 - 0.930 Pa*s. In conclusion, no effects of light on the	Fridrich,D. 2017 Report No. 1398

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			shelf life of the biocidal product C25 were observed under these experimental conditions.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Taking into account the composition of the biocidal products belonging to the family it can be concluded that temperature and humidity have not influence on the chemical and technical properties of the products.	Waiving[13]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the stability of packaging regarding storage stability test are sufficient.	
Wettability			Based on the formulation type these technical characteristics have not to be determined	Waiving[13]
Suspensibility, spontaneity and dispersion stability				Waiving[13]

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

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Wet sieve analysis and dry sieve test				Waiving[13]
Emulsifiability, re-emulsifiability and emulsion stability				Waiving[13]
Disintegration time				Waiving[13]
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 – Particle Size Analysis by laser diffraction	C 20 solution, , 1 L PE bottle with PP screw cap and extra trigger, Batch No. 1902042 (meta SPC 2 and 4)	Sample pouch trigger is placed 20 cm away from laser beam. Dv(10),µm = 77.45 Dv(50),µm = 251.98 Dv(90),µm = 552.83 %V<10µ,% = 0.08 %V<5µ,% = 0.01	Determination Particle Size distribution on the Sample C 20 Hand + Skin Disinfectant 1L Mazzei ,A. 2019b Report No. 1903942
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 – Particle Size Analysis by laser diffraction	C 20 solution, 0.125 L PE bottle with PP spray nozzle, Batch No. 1808108 (meta SPC 2 and 4)	Sample pouch trigger is placed 15 cm away from laser beam. Mean values of 3 measurements: Dv(10),µm = 28.25 Dv(50),µm = 51.34	Determination Particle Size distribution on the Sample C 20 Hand + Skin Disinfectant 125 mL Mazzei ,A. 2019a Report No. 1903941

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Dv(90),µm = 87.23 %V<10µ,% = 0.92 %V<5µ,% = 0.28	
Persistent foaming			Based on the formulation type these technical characteristics have not to be determined.	Waiving[13]
Flowability/Pourability/Dustability				Waiving[13]
Burning rate — smoke generators				Waiving[13]
Burning completeness — smoke generators				Waiving[13]
Composition of smoke — smoke generators				Waiving[13]
Spraying pattern — aerosols		C 20 hand + skin disinfectant, ready to use; (Meta-SPC 2 – 5) Batch number: 1514217	Determination of the spray diameter with a distance of 30 cm ± 05 cm between spray nozzle and paper Spray nozzle for 125 mL bottle: 8.5 cm (diameter of moistened surface [cm])	Schneider, A., 2017a Report No. 1403

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Spray nozzle for 1 L bottle: 9.4 cm (diameter of moistened surface [cm]) Spray nozzle for spray bottle: 10.1 cm (diameter of moistened surface [cm])	
Physical compatibility			The product will be used alone, (no co-applications with other substances is required)	Waiving[13]
Chemical compatibility			The product will be used alone, (no co-applications with other substances is required)	Waiving[13]
Degree of dissolution and dilution stability			The product will not be used in a soluble bag and is not delivered in the form of soluble tablets.	Waiving[13]
Surface tension	OECD 115 Ring method	C 20 Hand + Skin Disinfectant (meta SPC 2 – 5) Batch: 1602214	32 mN/m undiluted product	Schneider, A., 2017b Report No. 1395
	OECD 115 Ring method	C 25 Hand Disinfection gel (meta SPC 1) Batch: 1606302	42 mN/m undiluted product	Schneider, A., 2017c Report No. 1411

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th colspan="3">Results</th><th>Reference</th></tr>
<tr><td rowspan="11">Viscosity</td><td rowspan="11">OECD 114
Rotational Viscosimeter</td><td rowspan="11">C 20 Hände + Haut Desinfektion (meta SPC 2 – 5)
Charge: 1514217</td><td>Shear rate/ s^{-1}</td><td>20°C [mPa*s]</td><td>40°C [mPa*s]</td><td rowspan="11">Trillen, J.; 2016; Viscosity of C20 at 20°C and 40°C; Report no. 1321</td></tr>
<tr><td>20</td><td>3.56</td><td>1.86</td></tr>
<tr><td>65</td><td>3.74</td><td>2.01</td></tr>
<tr><td>110</td><td>3.85</td><td>2.09</td></tr>
<tr><td>155</td><td>3.99</td><td>2.18</td></tr>
<tr><td>200</td><td>4.11</td><td>2.28</td></tr>
<tr><td>200</td><td>4.13</td><td>2.29</td></tr>
<tr><td>155</td><td>4.00</td><td>2.18</td></tr>
<tr><td>110</td><td>3.87</td><td>2.08</td></tr>
<tr><td>65</td><td>3.74</td><td>1.96</td></tr>
<tr><td>20</td><td>3.57</td><td>1.08</td></tr>
<tr><td rowspan="11"></td><td rowspan="11">OECD 114
Rotational Viscosimeter</td><td rowspan="11">C 25 Händedesinfektionsgel (meta SPC 1)
Charge: 1606302</td><td>Shear rate/ s^{-1}</td><td>20°C [mPa*s]</td><td>40°C [mPa*s]</td><td rowspan="11">Trillen, J.; 2016; Viscosity of C25 at 20°C and 40°C; Report no. 1322</td></tr>
<tr><td>20</td><td>2.69</td><td>2.06</td></tr>
<tr><td>65</td><td>1.26</td><td>0.95</td></tr>
<tr><td>110</td><td>0.92</td><td>0.69</td></tr>
<tr><td>155</td><td>0.75</td><td>0.56</td></tr>
<tr><td>200</td><td>0.65</td><td>0.48</td></tr>
<tr><td>200</td><td>0.65</td><td>0.48</td></tr>
<tr><td>155</td><td>0.75</td><td>0.56</td></tr>
<tr><td>110</td><td>0.92</td><td>0.69</td></tr>
<tr><td>65</td><td>1.27</td><td>0.95</td></tr>
<tr><td>20</td><td>2.72</td><td>2.04</td></tr>
</table>

Table 24

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. The biocidal product family (BPF) consists of five meta SPCs with ready-to-use gel (meta SPC 1), ready to use liquids (meta SPC 2, 4) and ready-to-use wipes (meta SPCs 3 and 5) based on the active substance propan-2-ol. The applicant provided information on the physical-chemical and technical properties for biocidal products of meta SPC 1, meta SPC 2 and meta SPC 3. Due to the fact that the biocidal products of meta SPC 2 and 3 have the same composition as the biocidal products of meta SPC 4 and 5 the results of the physico-chemical and technical properties are also valid for meta SPC 4 and 5. The products of the family are all clear colourless liquids (meta SPC 2-5) respectively a clear colourless viscous liquid (meta SPC 1) with an alcoholic smell and a relative density of 0.875 respectively 0.877. For storage stability the product C 20 solution (meta SPC 2 and 4) was stored in different packaging (PE bottle with PP screw cap, with PP flip-top cap and with the spray nozzle) at 54° for 4 weeks with an active substance increase of max. 2.4%. Additionally the C20 wipes hand disinfection (meta SPC 3 and 5) and the C 25 gel were stored at 54° for 4 weeks which show an active substance decrease of 2.36% respectively increase of max. 3.1%. 48 month longterm storage stability tests were provided for C 20 solution (meta SPC 2 and 4) and C 25 gel (meta SPC 1). The active substance content during the longterm storage test for C 20 solution was indirectly determined through the measurement of the density, following European Pharmacopoeia (Ph. Eur.) which is acceptable for this kind of product. The product C 25 gel showed an active substance increase of 0,9 respectively 6.6% and showed no change in the appearance. Storage tests are completed with low storage stability tests for C 20 solution and C 25 gel, which show no change or separation after storage. In conclusion for the products (ready-to-use gel) of meta SPC 1 and products (ready-to-use liquids) of meta SPC 2 and 4 a shelf-life of 48 months can be granted. For the products (ready-to-use wipes) of meta SPC 3 and 5 an interim test report after 36 months (including wipes) is available. Therefore a shelf-life of 36 months can be granted. By submitting acceptable results after 48 months (December 2020) the shelf-life can be prolonged within a minor change application accordingly.

3.3 Physical hazards and respective characteristics

Table 25: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Meta SPC 1-5 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 with reference to the screening procedures in Appendix 6 of the UN-MTC, see Tables A6.1 and A6.3.	IUCLID[14]
Flammable gases	study scientifically unjustified			Waiver: The property is not relevant, since the product is not delivered as a flammable gas	IUCLID[14]
Flammable aerosols	study scientifically unjustified			Waiver: The products of the BPF are not flammable aerosol. The property is not relevant to be measured.	IUCLID[14]
Oxidising gases	study scientifically unjustified			Waiver: Determination of this property is not required since the products of the BPF are not an oxidising gas, and do not turn to oxidising gas at any conditions.	IUCLID[14]
Gases under pressure	study scientifically unjustified			Waiver: The determination of the property is not needed, since the products of the BPF are not delivered in the form of subpressed gas.	IUCLID[14]

[14] 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	DIN 51755	C 25 Händedesinfektionsgel (meta SPC 1) Charge: 13211H15	Flash point: 16,5 °C Boiling point: 80.6 °C of azeotropic mixture		Neger, E., 2013, Flammpunkt (AP) Report no. 124.002-Version 2
	DIN 51755	C 20 Hände + Haut Des. (meta SPC 2-5) Charge: 1518736	23,0 °C Boiling point: 80.6 °C of azeotropic mixture	Meta SPC 1 and 2 (gel; solution and spray) and meta SPC 3 (wipes): Flammable liquid, Category 2 based on GHS/CLP Criteria	Büchel, D., 2016, Flammpunkt (AP) Report no. 141.001
	study scientifically not necessary			Meta SPC 4 (solution and spray) and meta SPC 5 (wipes) Waiver: The minor changes in the composition of the products in comparison with the products of meta SPC 1 and 2 have no significant effect on the Flash point. Flammable liquid, Category 2 based on GHS/CLP Criteria	
Flammable solids	study scientifically unjustified			Meta SPC 1, 2 and 4 (gel; solution and spray) Waiver: The study does not need to be conducted because the products are liquids.	IUCLID[14]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	UN Test N.1 (in Part III of the UN-MTC)		Burning time:	Meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the biocidal products are liquids on a carrier.	
Self-reactive substances and mixtures	study scientifically not necessary			Meta SPC 1-5 Waiver:The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID[14]
Pyrophoric liquids	study scientifically not necessary			Meta SPC 1, 2 and 4 (gel; solution and spray) and meta SPC 3 and 5 (wipes) 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) and hence, the classification procedure does not need to be applied.	IUCLID[14]
Pyrophoric solids	study scientifically unjustified			Meta SPC 1, 2 and 4 (gel; solution and spray) and meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the products are liquids.	IUCLID[14]
Self-heating substances and mixtures	study scientifically unjustified			Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the products are liquids.	IUCLID[14]

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			Meta SPC 1-5 Waiver: The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	IUCLID[14]
Oxidising liquids	study scientifically not necessary			Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the products are flammable.	IUCLID[14]
Oxidising solids	study scientifically unjustified			Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the products are liquids.	IUCLID[14]
Organic peroxides	study scientifically not necessary			Waiver (Meta SPC 1-5): 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[14]
Corrosive to metals	study scientifically not necessary			Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) Waiver: The biocidal products are not corrosive, since it (as an organic liquid) does not contain halogens, acidic or basic functional groups and the pH value of the	IUCLID[14]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				undiluted product is not very acidic or basic (6.5 at 20 °C, i.e. within pH 4-10 range).	
Auto-ignition temperature (liquids and gases)	DIN 51794 study scientifically unjustified		Auto-ignition temperature 425 °C (for pure propan-2-ol)	Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) 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 (2016)
Relative self-ignition temperature for solids	study scientifically unjustified			Meta SPC 1, 2 and 4 (gel; solution and spray) and Meta SPC 3 and 5 (wipes) Waiver: The study does not need to be conducted because the products are liquids.	IUCLID[14]
Dust explosion hazard	study scientifically unjustified			Waiver: The property is irrelevant since the products of the BPF do not produce any dust/ are not provided in the form of powder.	IUCLID[14]

Table 26

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. The biocidal product family (BPF) consists of five meta SPCs with ready-to-use gel (meta SPCs 1) ready-to-use liquids (meta-SPC 2 and 4) and ready-to-use wipes (meta SPCs 3 and 5) based on the active substance propan-2-ol.

According to the document “Handling “carriers” in the authorisation of biocidal products” (CA-Nov16-Doc.4.3 – Final) the wipes containing the disinfection formulation are considered as a carrier material containing a mixture. Therefore the hazard and precautionary statements, as well as any other labelling elements deriving from the CLP Regulation, are based on the classification of the biocidal mixture/substance used in the product only.
The liquid biocidal products have flashpoints of ≤ 23°C according to non-equilibrium method DIN 51755. The boiling point of propan-2-ol is >35 °C according to CAR. Therefore, liquid products are considered as flammable liquids, hazard 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 be used for the products of the BPF orochemie hand- and surface disinfectants as a worst case.
Due to structural reasons explosive and oxidising properties can be excluded for the products of the BPF orochemie hand- and surface disinfectants. Based on experience in production and handling it can be concluded that the products of the BPF orochemie hand- and surface disinfectants are not pyrophoric and do not evolve any flammable gases in contact with water or humid air. Self-heating properties for the products of the BPF orochemie hand- and surface disinfectants are not expected and for liquids the study does not need to be conducted.
According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified as follows.
Test results for Liquid products (solution and spray):
Flam. Liq. 2; (Flammable liquids, hazard category 2)
H225: Highly flammable liquid and vapour

3.4 Methods for detection and identification

Table 27

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		
2-Propanol (active substance)	GC-FID	No signal in the range of the peaks of the analyte and the internal standard No interferences of the analyte and internal standard Resolution of internal standard, analytes and interfering peaks > = 1.5	0.1042g – 0.3046g pro sample (50 – 150% of nominal value) R^2= 0.99983	80, 100 and 120% of the nominal value respectively 50.47%, 63.11% and 75.72% absolute analyte added, n=3		99.36%	0.5%		Winkens, J., 2017; alcohols in raw material and formulations - basic method (M-A047-01) Winkens, J., 2017; Quantitative determination of propan-2-ol in C 20 solution (M-A047-02)
				100% product; N=6	62.5 – 63.4% (absolute values 2-	62.8%	0.54%		

					Propa-nol)				
2-Propanol (active substance)	GC-FID	No signal in the range of the peaks of the analyte and the internal standard No interferences of the analyte and internal standard Resolution of internal standard, analytes and interfering peaks > = 1.5	0.1042g – 0.3046g pro sample (50 – 150% of nominal value) R^2= 0.99983	80, 100 and 120% of the nominal value respectively 50.47%, 63.11% and 75.72% absolute analyte added, n=3		99.49%	0.5%		Winkens, J., 2017; alcohols in raw material and formulations - basic method (M-A047-01) Winkens, J., 2017; Quantitative determination of propan-2-ol in finished product C 20 wipes (M-A047-03)
				100% product; N=6	62.6 – 63.2% (absolute values 2-Propa-nol)	62.8%	0.34%		

2-Propanol (active substance)	GC-FID	No signal in the range of the peaks of the analyte and the internal standard No interferences of the analyte and internal standard Resolution of internal standard, analytes and interfering peaks > = 1.5	0.1042g – 0.3046g pro sample (50 – 150% of nominal value) R^2= 0.99983	80, 100 and 120% of the nominal value respectively 50.52%, 63.10% and 75.71% absolute analyte added, n=3		99.17%	0.5%		Winkens, J., 2017; alcohols in raw material and formulations - basic method (M-A047-01) Winkens, J., 2017; Quantitative determination of propan-2-ol in finished product C 25 Hand disinfection Gel (M-A047-04)
				100% product; N=6	62.2 – 62.8% (absolute values 2-Propanol)	62.4%	0.37%		

Table 28

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 (07/2014)
Drinking water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)
Surface water	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)

Air	propan-2-ol	3.2 mg/m³	$AEL_{medium\text{-}term}$:10.7 mg/kg bw/d (general population) AR for PT1, PT2, PT4; LoEP (07/2014)
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 (07/2014)
Food of animal origin	no relevant residues expected		AR for PT1, PT2, PT4; LoEP (07/2014)

Table 29

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**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 R²=0.9983	Air 21 °C, 80 % rel humidity (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6	 99.2-101 102-	 100.2 102.9	 0.8 0.8	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit of	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997

			matrix-matched cali-bration: 0.50 – 12.56 mg/mL R^2=0.9998	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	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	103.6 103.2 103.7 103.8 102.5 103.3 103.4 104.8 104.5 105.4	1.0 1.1 0.3 0.7 1.0 0.9 0.7 0.8 0.7 1.7	0.05 * OSHA target concentration of 983 mg/m³)	

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 30

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.2.1. Soil: Data waving is accepted. 2. 5.2.3. Water (including drinking water) and sediment: Data waving is accepted. 3. 5.2.4. Body fluids and tissues: Data waving is accepted. 4. 5.3. 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

Table 31

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

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The biocidal product family (BPF) “orochemie hand- and surface disinfectants” consists of five meta-SPCs with ready-to-use hand disinfection gel (meta-SPC 1), ready-to-use liquids (meta-SPCs 2, 4) and ready-to-use wipes (meta-SPCs 3, 5) based on the active substance propan-2-ol.
In PT 1 (meta-SPC 1-3), the products are used for hygienic handrub disinfection and surgical handrub disinfection (only meta-SPC 1, 2) in health care, in institutional, industrial, domestic and veterinary medical area as well as in the food and feed area (kitchens, restaurants, grocery, butcher etc.) under clean conditions.
In PT2 (meta-SPC 4, 5), the propan-2-ol based disinfectants of the BPF “orochemie hand- and surface disinfectants” are intended to be used for the disinfection of clean and dirty non-porous surfaces in health care (e.g. hospitals, medical facilities, care facilities, isolation rooms, dental surgeries) as well as institutional areas and healthcare industry.
In PT4, the propan-2-ol based disinfectants of the BPF “orochemie hand- and surface disinfectants” are intended to be used for the disinfection of clean and dirty non-porous surfaces in the food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and –handling, kitchens in retirement homes.

The products of the BPF “orochemie hand- and surface disinfectants” are intended for professional use.

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

The products of the BPF “orochemie hand- and surface disinfectants” are intended to have bactericidal (including tuberculocidal) and yeasticidal activity as well as limited spectrum virucidal activity (PT1 and PT2) and virucidal acitivity (PT4).

3.5.3 Effects on target organisms, including unacceptable suffering

Application of the products within the biocidal product family “orochemie hand- and surface disinfectants” leads to the irreversible inactivation of bacteria, yeast cells and enveloped as well as some non-enveloped viruses.

3.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of action. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation lead 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.

3.5.5 Efficacy data

As the products within the BPF are intended to be applied for disinfection, the formulations were tested in a tiered approach with phase 2, step 1 tests and phase 2, step 2 tests where available. Experimental data of the key studies are summarised in table 32.

The biocidal product family (BPF) "orochemie hand- and surface disinfectants" consists of five meta-SPCs with ready-to-use products based on the active substance propan-2-ol. The intended use concentration of the active substance is 63.1% (w/w) propan-2-ol in each meta-SPC. The intended use includes hygienic handrub disinfection (gel, liquid, ready-to-use wipes) and surgical handrub disinfection (gel, liquid) under clean conditions and disinfection of clean and dirty non-porous surfaces with mechanical action (liquid, ready-to-use wipes).

Table 32

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Hygienic hand disinfection	C20 (63.1 % (w/w) Propan-2-ol)	*E. coli K12*	EN 1500: 2013	Phase 2, step 2 Test concentration: undiluted Test amount: 2*3 ml Contact time: 30 sec Reference product: 2*3 ml 60 % (v/v) propan-2-ol	The tested product is suitable as hygienic hand rub under the test conditions.	Werner, 2017 a

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**
					rubbed in for 60 sec		
Bactericide	Hand disinfection	C 25 Händedesinfektionsgel (63.1% (w/w) Propan-2-ol; [redacted]	*E. coli K12*	EN1500:2013	Phase 2, step 2 Test concentration: undiluted Test amount: 2*3 ml Contact time: 30 sec Reference product: 2*3 ml 60 % (v/v) propan-2-ol rubbed in for 60 sec	The tested product is suitable as hygienic hand rub under the test conditions.	Werner, 2017y
Bactericide	Surgical hand disinfection	C20 (63.1 % (w/w) Propan-2-ol)	-	EN 12791: 2005	Phase 2, step 2 Test concentration: undiluted Test amount: 3 ml portions (keep the hands wet for the contact time) Contact time: 90 sec Reference product: 3 ml portions of 60 % (v/v) propan-1-ol rubbed in for 3 min (keep the hands wet for the contact time) 25 volunteers	The tested product is suitable for surgical hand disinfection under the test conditions.	Werner, 2017 b
Bactericide	Hygienic hand disinfection with wipes	C20 wipes (preimpregnated wipes) (63.1 % (w/w) Propan-2-ol in solution)	*E. coli K12*	Modified EN 1500:2017	Phase 2, step 2 test Test method: Rub 1 wipe over hands for 30 seconds, then a second wipe for another 30 seconds. The hand rub procedure followed the standard hand rub procedure of EN1500:2017, whereby steps 1	The tested product is suitable for hygienic hand rub under the test conditions.	Werner, 2018 c

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**
					to 6 were performed sequentially with a duration of 5 seconds each to confirm the contact of the wipes and the soaking liquid with the total surface of hands up to wrists. Reference product: 2*3 ml portions of 60 % (v/v) propan-2-ol for 60 seconds 20 volunteers		
-	Hygienic Hand disinfection	C 20 wipes (non-woven fabric, 100% PET; roll of 100 wipes soaked with 1400 ml C 20 solution; C 20: 63.1 % (w/w) propan-2-ol)	-	EN 1500	Determination of the quantity of disinfectant solution released from hand disinfection wipes 21 volunteers each used one wipe for 60 sec according to Annex A of EN 1500. The wipes were weighed prior and after use.	The quantity of disinfectant solution released from one hand wipe was determined to be 4.18 +/- 0.6 g (corresponding to 4.8 ml).	Fridrich, 2017
Bactericide	Hand disinfection / surface disinfection	C 20 (63.1 % (w/w) Propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa*	EN 13727: 2015	Quantitative suspension test Test concentrations: 25, 50, 80 % Contact times: 30 sec Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature:	Bactericidal efficacy was shown after 30 sec for 50 % product concentration for clean and dirty conditions. For hand disinfection, also *E. coli* should be tested. However, according to the DGHM/VAH guidelines, this is only required if *E. coli* behaves differently than P.	Werner, 2017 c

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**
					20°C	aeruginosa in DGHM method 7 and 8. Since this is not the case (see e.g. Marth, 2002) and a valid Phase 2, step 2 test with *E.coli* is available, it is deemed acceptable in this case.	
Bactericide	Hand disinfection, surface disinfection	C 20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. faecium* *E. hirae* *E. coli K12* *P. mirabilis* *P. aeruginosa* *C. albicans*	DGHM method 7	Determination of the bacteriostatic and fungistatic efficacy as well as suitable neutralisation method test concentrations: 0,1 – 15 % (0.1, 0.25, 0.5, 1, 2.5, 5, 7.5, 10, 15) contact time: 48 hours	*E. coli, P. mirabilis* and *P. aeruginosa* showed growth up to 5 % of product concentration, while all other test organisms were able to grow up to a product concentration of 10 %.	Marth, 2002
		C 20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. faecium* *E. hirae* *E. coli K12* *P. mirabilis* *P. aeruginosa* *C. albicans*	DGHM method 8	Qualitative suspension test Test concentrations: 5, 15, 25, 50, 100% Contact times: 15, 30, 60 sec Temperature: 20°C	After contact with the product, all tested bacteria were only able to grow if the product concentration had been 25 % or less. *C. albicans* was still able to grow if the product concentration had been 50 % or less.	
Bactericide / Yeasticide		C 20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	DGHM method 9	Quantitative suspension test Test concentrations: 25, 50, 100% and additionally 75 % for *C. albicans* Contact times:	A lg-reduction of >5 was achieved after 15 sec with 50 % product concentration for bacteria and after 15 sec with 75 % product	

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**
					15, 30, 60 sec Temperature: 20°C Interfering substance: None 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions)	concentration for yeast.	
	Hygienic hand disinfection	C20 (63.1 % (w/w) Propan-2-ol)	*E. coli K12*	prEN 1500	Phase 2, step 2 Test concentration: undiluted Test amount: at least 3 ml (keep hands wet) Contact time: 30 sec Reference product: 2*3 ml 60 % (v/v) propan-2-ol rubbed in for 2x30 sec	The tested product is suitable as hygienic hand rub when using at least 3 ml of the undiluted preparation for a contact time of 30 seconds (keep hands wet). The test included only 15 instead of at least 18 volunteers as required by the applicable EN1500:2013.	
Bactericide / Yeasticide	Hand disinfection	C20 (63.1 % (w/w) Propan-2-ol) C25 Händedesinfektionsgel (63.1% (w/w) Propan-2-ol; [redacted]	*S. aureus* *P. aeruginosa* *C. albicans*	DGHM Standard Method 9.1	Quantitative suspension test Test concentrations: 50, 75, 90 % Contact times: 15, 30 and 60 sec Interfering substance: 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: 20°C	Sufficient lg-reduction was shown for bacteria and yeast for 75 % product concentration after 15 seconds. No difference was determined in the efficacy between C20 and C25 Händedesinfektionsgel for the test bacteria. For *C. albicans*, only a difference at 50% product concentration was determined.	Werner, 2013

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Hand disinfection, Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli*	EN 1276: 2010	Quantitative suspension test Test concentrations: 25, 50, 80% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA (dirty conditions) Temperature: 20°C	Bactericidal efficacy was shown after 1 min at 50 % product concentration.	Werner, 2017 p
Yeasticide	Hand disinfection / surface disinfection	C 20 (63.1 % (w/w) Propan-2-ol)	*C. albicans*	EN 13624:2013/prA12015	Quantitative suspension test Test concentrations: 25, 50, 80 % Contact times: 30 and 60 sec Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: 20°C	Yeasticidal efficacy was shown after 30 sec for 80 % product concentration for clean and dirty conditions.	Werner, 2017 d
Yeasticide	Hand disinfection	C 20 (63.1 % (w/w) Propan-2-ol) C25 Händedesinfektionsgel (63.1% (w/w) Propan-2-ol; [redacted]	*C. albicans*	EN 13624:2013+prA12015	Quantitative suspension test Test concentrations: 50, 60, 70, 80 % Contact times: 30 sec Interfering substance: 0.3 g/L BSA (clean conditions)	Both products were sufficiently effective (lg-Reduction >4) at 80 and 70% product concentration. Both were not sufficiently efficacious at 60 and 50% product concentration.	Werner, 2017 x

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**
		[redacted]			Temperature: 20°C		
Yeasticide	Hand disinfection, Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*C. albicans*	EN 1650: 2013	Quantitative suspension test Test concentrations: 25, 50, 80% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA (dirty conditions) Temperature: 20°C	Yeasticidal efficacy was shown after 1 min at 80 % product concentration.	Werner, 2017 r
Tuberculocide	Hand disinfection/ surface disinfection	C 20 (63.1 % (w/w) Propan-2-ol)	*M. terrae*	EN 14348: 2005	Quantitative suspension test Test concentrations: 25, 50, 80 % Contact times: 30 and 60 sec Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: 20°C	Tuberculocidal efficacy was shown after 30 sec for 80 % product concentration for clean and dirty conditions.	Werner, 2017 e
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*Murine norovirus, S99*	EN 14476: 2016+pr A2:2016	Quantitative suspension test Test concentrations: 10, 50, 80, 97% Contact times: 30, 60 sec Interfering substance:	In this test, the control for cell susceptibility (chapter 5.5.4.2 of EN14476) has been carried out with a concentration of the product which is lower than necessary (0.01 % instead	Werner, 2017v

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**
					0.3 g/L BSA (clean conditions) Temperature: 20°C	of 9.7 % of product). The statement of the applicant to justify this approach was not traceable[15]. Therefore, it cannot be concluded that the test is valid.	
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*Murine norovirus, S99*	EN 14476: 2016+pr A2:2016	Quantitative suspension test Test concentrations: 10, 50, 80, 97% Contact times: 60, 120, 180 sec; 5 min Interfering substance: 3 g/L BSA + 3 ml/l sheep erythrocytes (dirty conditions) Temperature: 20°C	In this test, e.g. the control for cell susceptibility (chapter 5.5.4.2 of EN14476) has been carried out with a concentration of the product which is lower than necessary (0.01 % instead of 9.7 % of product). The statement of the applicant to justify this approach was not traceable[15]. Therefore, it cannot be concluded that the test is valid.	Werner, 2017w
Virucide	Hand disinfection, surface disinfection	H-19-HD-020 (63.1% w/w propan-2-ol)	*Murine norovirus, strain S99 Berlin*	EN 14476: 2013+A2: 2019	Quantitative suspension test Test concentrations: 25, 50, 80, 97% v/v Contact times: 30, 60, 120 sec	Efficacy against the test organism was shown after 1 min at 97% product concentration for clean conditions.	Werner, 2021a_11th add sub

[15] Statement: The laboratory documentation showed cytotoxicity for the product concentrations 97%, 80% and 50% for the 10^{-1} dilution meaning that a cytotoxicity in the transition area was measured. Culture cells were reduced und showed a stressed appearance at first but recovered in the following days. At the end of the test they were nearly not distinguishable from the cells of the cell control. To get an evaluable result during the short incubation period, further dilution steps of the product for testing cell susceptibility were carried out. For this reason, the laboratory thinks that the use of a 0.01 % product concentration was correct for the control of cell susceptibility.

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**
					Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: 20°C		
Virucide	Hand disinfection, surface disinfection	H-19-HD-020 (63.1% w/w propan-2-ol)	*Murine norovirus, strain S99 Berlin*	EN 14476: 2013+A2: 2019	Quantitative suspension test Test concentrations: 25, 50, 80, 97% v/v Contact times: 30, 60, 120 sec Interfering substance: 3 g/L BSA + 3 mL/L sheep erythrocytes (dirty conditions) Temperature: 20°C	Efficacy against the test organism was shown after 1 min at 97% product concentration for dirty conditions.	Werner, 2021b_11th add sub
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*Adenovirus type 5, strain adenoid 75*	EN 14476: 2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80, 97% Contact times: 30 sec , 60 sec, 2 min, 30 min Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: 20°C	Efficacy against the test organism was shown after 1 min at 80 % and 97 % product concentration for clean conditions.	Steinmann, 2016 d
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*Adenovirus type 5, strain adenoid 75*	EN 14476: 2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80% Contact times: 30, 60, 90 sec; 2, 30 min	Efficacy against the test organism was shown after 2 min at 80 % product concentration for dirty conditions.	Steinmann, 2017b

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**
					Interfering substance: 3 g/L BSA + 3 g/l sheep erythrocytes (dirty conditions) Temperature: 20°C		
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*Modified Vacciniavirus Ankara (MVA)*	EN 14476:2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80 % Contact times: 30, 60, 90 sec and 30 min Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: 20°C	Efficacy against the test organism was shown after 30 sec at 80 % product concentration for clean conditions.	Steinmann, 2016 c
Virucide	Hand disinfection, surface disinfection	C 20 (63,1 % (w/w) propan-2-ol)	*Modified Vacciniavirus Ankara (MVA)*	EN 14476:2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80 % Contact times: 30, 60 sec and 30 min Interfering substance: 3 g/L BSA + 3 g/l sheep erythrocytes (dirty conditions) Temperature: 20°C	Efficacy against the test organism was shown after 30 sec at 80 % product concentration for dirty conditions.	Steinmann, 2017a
Virucide	Hand disinfection	C 20 (63.1 % (w/w) propan-2-ol)	*Vacciniavirus strain Elstree*	DVV/RKI Guideline (2008)	Quantitative suspension test Test concentrations: 10, 80 % Contact times: 15, 30, 60 sec	Efficacy against the test organism was shown after 15 sec at 80 % product concentration for both test conditions.	Steinmann, 2016 e

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**
					Interfering substance: None 10 % fetal calf serum (dirty conditions) Temperature: 20°C	No suppression control was done since testing directly continued with the dilution series.	
Virucide	Hand disinfection, surface disinfection	C 20 (63,1 % (w/w) propan-2-ol)	*Bovine Viral Diarrhea Virus (BVDV) strain NADL (surrogate virus for HCV)*	DVV/RKI Guideline (2008)	Quantitative suspension test Test concentrations: 10, 80 % Contact times: 15, 30, 60, 120 and 300 sec Interfering substance: None 10 % fetal calf serum (dirty conditions Temperature: 20°C	Efficacy against the test organism was shown after 15 sec at 80 % product concentration for both test conditions. No suppression control was done since testing directly continued with the dilution series.	Steinmann, 2016 f
Virucide	Hand disinfection, surface disinfection	C 20 (63,1 % (w/w) propan-2-ol)	*Bovine corona virus strain L9 (surrogate of SARS-CoV)*	DVV/RKI Guideline (2014)	Quantitative suspension test Test concentrations: 10, 80 % Contact times: 30, 60 sec Interfering substance: None 10 % fetal calf serum (dirty conditions Temperature: 20°C	Efficacy against the test organism was shown after 30 sec at 80 % product concentration for both test conditions. No suppression control was done since testing directly continued with the dilution series.	Steinmann, 2016 a
Virucide	Hand disinfection, surface disinfection	C 20 (63,1 % (w/w) propan-2-ol)	*Human Rotavirus strain Wa*	DVV/RKI Guideline (2014)	Quantitative suspension test Test concentrations: 10, 80 % Contact times: 30, 60 sec	Efficacy against the test organism was shown after 30 sec at 80 % product concentration under the test conditions.	Steinmann, 2016 b

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**
					Interfering substance: None, because Rotavirus needs trypsin for propagation Temperature: 20°C	No suppression control was done since testing directly continued with the dilution series.	
Virucide	Hand disinfection	C25 Händedesinfektionsgel (63.1% (w/w) Propan-2-ol; [redacted]	*Adenovirus type 5, strain adenoid 75*	EN 14476: 2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80, 97% Contact times: 30 sec , 60 sec, 2 min, 30 min Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: 20°C	Efficacy against the test organism was shown after 1 min at 80 % and 97 % product concentration for clean conditions.	Steinmann, 2016 g
Virucide	Hand disinfection	C25 Händedesinfektionsgel (63.1% (w/w) Propan-2-ol; [redacted]	*Modified vaccinia virus Ankara (MVA)*	EN 14476: 2013 + A1:2015	Quantitative suspension test Test concentrations: 10, 50, 80 % Contact times: 30 sec , 60 and 90 seconds, 30 minutes Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: 20°C	Efficacy against the test organism was shown after 30 seconds at 80 % product concentration for clean conditions.	Steinmann, 2016 h
Virucide	Hand disinfection, surface disinfection	C20 (63.1 % (w/w) propan-2-ol) C25 Händedesinfektionsgel	*Murine norovirus, S99*	Screening assay based on EN 14476	Quantitative suspension test Test concentrations: 50, 80% Contact times: 5 minutes	Lg reductions were comparable between C20 and C25 Händedesinfektionsgel after 5 minutes contact time for 50 and 80% product concentration.	Werner, 2018 d

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**
		(63.1% (w/w) Propan-2-ol; [redacted]			Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: 20°C	However, the information can only be used as supportive data since no raw data and no controls are available for the comparison.	
Bactericide	Surface disinfection	C 20 wipes Wipes: 100 % polyethylenterephtalat (50 g/m^2), soaked with 14 ml product each Wipes for water control: FD multi wipes (63.1 % (w/w) propan-2-ol)	*E. hirae* *P. aeruginosa*	EN 16615:2015	Quantitative surface test with mechanical action Immediate test and test after 28 days Test concentrations: undiluted Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Efficacy against test organisms was shown after 1 min for clean and dirty conditions (immediate test and test after 28 days).	Werner, 2017 f
Bactericide	Surface disinfection	C 20 wipes Wipes: 100 % polyethylenterephtalat (50 g/m^2), Size: 20x30cm, soaked with 14 ml product each (63.1 % (w/w) propan-2-ol)	*E. hirae* *P. aeruginosa*	EN 16615:2015	Quantitative surface test with mechanical action Test 12 weeks after opening of the container Test concentrations: undiluted Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions)	Efficacy against both test organisms was shown after 1 min for clean and dirty conditions.	Werner, 2017 g.2

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		Wipes for water control: FD multi wipes			3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT		
Tuberculocide	Surface disinfection	C 20 (63.1 % (w/w) propan-2-ol) Wipes: standardised wipe material as defined in EN 16615, soaked with 16 ml product each	*M. terrae*	EN 16615: 2015	Quantitative surface test with mechanical action, 2 test runs Test concentrations: undiluted Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Tuberculocidal efficacy (≥4 lg reduction as defined in EN14348) was shown in two test runs after 1 min for the undiluted product for clean and dirty conditions.	Werner, 2017 h
Bactericide Yeasticide	Surface disinfection	C 20 (63.1 % (w/w) propan-2-ol) Wipes: standardised wipe material from EN 16615, soaked with 16 ml product each	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	EN 16615: 2015	Quantitative surface test with mechanical action Test concentrations: 100%, 10% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) Temperature: RT	Bactericidal and yeasticidal efficacy was shown after 1 min at 100% product concentration for clean conditions.	Werner, 2017 j
		C 20 (63.1 % (w/w) propan-2-ol) Wipes: standardised wipe	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	EN 16615: 2015	Quantitative surface test with mechanical action Test concentrations: 100% Contact times:	Bactericidal and yeasticidal efficacy was shown after 1 min at 100% product concentration for	

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**
		material from EN 16615, soaked with 16 ml product each			1 min, 5 min (additionally 15 min for *E. hirae*) Interfering substance: 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	clean conditions.	
		C 20 (63.1 % (w/w) propan-2-ol) Wipes: standardised wipe material from EN 16615, soaked with 16 ml product each	*E. hirae* *P. aeruginosa*	EN 16615: 2015	Quantitative surface test with mechanical action Test concentrations: undiluted Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Efficacy against both test organisms was shown after 1 min for clean and dirty conditions.	
Bactericide, Yeasticide	Surface disinfection	C 20 (63.1 % (w/w) propan-2-ol) Wipes: FD multi wipes (100 % polyethylenterephtalat (50 g/m^2)), Size: 20x30cm, soaked with 14 ml product each Wipes for water control: FD multi wipes	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	EN 16615: 2015	Quantitative surface test with mechanical action Test concentrations: 100% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Bactericidal and yeasticidal efficacy was shown after 1 min at 100% product concentration for clean and dirty conditions.	Werner, 2017 m

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**
		C 20 (63.1 % (w/w) propan-2-ol) Wipes: FD multi wipes in a dispenser (100 % polyethylenterephtalat (50 g/m^2)), Size: 20x30cm, soaked with 14 ml product each Wipes for water control: FD multi wipes	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	EN 16615: 2015	Quantitative surface test with mechanical action Test 28 days after opening of the container Test concentrations: 100% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Bactericidal and yeasticidal efficacy was shown after 1 min at 100% product concentration for clean and dirty conditions.	
		C 20 (63.1 % (w/w) propan-2-ol) Wipes: FD multi wipes in a dispenser (100 % polyethylenterephtalat (50 g/m^2)), Size: 20x30cm, soaked with 14 ml product each Wipes for water control: FD multi wipes	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*	EN 16615: 2015	Quantitative surface test with mechanical action Test 8 weeks after opening of the container Test concentrations: 100% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) Temperature: RT	Bactericidal and yeasticidal efficacy was shown after 1 min at 100% product concentration for clean and dirty conditions.	
Bactericide Yeasticide	Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli*	EN 13697: 2015	Quantitative surface test	Bactericidal and yeasticidal efficacy was shown after 1 min at 50 %	Werner, 2017 q

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**
			C. albicans		Test concentrations: 25, 50, 100% Contact times: 1 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA (dirty conditions) Temperature: 20°C	product concentration under clean and dirty conditions.	
Bactericide and Yeasticide	Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli* *C. albicans*	EN 13697: 2015	Quantitative surface test Test concentrations: 25, 50, 100% Contact times: 2 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions medical area) Temperature: 20°C	Bactericidal and yeasticidal efficacy was shown after 2 min at 50 % product concentration under clean and dirty conditions from the medical area.	Werner, 2018 a
Bactericide and Yeasticide	Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae* *P. aeruginosa* *E. coli* *C. albicans*	VAH method 14.1	Quantitative surface test Test concentrations: 25, 50, 80, 100 % Contact times: 1, 5 min Interfering substance: 0.3 g/L BSA (clean conditions)	Bactericidal efficacy was shown after 1 min at 50 % product concentration for clean conditions and after 5 min at 50% produc concentration for dirty conditions. It has to be considered that inoculation of *S. aureus* was not	Werner, 2017 s

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**
					3 g/L BSA + 3 ml/l sheep erythrocytes (dirty conditions) Temperature: 20°C	high enough in this test. Yeasticidal efficacy was shown after 5 min at 100% product concentration for clean and dirty conditions.	
			S. aureus *C. albicans*	VAH method 14.1	Quantitative surface test Test concentrations: 50, 100 % Contact times: 5 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/l sheep erythrocytes (dirty conditions medical area) Temperature: 20-23°C	Efficacy against *S. aureus* was shown after 5 min at 50 % product concentration for clean and dirty conditions. Yeasticidal efficacy was shown after 5 min at 100% product concentration for clean and dirty conditions.	
Bactericide and Yeasticide	Surface disinfection	C20 (63.1 % (w/w) propan-2-ol)	*S. aureus* *E. hirae*	VAH method 14.1	Quantitative surface test Test concentrations: 50, 100 % Contact times: 2 min Interfering substance: 0.3 g/L BSA (clean conditions) 3 g/L BSA + 3 ml/l sheep erythrocytes (dirty conditions medical area) Temperature: 23°C	Efficacy against *S. aureus* and *E. hirae* was shown after 2 min at 50 % product concentration for clean and dirty conditions.	Werner, 2018 b

Summary on efficacy

The results of the studies used for the evaluation are summarized in the table below.

Method	Test organisms	Interfering substances			
		-	0.3 g/L BSA	3 g/L BSA	3 g/L BSA + 3 ml/L SE[4]
EN 1276	*Standard bacteria*		50 %, 1 min	50 %, 1 min	
EN 13727	*Standard bacteria*		50 %[1] 30 sec		50 %[1] 30 sec
DGHM Method 9	*Standard bacteria*	50 % 15 sec			50 % 15 sec
DGHM Method 9 (with and without thickener)	*S. aureus, P. aeruginosa, C. albicans*				75 % 15 sec
EN 1650	*C. albicans*		80 %, 1 min	80 %, 1 min	
EN 13624	*C. albicans*		80 %, 30 sec		80 %, 30 sec
EN 13624 (with thickener)	*C. albicans*		70 % 30 sec		
EN 14348	*Mycobacterium terrae*		80 %, 30 sec		80 %, 30 sec
EN 14476	*MVA*		80 %, 30 sec		80 %, 30 sec
EN 14476 (with thickener)	*MVA*		80 %, 30 sec		
DVV/RKI	*Vacciniavirus Elstree*	80%, 15 sec			80 %,[2] 15 sec
DVV/RKI	*BVDV*	80%, 15 sec			80 %,[2] 15 sec
DVV/RKI	*Bovine Corona Virus*	80 %, 30 sec			80 %,[2] 30 sec
DVV/RKI	*Human Rotavirus Wa*	80 %, 30 sec			
EN 14476	*Adenovirus*		80 %, 1 min		80 %, 2 min
EN 14476 (with thickener)	*Adenovirus*		80 %, 1 min		
EN 14476	*MNV*		97%, 1 min		97%, 1 min
EN 14476	*MNV*		*97%, 1 min[3]*		*80 %, 5 min[3]*

Method	Test organisms	Interfering substances			
		-	0.3 g/L BSA	3 g/L BSA	3 g/L BSA + 3 ml/L SE[4]
EN 14476 (with and without thickener)	*MNV*		*Comparable efficacy after 5 min*[5]		*Comparable efficacy after 5 min*[5]
EN 1500	*E. coli*	2*3 ml, 30 sec			
EN 1500 (with thickener)	*E. coli*	2*3 ml, 30 sec			
EN 1500 (wipes)	*E. coli*	Rub 1 wipe over hands for 30 sec, then a second wipe for another 30 sec			
EN 12791	-	Rub 3 ml portions of product onto the hands and keep them moist for at least 90 sec			
EN 13697	*Standard bacteria* *C. albicans*		50 %, 1 min	50 %, 1 min	50 % 2 min
VAH Method 14.1	*Standard bacteria (clean)* *S. aureus* *E. hirae (dirty)*		50 %, 1 min		50 % 2 min
VAH Method 14.1	*C. albicans*		100%, 5 min		100 %, 5 min
EN 16615[4] (100% PET wipes, 20x30 cm, 14 ml/wipe)	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans* Immediate test, 28 days and 8 weeks in a dispenser system		100 %, 1 min		100 %, 1 min
EN 16615 (100 % PET wipes, 20x30 cm, 14 ml/wipe)	*E. hirae* *P. aeruginosa* Immediate test, 28 days or 12 weeks after opening of the container		100 %, 1 min		100 %, 1 min
EN 16615 (standard wipes)	*S. aureus* *E. hirae* *P. aeruginosa* *C. albicans*		100 %, 1 min		100 %, 1 min
EN 16615 (standard wipe)	*M. terrae*		100 %, 1 min		100 %, 1 min

[1] without *E.coli* (sufficient for surface disinfectants according to EN 13727, sufficient for hand disinfection according to DGHM/VAH methods, see e.g. Marth, 2002)
[2] not tested with BSA + sheep erythrocytes but with 10% fetal calf serum

[3] validity cannot be confirmed due to modified control (cell susceptibility)
[4] SE = sheep erythrocytes
[5] can only be used as supportive data

It can be concluded that all necessary Phase 2, step 1 and Phase 2, step 2 tests have been provided. Efficacy against bacteria (incl. *Mycobacterium terrae*) and yeast has been proven under the tested conditions for the intended uses hygienic handrub disinfection, surgical handrub disinfection as well as disinfection of non-porous surfaces by spraying and pouring each followed by wiping or wiping with ready-to-use wipes (see above, table "summary on efficacy"). The data provided include Phase 2, step 2 tests with the intended wipe material for the ready-to-use wipes of meta-SPC 3 and 5 (100 % PET) as well as the reference wipe material of EN16615. Additionally, efficacy against enveloped viruses was shown for hygienic handrub disinfection and surface disinfection in PT 2.
Furthermore, valid efficacy data against Adenovirus and Murine Norovirus have been provided.
In conclusion, a virucidal claim (surface disinfection in PT 4, necessary test organisms Adenovirus and murine Norovirus) and a limited spectrum virucidal claim (hand disinfection in PT 1 and surface disinfection in PT 2, necessary test organisms Adenovirus and murine Norovirus) is proven for the products of "orochemie hand- and surface disinfectants".

Read-across approach: Thickener

Products of the meta-SPCs 2-5 solely contain 63.1% (w/w) propan-2-ol and water. In addition to these two components, the products of meta-SPC 1 contain two thickeners (please refer to confidential Annex regarding these co- fourmulants). The uses included in meta-SPC1 are hygienic handrub disinfection and surgical handrub disinfection of clean skin.
In order to prove that the thickener does not influence the efficacy, the applicant submitted several studies. A test according to DGHM standard methods (9.1, quantitative suspension test) has been submitted which compares the efficacy of a product with (C25) and without thickeners (C20) under dirty conditions against bacteria (*S. aureus, P. aeruginosa*) and yeast (*C. albicans*). Since no difference in efficacy after 15, 30 and 60 seconds with a test concentration of the products of 80% could be observed, it is to be expected that the thickeners do not influence the efficacy of the biocidal products against bacteria and yeast.
Furthermore, a study according to EN 13624 has been provided showing efficacy of C25 against *C. albicans* under clean conditions. In this test, again no difference was observed in the efficacy of C25 in comparison to C20 at 80 % product concentration.
To prove the virucidal efficacy, studies according to EN 14476 have been provided for MVA and Adenovirus under clean conditions. Efficacy was shown after 30 seconds (MVA) or 60 seconds (Adenovirus) at 80 % product concentration.
To prove the efficacy of C25 against murine Norovirus, a screening test based on EN 14476 comparing efficacy of C20 with C25 under clean and dirty conditions within 5 minutes has been provided. The results suggest, that both products may have comparable efficacy against murine Norovirus. However, e.g. no

raw data or information on controls are available in this screening test. Therefore, this data can only be used as supportive data.
Finally, a phase 2, step 2 test according to EN1500 has been provided comparing the efficacy of a product with and without thickener. No difference in efficacy was observed.
Thus, the read-across between products without thickener to products with thickener is deemed acceptable for the target organisms bacteria, yeast, MVA and Adenovirus. This would allow the claims bactericidal, yeasticidal (hygienic and surgical hand disinfection) and activity against enveloped viruses (hygienic hand disinfection) for products of meta-SPC1 when used according to the tested conditions.

3.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of the active substance propan-2-ol, 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, propan-2-ol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.
No management strategies have been developed since no occurrence of resistance has been observed.

3.5.7 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 “orochemie hand- and surface disinfectants” biocidal product family.

3.5.8 Evaluation of the label claims

The following biocidal label claims are considered to be suitable for product labels of the „orochemie hand- and surface disinfectants“:

Hygienic handrub disinfection:

- Rub in at least 2*3 ml of the undiluted product on clean hands for a duration of at least 30 seconds for bactericidal (incl. tuberculocidal) and yeasticidal efficacy as well as activity against enveloped viruses. Limited spectrum virucidal activity is achieved after rubbing clean hands for 60 seconds.

Hygienic handrub disinfection (wipes):

- Rub one wipe thoroughly over clean hands for 30 seconds, then rub a second wipe over hands for an additional 30 seconds for bactericidal (incl. tuberculocidal) and yeasticidal efficacy as well as activity against enveloped viruses and limited spectrum virucidal activity.

Surgical handrub disinfection (without long-term effect according to EN 12791):

- Rub in 3 ml portions of the undiluted product on clean hands and forearms. Keep the skin moist for at least 90 seconds for bactericidal (incl. tuberculocidal) and yeasticidal efficacy.

Surface disinfection in PT 2, healthcare industries and institutional area (clean and dirty conditions):

- For disinfection of non-porous surfaces at room temperature (20 ± 2°C)
- Spraying and Wiping: Spray on surfaces from a distance of 20-30 cm and wipe the surfaces or spray on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.
- Pouring and Wiping: Pour on surfaces and wipe the surfaces or pour on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.
- Wiping (ready-to-use wipes): Make sure to wet surfaces completely by wiping. Allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

Surface disinfection in PT 2, health care area (clean and dirty conditions):

- For disinfection of non-porous surfaces at room temperature (20 ± 2°C)
- Spraying and Wiping: Spray on surfaces from a distance of 20-30 cm and wipe the surfaces or spray on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.
- Pouring and Wiping: Pour on surfaces and wipe the surfaces or pour on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

- Wiping (ready-to-use wipes): Make sure to wet surfaces completely by wiping. Allow to act for 1minute for bactericidal (incl. tuberculocidal) and yeasticidal activity as well as activity against enveloped viruses. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

Surface disinfection in PT4, food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and –handling, kitchens in retirement homes (clean and dirty conditions):

- For disinfection of non-porous surfaces at room temperature (20 ± 2°C)
- Spraying and Wiping: Spray on surfaces from a distance of 20-30 cm and wipe the surfaces or spray on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1minute for bactericidal (incl. tuberculocidal) and yeasticidal activity. For virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.
- Pouring and Wiping: Pour on surfaces and wipe the surfaces or pour on wipe until the wipe is soaked and wipe the surfaces. Make sure to wet surfaces completely and allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity. For virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.
- Wiping (ready-to-use wipes): Make sure to wet surfaces completely by wiping. Allow to act for 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity. For virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

General considerations:

Unspecified terms like “fast acting” or “immediate effect” would only be possible if marked with an asterisk and a following clarification with the proven contact time, e.g. “hygienic hand rub: bactericidal and yeasticidal efficacy within 30 seconds”

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

The products within this BPF are not intended to be authorised for use in combination with other biocidal products.

3.5.10 Data waiving and conclusion

Table 33

Data waiving was acceptable for the following information requirements

Information requirement	6.7 Efficacy data to support these claims: Read-across to support efficacy of products with thickeners
Justification	The applicant submitted several studies comparing efficacy of products with and without thickeners (see above "**Read-across approach: Thickener**" for more details). The provided tests show bactericidal, yeasticidal activity as well as activity against enveloped viruses and Adenovirus for products with thickener when used according to the tested conditions.

Table 34

Conclusion on the efficacy
Proven efficacy of ready-to-use gel (PT 1, meta-SPC 1): For hygienic handrub disinfection, the following efficacy has been proven. Bactericidal (including tuberculocidal) and yeasticidal efficacy as well as activity against enveloped viruses with an application rate of 2*3 ml of the undiluted product within a contact time of at least 30 seconds under clean conditions. Limited spectrum virucidal activity is achieved after rubbing clean hands for 60 seconds. For surgical handrub disinfection, bactericidal (including tuberculocidal) and yeasticidal efficacy within a contact time of at least 90 seconds under clean conditions has been proven when 3 ml portions of the product are rubbed into the skin. The skin has to be kept sufficiently moist for the required contact time. A long term effect in accordance to EN 12791 can not be claimed, since no stronger effect than the reference product 3 hours after application of the test product for 90 s has been demonstrated. Proven efficacy of ready-to-use liquids (PT 1, meta-SPC 2): For hygienic handrub disinfection, the following efficacy has been proven. Bactericidal (including tuberculocidal) and yeasticidal efficacy as well as activity against enveloped viruses with an application rate of 2*3 ml of the undiluted product within a contact time of at least 30 seconds under clean conditions. Limited spectrum virucidal activity is achieved after rubbing clean hands for 60 seconds. For surgical handrub disinfection, bactericidal (including tuberculocidal) and yeasticidal efficacy within a contact time of at least 90 seconds under clean conditions has been proven when 3 ml portions of the product are rubbed into the skin. The skin has to be kept sufficiently moist for the required contact time. A long term effect in accordance to EN 12791 can not be claimed, since no stronger effect than the reference product 3 hours after application of the product for 90 s has been demonstrated. Proven efficacy of ready-to-use wipes (PT 1, meta-SPC 3): The following efficacy has been proven for the use as a hygienic handrub disinfectant. Bactericidal (including tuberculocidal) and yeasticidal efficacy as well as efficacy against enveloped viruses and limited spectrum virucidal activity with an application rate of rubbing one wipe over the hands for 30 seconds followed by a second wipe rubbed over the hands for another 30 seconds (contact time of at least 60 seconds) under clean conditions. Phase 2, step 2 testing has been carried out following the procedure described in Annex A of EN 1500. Proven efficacy of ready-to-use liquids (PT2, PT4, meta-SPC 4): In general, efficacy has been proven for disinfection of non-porous surfaces at room temperature (20 ± 2°C). For further information, see below. *Surface disinfection in PT 2* On the one hand, the intended use area in PT 2 is the healthcare industry and institutional area (clean and dirty conditions). For disinfection with mechanical action (spraying or pouring followed by wiping / soaking a wipe followed by wiping), efficacy has been shown for this use area with a contact time of

at least 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity and activity against enveloped viruses under clean and dirty conditions. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions
On the other hand, disinfection in the healthcare area has been included in the application in PT 2. For disinfection with mechanical action (spraying or pouring followed by wiping / soaking a wipe followed by wiping) efficacy has been shown for this use area with a contact time of at least 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity and activity against enveloped viruses under clean and dirty conditions. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

Surface disinfection in PT 4

The intended use area includes food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and –handling, kitchens in retirement homes.
For disinfection with mechanical action (spraying or pouring followed by wiping / soaking a wipe followed by wiping), efficacy has been shown with a contact time of at least 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity under clean and dirty conditions. For virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

Proven efficacy of ready-to-use wipes (PT 2/4, meta-SPC 5):

In general, efficacy has been proven for disinfection of non-porous surfaces at room temperature (20 ± 2°C). For further information, see below.

Surface disinfection in PT 2

The intended use area in PT 2 is the healthcare industry and institutional area as well as healthcare area (clean and dirty conditions). For disinfection with ready-to-use wipes, efficacy has been shown for a contact time of at least 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity and activity against enveloped viruses under clean and dirty conditions. For limited spectrum virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

Surface disinfection in PT 4

The intended use area includes food industry (non-alcoholic beverages), food processing (e.g. meat, gourmet food, vegetables, fruit), food preparation and –handling, kitchens in retirement homes.
For disinfection with ready-to-use wipes, efficacy has been shown with a contact time of at least 1 minute for bactericidal (incl. tuberculocidal) and yeasticidal activity under clean and dirty conditions. For virucidal activity, contact time is 1 min under clean conditions or 2 min under dirty conditions.

It can be concluded that products of the BPF “orochemie hand- and surface disinfectants” show sufficient bactericidal (incl. tuberculocidal) and yeasticidal activity as substantiated according to European Standards (EN) for the intended uses in PT1, PT2 and PT4. Furthermore, the products show sufficient efficacy against enveloped viruses in PT1 and PT 2. The products show limited spectrum virucidal activity in PT1 and PT2 as well as virucidal activity in PT4.
Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of the BPF “orochemie hand- and surface disinfectants” have been met.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 35 Reference values for the Active Substance

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
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

Table 36

Propan-2-ol	Value	Reference
Inhalative absorption	100 %	Assessment-Report (RMS DE (2014)
Oral absorption	Nearly complete following oral, inhalation and intravenous exposure.	Assessment-Report (RMS DE (2014)
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) – for biocidal products of the BPF containing only as and water or as and co-formulants which are not expected to have a significant impact on dermal systemic exposure (meta-SPC 1, 2 and 3).	Assessment-Report (RMS DE (2014)

	25 % - for biocidal products of the BPF containing a surfactant (meta-SPC 4 and 5)	Default according to the EFSA Guidance on Dermal Absorption (2012

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal products of the BPF are not required. According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 compositions of the biocidal products belonging to the BPF are 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 since the biocidal products are dilutions of the active substance in water with some minor co-formulants (only in meta-SPC 1). Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products of the BPF is not required.

Table 38

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin. Repeated exposure may cause skin dryness or cracking.
Justification for the value/conclusion	According to Regulation (EC) No 1272/2008 propan-2-ol Annex VI is not skin irritating in rabbits. Studies on skin irritation in human subjects reveal no skin irritating properties. According to the CLP criteria, the individual biocidal products of the BPF, and thus the BPF itself, do not need to be classified with respect to local effects on the skin. Biocidal products of meta-SPC 1 contain co-formulants in minor concentrations classified for skin irritation and corrosion. However, their concentrations are far below the generic concentration limits.

	However, according to the third party dossier and CAR 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:
Classification of the product according to CLP	Classification for skin corrosion or irritation is not required. Supplemental hazard statement: EUH066 (Repeated exposure may cause skin dryness or cracking.)

3.6.2.2 Eye irritation

Table 39

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal products of the BPF are not required. According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 compositions of the biocidal products of the BPF are 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 since the biocidal products are simple dilutions of the active substance in water (all other meta-SPCs) with some minor co- formulants (only in meta-SPC 1) Consequently, classification of the mixture can be 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.

Table 40

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to the eyes.
Justification for the value/conclusion	Classification of the active substance according to Regulation (EC) No 1272/2008 and its concentration in the biocidal products Propan-2-ol (63.1 %, w/w): Eye Irrit. 2, H319; Generic concentration limit: 10 % (w/w) Biocidal products of meta-SPC 1 contain co-formulants classified for eye irritation and eye damage in minor concentrations below the corresponding concentration limits.

Classification of the product according to CLP	Eye Irrit. 2, H319 (Causes serious eye irritation.)

3.6.2.3 Respiratory tract irritation

Table 41

Data waiving	
Information requirement	8.10, “Other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal products of the BPF has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal products of the BPF do not contain components classified for respiratory irritation in relevant concentrations.

Table 42

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation the biocidal products of the BPF are not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 43

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin-sensitising properties of the biocidal products of the BPF are not required. According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), “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 compositions of the biocidal products of the BPF are 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 since the biocidal products are simple dilution of the active substance in water with some minor co-formulants (only in meta-SPC 1). Consequently, classification of the mixtures can be 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.

Table 44

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation the biocidal products of the BPF are not skin-sensitising.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 45

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Standard test systems for respiratory sensitisation do not exist. Data on respiratory sensitisation for the biocidal products of the BPF or their components are not available.

Table 46

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 of the BPF or their components with the corresponding concentration are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 47

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 compositions of the biocidal products of the BPF are 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 since the biocidal products of the BPF are simple dilutions of the active substance in water with some minor co-formulants (only in meta-SPC 1). Consequently, classification of the mixtures can be 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.

Table 48

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acute toxicity via the oral route.
Justification for the selected value	The oral LD_{50} of all relevant components are > 2000 mg/kg bw. Hence, the oral LD_{50} of the biocidal products of the BPF are estimated as > 2000 mg/kg bw .
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 49

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "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 compositions of the biocidal products of the BPF are 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 since the biocidal products of the BPF are simple dilutions of the active substance in water with some minor co- formulants (only in meta-SPC 1). Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products of the BPF is not required.

Table 50

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acute toxicity via the inhalation route.
Justification for the selected value	The inhalation LC_{50} of all relevant components are above the limits for classification. Hence, the inhalation LC_{50} of the biocidal products of this family will also be above these limits.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 51

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	According to the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), “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 compositions of the biocidal products of the BPF are 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 since the biocidal products of the BPF are simple dilutions of the active substance in water with some minor co- formulants (only in meta-SPC 1). Consequently, classification of the mixtures can be 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.

Table 52

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute toxicity via the dermal route.
Justification for the selected value	The dermal LD_{50} of all relevant components are > 2000 mg/kg bw. Hence, the dermal LD_{50} of the biocidal products of this family are estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 53

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	The applicant has access to a 3rd party dossier. This dossier contains the same studies and information on dermal absorption submitted and evaluated for the the approval of the active substance and as presented in the Competent Authority Report (CAR). Additional information in the third party dossier was considered not relevant for the derivation of a dermal absorption value. 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. a dermal flux rate of 0.85 mg/cm²/h was derived for a 70 % aqueous dilution on rat skin. Meta-SPC 2 to 5: The composition of the test formulation and biocidal products of the BPF in meta-SPC 2, 3, 4 and 5 are very similar. It is not expected that the slightly lower concentration in the biocidal products 63.1 % vs. 70 % has a significant effect: Hence, the derived dermal flux rate can also be used for these biocidal products in meta SPC 2, 3, 4 and 5. Meta-SPC 1: The concentration of the active substance of biocidal products in meta- SPC 1 is identical to meta-SPC 2 and 3. However, the biocidal products of meta-SPC 1 contain additional co-formulants, which may affect dermal absorption. However, these effects are only minimal and are not expected to have a significant impact on dermal systemic exposure (for details refer to the Confidential Annex). In conclusion, the dermal flux rate of 0.85 mg/cm²/h can also be applied for biocidal products of this Meta-SPC.

Table 54

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s	Meta-SPC 1 to 5: All scenarios with dermal contact Concentration a.s.: 63.1 % (w/w)
Value(s)	0.85 mg/cm²/h
Justification for the selected value(s)	Boatman, 1998; see table above

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

Substances of concern were not identified. The other classified components of the biocidal product family, do not contribute to the classification of the BPF due to their low concentration.

3.6.2.9 Available toxicological data relating to a mixture

Not available.

3.6.2.10 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 family (> 60 %) and the recommended generic concentration limit of 20 % for substances classified as STOT SE 3, this classification is also required for the biocidal products of the BPF.

3.6.2.11 Summary of effects assessment

Table 55

Endpoint	Brief description
Skin corrosion and irritation	Based on the intrinsic properties of single components. Not corrosive or irritating to the skin. Repeated exposure may cause skin dryness or cracking. Labelling with EU066 is required.
Eye irritation	Based on the intrinsic properties of single components. Irritating to the eyes (Eye Irrit. 2, H319).
Respiratory tract irritation	Based on the intrinsic properties of single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of single components. Not skin-sensitising.
Respiratory sensitization (ADS)	Based on the known intrinsic properties of single components. Not sensitising to the respiratory tract.
Acute toxicity by oral route	Based on the known intrinsic properties of single components. No acute toxicity via the oral route.
Acute toxicity by inhalation	Based on the known intrinsic properties of single components. No acute toxicity via the inhalation route.

Acute toxicity by dermal route	Based on the known intrinsic properties of single components. No acute toxicity via the dermal route.
Information on dermal absorption	All meta-SPCs: Based on a study with a comparable formulation. 0.85 mg/cm^2/h (dermal flux rate)
Available toxicological data relating to non-active substance(s)	Not relevant
Available toxicological data relating to a mixture	Not available
Other relevant information	Based on the intrinsic properties of the active substance also the biocidal products are classified with STOT SE 3, H336 (May cause drowsiness or dizziness).

3.6.3 Exposure assessment

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

Table 56 Meta SPC 1-5

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

List of scenarios

Table 57

Summary table: scenarios				
Scenario number	**Scenario**	**Use no. (Product type)**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	Hand disinfection - hygienic	Use 1, in meta SPC 1 - 3 and use 2, in meta SPC 2 (PT01)	Primary exposure of a 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 all uses in meta SPCs 1, 2 and 3**	Professional
2	Small surface disinfection - in between disinfection 2a – in medical practices 2b – in hospitals	Use 1 in meta-SPC 4 and 5 ; use 2 in meta SPC 4 (PT02)	Primary exposure of a professional user resulting from application (wiping, pouring & wiping or spraying & wiping) 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 or a room in a medical practice. Secondary exposure of a professional bystander who is present in the patient room where the surface disinfection is carried out can be expected. **Applies to uses 1 and 2 in meta SPC 4 and to use 1 in meta-SPC 5**	Professional
3	Small surface disinfection in laboratory	Use 1 in meta-SC 4 and 5 ; use 2 in meta SPC 4 (PT02)	Primary exposure of a professional user resulting from (wiping, pouring & wiping or 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 uses 1 and 2 in meta SPC 4 and to use 1 in meta-SPC 5**	Professional

4	Refilling	Use 1 in meta SPC 1,2 and 4; Use 2 in meta-SPC 2 and 4; use 3 and 4 in meta SPC 4 , (PT01, PT02, PT04)	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 all uses in meta SPCs 1,2 and 4)**	Professional
5	Small surface disinfection in kitchens and canteens	Uses 3 and 4 in meta-SPC 4 and use 2 in meta-SPC 5 (PT04)	Primary exposure of a professional user resulting from application (wiping, pouring & wiping and 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 uses 3 and 4 in meta-SPC 4 and use 2 in meta-SPC 5**	Professional
6	Disinfection of food processing machinery	Uses 3 and 4 in meta-SPC 4 and use 2 in meta-SPC 5 (PT04)	Primary exposure of a professional user resulting from application (wiping, pouring & wiping or 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 uses 3 and 4 in meta-SPC 4 and use 2 in meta-SPC 5**	Professional
7a.	post-application	Meta –SPC 1 -3 (PT 1)	PT1; Secondary exposure from professional hand disinfection, e.g. in hospitals (adult)	general public, bystanders
7b.	post-application	Meta –SPC 1-3 (PT 1)	PT1; Secondary exposure from professional hand disinfection, e.g. in hospitals (child)	general public, bystanders

7c.	post-application	Meta –SPC 1-3 (PT 1)	PT1; Secondary exposure from professional hand disinfection, e.g. in hospitals (toddler)	general public, bystanders
8a.	post-application	Meta –SPC 4 and 5 (PT 2)	PT2: Secondary professional disinfection of small surfaces, e.g. in patient rooms of hospitals (adult)	general public, bystanders
8b.	post-application	Meta –SPC 4 and 5 (PT 2)	PT2: Secondary exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals (child)	general public, bystanders
8c.	post-application	Meta –SPC 4 and 5 (PT 2)	PT2: Secondary exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals (toddler)	general public, bystanders
9a.	post-application	Meta –SPC 4 and 5 (PT 4)	PT4: Secondary exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (adult)	general public, bystanders
9b.	post-application	Meta –SPC 4 and 5 (PT 4)	PT4: Secondary exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (child)	general public, bystanders
9c.	post-application	Meta –SPC 4 and 5 (PT 4)	PT4: Secondary exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (toddler)	general public, bystanders

3.6.3.1.1 Professional exposure

Overview of the intended applications within the five meta SPCs of the BPF

The orochemie hand- and surface disinfectants product family is a biocidal product family (BPF) of propan-2-ol based disinfectants comprising of five meta SPCs.
An overview of the applications applied for the meta SPCs 1-5 is given in

Table 57 All members of the biocidal product family orochemie hand- and surface disinfectants contain “propan-2-ol” (CAS No.: 67-63-0; 63.1% w/w) as active substance.

The exposure to the active substance propan-2-ol is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonized document “Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

The products of meta-SPCs 1-3 are used for hand disinfection, while the products of meta-SPCs 4 and 5 are used for different kinds of surface disinfection. For the sake of clarity and to take advantage of similarities between the different meta-SPCs, the assessment of the hand disinfection products of meta-SPC 1-3, and that of the surface disinfection products of meta-SPCs 4 and 5 are presented in two separate subsections.

Professional exposure assessment of meta SPC 1 to 3

Within PT 1, the products of meta SPC 1, 2 and 3 are used for hygienic/surgical hand disinfection by hand rubbing or rubbing the hands with a wipe, which is described in the following section.

The summary Table 58 gives an overview of the in use products for the meta SPCs 1 to 3 of the orochemie hand- and surface disinfectants product family.

Table 58

meta SPC	Formulation type
1	Ready to use hand gels (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0))
2	Ready to use hand solutions (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0))
2	Ready to use hand sprays (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0))
3	Ready to use hand wipes (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0))

The summary Table 59 presents an overview on the exposure scenarios for the different meta SPCs 1 to 3 of the orochemie hand- and surface disinfectants product family which are assessed in this PAR.

Table 59

Summary table: Presentation of the exposure assessment in the meta SPCs 1 to 3 of this PAR Scenarios with the same scenario no. were assessed identically, even if they appear in more than one meta SPC.			
meta SPC	**Use No.**	**Scenario No.**	**Intended applications**
meta SPC 1	1	1	Hand disinfection – hygienic[1)]
	1	4	Refilling[1)]
meta SPC 2	1 and 2	1	Hand disinfection - hygienic[1)]
	1 and 2	4	Refilling[1)]
meta SPC 3	1	1	Hand disinfection - hygienic[1)]

[1)] covered by the assessment laid out in meta SPC 1

The products of meta SPC 1 are made available on the market in different package sizes: Bottle containing 100 ml; bottle or jerrycan containing 500 ml to 10 L; drum containing 220 L and container containing 1000 L.
The products of meta SPC 2 made available on the market in different package sizes: Bottle or jerrycan containing 125 ml to 10 L; pump spray bottle containing 125 ml; drum containing 220 L and container containing 1000 L.
The products of meta SPC 3 are marketed in different package sizes: single wipe or box containing 40 to 300 wipes.

The exposure assessment for professional users for biocidal products of meta SPCs 2 and 3 is covered by the exposure assessment for biocidal products as presented in meta SPC 1.

In Annex 4.3.1 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 the chapter on Risk for professional users 3.6.4.5.

- **Scenario 1 – Hand disinfection**

Description

The exposure assessment of hand disinfection is based on the approach described in detail in the recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure “Hand disinfection in hospitals”.

The products of meta SPC 1 are ready-to-use hand disinfectant gels which may be decanted from a canister into a smaller unit prior to application (refilling).

For hand disinfection, the application liquid is applied onto dry hands which are then rubbed intensively. The disinfectant is left on the skin and evaporates off. For hand disinfection with ready-to-use wipes (meta SPC 3) the surface of both hands is wiped with an impregnated wipe.

When sprayed (meta SPC 2), the spraying is carried out directly on the hands from a very short distance. This is not comparable with spraying in a room. Therefore the exposure relevant task is the hand disinfection and the resulting evaporation and not the spraying.

The disinfectant is used in health care, domestic, institutional, veterinary, industry, food preparation and handling (kitchen, restaurants, grocery shops, butcher etc.) sector.

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 again 3 hand disinfections in each room. In summary, 25 applications per shift are performed.

According to information from the applicant, the use rate for a ready-to-use gel (meta SPC 1) is 3 mL per hand rub, for a ready-to-use liquid (meta SPC 2) it is 4 ml per hand rub and for a ready-to-use spray (meta SPC 2) it is 3 - 4 mL per hand rub. According to Table 32 the use rate for ready to use wipes (meta SPC 3) is 9.52 ml per hand rub. Gel, spray, wipe and liquid application can well be compared. Accordingly, the application rate of 9.52 ml per hand disinfection for a ready-to-use wipe represents the worst-case situation and is assessed for meta SPC 1 to 3.

Dermal exposure

Especially during the application phase, exposure to skin occurs as the biocidal product is directly applied to both hands. The 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. For a realistic worst case assumption, the total amount of the biocidal product is taken into account.

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (30 °C, skin temperature). A refined calculation of the inhalation exposure for the professional user to the a.s. is carried out as described in recommendation no. 9 using the consumer

exposure 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

The products of meta SPC 1 and 2 are taken from a bottle or dispenser and are applied on the hands. This procedure is carried out below eye height so that an exposure of the eyes is not expected. Moreover the application liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

The products of meta SPC 3 ready-to-use wipes which are impregnated with the disinfectant liquid. Therefore, exposure to the eyes during disinfection of hands can be excluded.

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 skin. It is possible that inhalation exposure occurs to a professional bystander who is present in the patient room where the hand disinfection is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 60

Details of Scenario 1	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Number of hand disinfections	25
Volume of b.p. per application (meta SPC 3)	9.52 ml (wipe)
Area of the 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	2.39 min (143.65 sec*)
Product amount for one hand disinfection (Volume b.p. x density)	8.36 g
Exposure duration per application	10 min**
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 and dermal exposure (Tier 1) are summarised in Table 62 and Table 63. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the hand disinfection are given in Table 64.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

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 ready-to-use wipes have to be discarded into a closable container after use to prevent secondary inhalation exposure to the a.s. which further evaporates from the used wipe.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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 downwards

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.

A surgical hand disinfection includes both hands and forearms but due to the specific situation it is carried out less frequently than a hygienic hand disinfection. It is assumed that the exposure scenario for hygienic hand disinfection also covers the situation for surgical hand disinfection (according to HEAdhoc recommendation 1). Scenario 1, as described for meta SPC 1, applies also to the respective application of meta SPCs 2 and 3.

For refilling of the application bottles from larger storage containers, please refer to scenario 4.

- **Scenario 4 – Refilling**

Description

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. So, refilling requires the use of an adequate funnel. After the refilling process 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. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.

For informational purpose the external dermal exposure is also calculated based on “Mixing and loading model 4” (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG).

Inhalation exposure

Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the active substance during the 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. A calculation of the 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 the 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 to the eyes

Accidental splashes to the eyes cannot be excluded during manual decanting. Even if the local effects for eye irritation are taken into account via the AEL 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

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. It is possible that inhalation exposure occurs to a professional bystander who is present in the room where the refilling is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 61

Details of Scenario 4	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ART parameters for the loading phase	
Room	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 and dermal exposure (Tier 1 and Tier 2) are summarised in Table 62 and Table 63. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the hand disinfection are given in Table 64.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR. For risk characterisation, see chapter 3.6.4.5.

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.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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, e.g. drums or IBCs, is carried out by the help of dosing pumps or connecting lines leading to less exposure as manual decanting.

Experts in Germany (VAH) recommend using non-refillable bottles for applications in the health care sector as bottles that are refilled but not cleaned properly may lead to the development of microbial resistance and a reduction of efficacy. Refilling of bottles for use in PT 1 nevertheless may e.g. occur in the pharmaceutical industry.

The refilling scenario is not applicable for disinfection with ready-to-use wipes (meta SPC 3). Scenario 4 applies also to the respective applications of meta SPCs 2 and 4.

- **Summary of professional exposure for meta SPC 1 to 3**

The following tables give an overview of the assessed exposure values. In Table 62 the estimated external inhalation exposure and external dermal exposure are listed. In Table 63 the values of the assumed exposed skin area and application time for dermal exposure are summarised. In chapter 3.6.4.5 especially in table Table 79 the risk for the professional user is described. The combined risk for the procedures of refilling and hand disinfection is given in **Table 80**. Please refer to Annex 4.3.1 for the external and internal exposure values for the scenarios.
The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are combined exposure values of all phases.

Table 62

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenario	**Use no. (Product type)**	**Tier/PPE**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1 Hand disinfection - hygienic	Use 1 in meta SPC 1 - 3 and use 2 in meta SPC 2 (PT01)	Tier 1	28.140	131856.28*
		Tier 2	n.a.	n.a.
Scenario 4 Refilling	Use 1 in meta SPC 1 and 2 and use 2 in meta SPC 2 (PT01)	Tier 1	0.790	277.01*
		Tier 2 - chemical protective gloves	0.790	27.70*

*) The dermal risk assessment is based on calculation of dermal flux which does not include the external dermal exposure.

Table 63

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	2.39	25	820	4	59.85
Scenario 4 Refilling	PT01	0.5	1	205	1	0.5

* Contact time = evaporation time or application time (depending on scenario)

- **<u>Combined scenarios for meta SPC 1 to 3:</u>**

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 64

Summary table: estimated exposure from professional uses for combined scenarios. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenarios – numbers	**Exposure scenarios - names**	**Tier/PPE**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
4 + 1	Refilling + Hand disinfection - hygienic	Tier 1	28.930	132133.29*
		Tier 2	n.a	n.a.

*) The dermal risk assessment is based on calculation of dermal flux which does not include the external dermal exposure.

Professional exposure assessment for meta SPC 4 to 5

Within PT 2 the products of meta SPC 4 and meta SPC 5 are used for disinfection of small surfaces in the health care industry, institutions, health care facilities, hospital rooms, dentists and isolation rooms. Within PT 4 the products of meta SPC 4 and meta SPC 5 are used for disinfection of small surfaces in food contact areas and of food processing machinery for non-alcoholic beverages, processed food (meat, deli, vegetables, fruits etc.), food preparation and handling and kitchen in nursing homes.

The summary Table 65 gives an overview of the in use products for the meta SPCs 4 and 5 of the orochemie hand- and surface disinfectants product family.

Table 65

meta SPC	Formulation type
4	Ready to use solutions (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0)
4	Ready to use sprays (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0)
5	Ready to use wipes (63.1 % (w/w) active substance “propan-2-ol” (CAS-No.: 63-67-0)

The summary in Table 66 presents an overview on the exposure scenarios for the meta SPCs 4 to 5 of the orochemie hand- and surface disinfectants product family which are assessed in this PAR.

Table 66

Summary table: Presentation of the exposure assessment in meta SPCs 4 and 5 of this PAR Scenarios with the same scenario no. were assessed identically, even if they appear in more than one meta SPC.			
meta SPC	**Use No.**	**Scenario No.**	**Intended applications**
Meta SPC 4	1,2	2	Small surface disinfection - in between disinfection: 2a – in medical practices 2b – in hospitals
	1, 2	3	Small surface disinfection in laboratory
	1,2,3,4	4	Refilling[1)]
	3,4	5	Small surface disinfection in kitchens and canteens
	3,4	6	Disinfection of food processing machinery
Meta SPC 5[1)]	1	2	Small surface disinfection - in between disinfection: 2a – in medical practices 2b – in hospitals
	1	3	Small surface disinfection in laboratory
	2	5	Small surface disinfection in kitchens and canteens
	2	6	Disinfection of food processing machinery

[1)] covered by the assessment laid out in meta SPC 1

The products of meta SPC 4 are made available on the market in different package sizes: bottle or jerrycan containing 125 ml to 10 L, pump spray bottle containing 125 ml, drum containing 220 L and container containing 1000 L.
The products of meta SPC 5 are made available on the market in different package sizes: single wipe or box containing 40 to 300 wipes.

In Annex 4.3 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 the chapter on Risk for professional users 3.6.4.5.

- **Scenario 2 – Small surface disinfection - in between disinfection:**
  - **2a – in medical practices**
  - **2b – in hospitals**

Description

The following scenarios cover the disinfection of small surfaces with an alcohol based disinfectant in a naturally ventilated room e.g. for disinfection of a small area in a medical practice (Scenario 2a) or a patient room in a hospital (Scenario 2b). 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".

Scenario 2a: Small surface disinfection – in-between disinfection in medical practices
Scenario 2b: Small surface disinfection – in-between disinfection in hospitals
The complete exposure assessments of both types of users are available in Annex 4.3.1 Based on the results the Scenario 2a: Small surface disinfection – in-between disinfection in medical practices is the worst case. Therefore, scenario 2a is described in more details in the following section and is brought to the risk characterisation.

Ready-to-use surface disinfectant solutions and sprays which may be decanted from a canister into a smaller unit prior to application (refilling) are used in meta-SPC 4.

For the 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, the spraying is carried out directly from a very short distance. Therefore, the process relevant for inhalation exposure is evaporation of the use solution from the treated surface.

This scenario also covers the disinfection of small surface areas with impregnated ready-to-use wipes (meta SPC 5) which are used to wipe over the surface.

The disinfectant is used in health care industry, institutions, health care facilities, hospital rooms, dentists and isolation rooms.

Based on HEAdhoc recommendation 15, during the working day a nurse or health care worker 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).
According to information from the applicant, the use rate for the ready-to-use liquid (meta SPC 4) is 50 ml per m², and 2 times 8 ml per m² for the ready-to-use wipes (meta SPC 5). Thus, the application rate

for the ready-to-use liquid represents the worst-case situation. The exposure assessment for the liquid products of meta SPC 4 is also applicable for the ready-to-use wipes in meta SPC 5, as presented in the following.

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. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.

For information purposes 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).

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. A calculation of the 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 4 are ready-to-use surface disinfectant solutions and sprays. For the 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 rapidly and no residues on the skin are available for a possible hand to eye contact.

The products of meta SPC 5 are presented in form of ready-to-use wipes which are impregnated with the disinfectant liquid. The application liquid rapidly evaporates 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 patient room 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 67

Details of Scenario 2: Small surface disinfection - in between disinfection **o 2a – in medical practices** **o 2b – in hospitals**	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	8
Area of one palm	205 cm²
Application duration	1 min
Application rate	50 ml / m^2
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	20 m^3 (Scenario 2a – in medical practices) 80 m^3 (Scenario 2b – in hospitals)
Ventilation rate	1.5 / h
Surface area	0.5 m²
Product amount	21.95 g (25 ml)
Frequency of use	4 rooms visited (2 visits per room per day)
Exposure duration	20 min
Mode of release	Evaporation

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 70 and Table 71. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 72. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations

For scenario 2a “Small surface disinfection - in between disinfection in medical practices” a risk was identified resulting from the quantitative risk assessment in Tier 1 and thus a Tier 2 refinement was calculated taking improved ventilation (cross ventilation providing an air exchange rate of 5 /h) into account. Since no risk was identified for scenario 2b “Small surface disinfection - in between disinfection in hospitals” 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 for scenario 2b “Small surface disinfection - in between disinfection in hospitals” taking the use of protective gloves into account.
The used paper towels or ready-to-use wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels and ready-to-use wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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 on the surface in downwards direction, so that exposure to the eyes is not expected. Anyway, contact with eyes should be avoided.

For refilling of the application bottles from larger storage containers, please refer to scenario 4.

Scenario 2, as described applies to meta SPC 4, and also to the respective application of meta SPC 5.

- **Scenario 3 – Small surface disinfection in laboratory**

Description

The exposure assessment of small surface disinfection in technically ventilated rooms (e.g. laboratories) 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 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 products of meta SPC 4 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 the 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, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

This scenario also covers the disinfection of small surface areas with impregnated ready-to-use wipes (meta SPC 5) which are used to wipe over the surface.

The disinfectant is used in health care industry, institutions, health care facilities, hospital rooms, dentists and isolation rooms.

The scenario covers rapid disinfection of small surfaces in technically ventilated rooms such as laboratories. 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 (realistic worst-case assumption).

According to information from the applicant the use rate for a ready-to-use liquid (meta SPC 4) is 50 ml per m² and a ready-to-use wipe (meta SPC 5) is 2 time 8 ml per m². Thus, the application rate for a ready-to-use liquid represents the worst-case situation and the exposure assessment for the products of meta SPCs 4 is also applicable for products in meta SPC 5 as presented in the following.

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. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.
For information purpose 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).

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. A calculation of the 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 4 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 rapidly and no residues on the skin are available for a possible hand to eye contact.

The products of meta SPC 5 are presented in form of ready-to-use wipes which are impregnated with the disinfectant liquid. The application liquid evaporates rapidly 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 68

Details of Scenario 3: **Small surface disinfection in laboratory**	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	10
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	50 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	21.95 g (25 ml)
Exposure duration per application	45 min
Mode of release	Evaporation

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 70 and Table 71. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 72. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR. For risk characterisation, see chapter 3.6.4.5.

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.

The used paper towels or ready-to-use wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels and ready-to-use wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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 on the surface in

downwards direction, so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

For refilling of the application bottles from larger storage containers, please refer to scenario 4.

Scenario 3, applies to meta SPC 4, and also to the respective application of meta SPC 5.

- **Scenario 4 – Refilling**

Description

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. So, refilling requires the use of an adequate funnel. After the refilling process 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. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.

For information purposes the dermal exposure is also calculated based on “Mixing and loading model 4” (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG).

Inhalation exposure

Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the active substance during the 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. A calculation of the 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 the 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 to the eyes

Accidental splashes to the eyes cannot be excluded during manual decanting. Even if the local effects for eye irritation are taken into account via the AEL 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

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. It is possible that inhalation exposure occurs to a professional bystander who is present in the room where the refilling is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 69

Details of Scenario 4	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ConsExpo Web parameters for the loading phase	
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 and dermal exposure (Tier 1 and Tier 2) are summarised in Table 70 and Table 71. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the hand disinfection are given in Table 72.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR.
For risk characterisation, see chapter 3.6.4.5.

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. 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.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. Accidental splashes to the eyes cannot be excluded during manual decanting, thus, eye protection is necessary.

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

Experts in Germany (VAH) recommend using non-refillable bottles for applications in the health care sector as bottles that are refilled but not cleaned properly may lead to the development of microbial resistance and a reduction of efficacy. Refilling of bottles for use in PT01 nevertheless may e.g. occur in the pharmaceutical industry.

The refilling scenario is not applicable for disinfection with ready-to-use wipes (meta SPC 3). Scenario 4 applies also to the respective applications of meta SPCs 1, 2 and 4.

- **Scenario 5 – 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 4 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 the 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, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

This scenario also covers the disinfection of small surface areas with impregnated ready-to-use wipes (meta SPC 5) which are used to wipe over the surface.

The disinfectant is used in food contact areas and of food processing machinery for non-alcoholic beverages, processed food (meat, deli, vegetables, fruits etc.), food preparation and handling and kitchen in nursing homes.

The scenario covers rapid disinfection of small surfaces in kitchens and canteens. 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).

According to information from the applicant the use rate for a ready-to-use liquid (meta SPC 4) is 50 ml per m² and a ready-to-use wipe (meta SPC 5) is 2 time 8 ml per m². Thus, the application rate for a ready-to-use liquid represents the worst-case situation and the exposure assessment for the products of meta SPCs 4 is also applicable for products in meta SPC 5 as presented in the following.

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. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.

For information purposes 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).

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. A calculation of the 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 4 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 rapidly and no residues on the skin are available for a possible hand to eye contact.

The products of meta SPC 5 are presented in form of ready-to-use wipes which are impregnated with the disinfectant liquid. The application liquid rapidly evaporates 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 kitchen or canteen 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.

Details of Scenario 5	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	4
Area of one palm	205 cm²
Application duration	2 min
Application rate	50 ml / m²
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume*	25 m³
Ventilation rate	15 / h
Surface area	1 m²
Product amount per application	43.9 g (50 ml)
Exposure duration	120 min
Mode of release	Evaporation

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 70 and Table 71. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 72. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR. For risk characterisation, see chapter 3.6.4.5.

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.

The used paper towels or ready-to-use wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels and ready-to-use wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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 on the surface in downwards direction, so that exposure to the eye is not expected. Anyway, contact with eyes should be avoided.

For refilling of the application bottles from larger storage containers, please refer to scenario 4.

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.

Scenario 5, applies to meta SPC 4, also to the respective application of meta SPC 5.

- **Scenario 6 – 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 1 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 the 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, the spraying is carried out directly from a very short distance. Therefore, the exposure relevant process is evaporation of the use solution from the treated surface.

This scenario also covers the disinfection of small surface areas with impregnated ready-to-use wipes (meta SPC 5) which are used to wipe over the surface.

The disinfectant is used in food contact areas and of food processing machinery for non-alcoholic beverages, processed food (meat, deli, vegetables, fruits etc.), food preparation and handling and kitchen in nursing homes.

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, the 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.
The scenario represents a slightly modified version of the respective scenario in the assessment report (CAR) for propan-2-ol. In the present scenario the worker is present in the production hall for the complete working day and performs disinfection every 120 min whereas in the CAR he leaves the production hall for a short break after the disinfections. Also, this scenario considers a production hall with a temperature of 20°C (instead of 10°C) as in contrast to the CAR for propan-2-ol disinfections are also intended for the use in e.g. beverage processing plants. The changes to the corresponding scenario of the CAR for propan-2-ol only trigger negligible deviations in exposure.

According to information from the applicant the use rate for a ready-to-use liquid (meta SPC 4) is 50 ml per m² and a ready-to-use wipe (meta SPC 5) is 2 time 8 ml per m². Thus, the application rate for a ready-to-use liquid represents the worst-case situation and the exposure assessment for the products of meta SPCs 4 is also applicable for products in meta SPC 5 as presented in the following.

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 and its parts which may not be easily accessible. Thus, the palms of both hands are exposed to the product. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.
For information purpose 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).

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. A calculation of the 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 pouring or 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 the local effects for eye irritation are taken into account via the AEL 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

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 production hall 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.

Details of Scenario 6	
Parameters	**Value**
Concentration of a.s. propan-2-ol in b.p.	63.1 % (w/w)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	4
Area of two palms	410 cm²
Application duration	5 min
Application rate	50 ml / m^2
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	201.94 g (230 ml)
Exposure duration	120 min
Mode of release	Evaporation

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 70 and Table 71. Results of the calculation for a combined scenario which includes refilling of the application bottles prior to the surface disinfection are given in Table 72. For details of the

calculation of dermal and inhalation exposure, please refer to Annex 4.3 of this PAR. For risk characterisation, see chapter 3.6.4.5.

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.

This scenario also covers the disinfection of food processing machinery at lower temperature which is applicable e.g. in a meat processing factory (10 °C). The decrease in temperature triggers a slight decrease in inhalation exposure, only.

The used paper towels or ready-to-use wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from used towels and ready-to-use wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). 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 4.

Scenario 6, applies to meta SPC 4, and also to the respective application of meta SPC 5.

- **Summary of exposure assessment for meta SPC 4 and 5:**

The following tables give an overview of the assessed exposure values. In Table Table 70 the estimated external inhalation exposure and external dermal exposure are listed. In Table 71 the values of the assumed exposed skin area and application time for dermal exposure are summarised. In chapter 3.6.4.5, Table 84, the internal total exposure (total uptake) is available. In Annexes 4.3.1 the external and internal exposure values are available for the scenarios.

Table 70

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenario	**Use no. (Product type)**	**Tier/PPE**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]***
Scenario 2a: Small surface disinfection - in between disinfection in medical practices	Use 1, 2 in meta SPC 4 and use 1 in meta SPC 5 (PT02)	Tier 1	153.662	948.48*
		Tier 2 (Improved ventilation / air exchange rate of 5/h; Protective gloves)	100.000	94.85*
Scenario 2b: Small surface disinfection - in between disinfection in hospitals	Use 1, 2 in meta SPC 4 and use 1 in meta SPC 5 (PT02)	Tier 1	40.080	948.48*
		Tier 2 (Protective gloves)	40.080	94.85*
Scenario 3 Small surface disinfection in laboratory	Use 1, 2 in meta SPC 4 and use 1in meta SPC 5 (PT02)	Tier 1	85.313	1185.60*
		Tier 2 (Protective gloves)	85.313	118.56*
Scenario 4 Refilling	Use 1, 2, 3, 4 in meta SPC 4 (PT01,PT02, PT04)	Tier 1	0.790	277.01*
		Tier 2 (Protective gloves)	0.790	27.70*
Scenario 5 Small surface disinfection in kitchens and canteens	Use 3, 4 in meta SPC 4 and Use 2 in meta SPC 5 (PT04)	Tier 1	37.000	948.48*
		Tier 2 (Protective gloves)	37.000	94.85*
Scenario 6 Disinfection of food processing machinery	Use 3, 4 in meta SPC 4 and Use 2 in meta SPC 5 (PT04)	Tier 1	11.000	2371.20*
		Tier 2 (Protective gloves)	11.000	237.12*

*) The dermal risk assessment is based on calculation of dermal flux which does not include the external dermal exposure.

Table 71

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 2 – Small surface disinfection - in between disinfection: 2a – in medical practices 2b – in hospitals	PT02	1	8	205	1	8
Scenario 3 Small surface disinfection in laboratory	PT02	1	10	205	1	10
Scenario 4 Refilling	PT02, PT04	0.5	1	205	1	0.5
Scenario 5 Small surface disinfection in kitchens and canteens	PT04	2	4	205	1	8
Scenario 6 Disinfection of food processing machinery	PT04	5	4	410	2	20

* Contact time = evaporation time or application time (depending on scenario)

- **Combined scenarios for meta SPC 4 and 5**

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 72

Summary table: estimated exposure from professional uses for combined scenarios. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenarios – numbers	**Exposure scenarios - names**	**Tier/PPE**	**Active substance propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
4 + 2a	Refilling + Small surface disinfection - in between disinfection in medical practices	Tier 1	154.452	1225.49*
		Tier 2 (Improved ventilation / air exchange rate of 5/h; Protective gloves)	100.790	122.55*
4 + 2b	Refilling + Small surface disinfection - in between disinfection in hospitals	Tier 1	40,870	1225.49*
		Tier 2 (Protective gloves)	40.870	122.55*
4 + 3	Refilling + Small surface disinfection in laboratory	Tier 1	86.103	1462.61*
		Tier 2 (Protective gloves)	86.103	146.26*
4 + 5	Refilling + Small surface disinfection in kitchens and canteens	Tier 1	37.790	1225.49*
		Tier 2 (Protective gloves)	37.790	122.55*
4 + 6	Refilling + Disinfection of food processing machinery	Tier 1	11.790	2648.21*
		Tier 2 (Protective gloves)	11.790	264.82*

*) The dermal risk assessment is based on calculation of dermal flux which does not include the external dermal exposure.

3.6.3.1.2 Non-professional exposure

Non-professional exposure is not assessed since the biocidal products are for professional use only.

3.6.3.1.3 Secondary exposure of the general public

The exposure assessments for the general public according to the CAR are based on the TNsG models/defaults and Consexpo 4. 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 are applicable. Therefore, the exposure assessments for the general public are amended accordingly.

- **Scenario [7]**

Table 73

Description of Scenario [7]		
PT1; Secondary exposure from hand disinfection, Secondary inhalation exposure to bystanders (general public) in patients' rooms or in a medical consulting room may occur if the medical staffs perform hand disinfection. In a reasonable worst case scenario it is assumed that the bystander stays in the room where hand disinfection is performed. The mean event concentration for hand disinfection performed by a professional user is 23.95 mg/m³ for a whole working day (see section 3.6.3.1.1, Professional exposure). This value is used as a worst case for bystanders in patient`s rooms. Defaults according to HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products (2013) are applied. It is assumed that a patient stay for 24 h in such a room. Hence, inhalation rates for long-term exposure are applied. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable. Since the professional user of the biocidal product do not perform all applications in the same room the aerial concentration over the total exposure time of the bystander (24 h) will be considerably lower. For Tier 2 it is assumed that a patient (bystander) is exposed to 5 hand desinfections per 24 h in one room. All other parameters remain identical to the Consexpo calculation for professional users (see section 3.6.3.1.1, Professional exposure and the Consexpo report in section 4.3.2).		
	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.1, professional exposure)	23.95 mg/m³
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Body weight, child, 6 – 11 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg

	Body weight, toddler, 1 – 2 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Exposure duration (expert judgement)	24 h
	Inhalation rate, adult (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	16 m³/d
	Inhalation rate, child, 6 – 11 y (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	12 m³/h
	Inhalation rate, toddler, 1 – 2 y (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	8 m³/h
	Uptake fraction (inhalation absorption)	100 %
Tier 2	Aerial concentration (see section above, section 3.6.3.1.1 Professional exposure and the Consexpo report in section 4.3.1)	1.54 mg/m³

Calculations for Scenario [7]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

Tier 1

7a. Adults

Inhalation exposure = 23.95 mg/m³ x 16 m³/d x 1 d x 100 % / 60 kg

6.39mg/kg bw/d

7b. Children

Inhalation exposure = 23.95 mg/m³ x 12 m³/d x 1 d x 100 % / 23.9 kg

12.03 mg/kg bw/d

7c. Toddlers

Inhalation exposure = 23.95 mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

19.16 mg/kg bw/d

Tier 2

7a. Adults

Inhalation exposure = 1.54 mg/m³ x 16 m³/d x 1 d x 100 % / 60 kg

0.41 mg/kg bw/d

7b. Children

Inhalation exposure = 1.54 mg/m³ x 12 m³/d x 1 d x 100 % / 23.9 kg

0.77 mg/kg bw/d

7c. Toddlers

Inhalation exposure = 1.54 mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

1.23 mg/kg bw/d

- **Scenario [8]**

Table 74

Description of Scenario [8]		
PT2; Secondary exposure from small surface disinfection by professional users (e.g. in hospitals) Secondary inhalation exposure may occur to bystanders (general public) in a room where surface disinfection has been performed (e.g. in hospitals by medical staff). The maximum aerial concentration of propan-2-ol after professional use for such an application is 9.344 mg/m³ (TWA see section 3.6.3.1.1). This value was applied for exposure assessment. Defaults according to HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products (2013) are used. It is assumed that a patient stay for 24 h in such a room. Hence, inhalation rates for long-term exposure are applied. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.		
	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.1)	9.344 mg/m³
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Body weight, child, 6 – 11 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Body weight, toddler, 1 – 2 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Exposure duration (expert judgement)	24 h
	Inhalation rate, adult (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	16 m³/d

	Inhalation rate, child, 6 – 11 y (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	12 m³/h
	Inhalation rate, toddler, 1 – 2 y (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	8 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [8]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

Tier 1

8a. Adults

Inhalation exposure = 9.344 mg/m³ x 16 m³/d x 1 d x 100 % / 60 kg

2.49 mg/kg bw/d

8b. Children

Inhalation exposure = 9.344 mg/m³ x 12 m³/d x 1 d x 100 % / 23.9 kg

4.69 mg/kg bw/d

8cToddlers

Inhalation exposure = 9.344 mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

7.48 mg/kg bw/d

- **Scenario [9]**

Table 75

Description of Scenario [9]		
PT4; Secondary exposure from small surface disinfection in kitchens and canteens Secondary exposure of bystanders (general public) after professional application in kitchens and canteens is probably a rare event. The general public has normally no access to areas where such surfaces are treated. They will only stay in the dining room, which is usually not in the vicinity of the treated surfaces. In addition, disinfection will normally be performed at the end of the working day, when the canteens or restaurants are already closed and bystanders are not present. However, as a worst case it is assumed that bystanders are exposed to the same aerial concentration than the professional user. An exposure duration of 1 h equivalent to a long lunch break is assumed. Short-term inhalation rates are applied. Dermal exposure is not expected since propan-2-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable.		
	Parameters	Value
Tier 1	Aerial concentration (section 3.6.3.1.1)	37.1 mg/m^3
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Body weight, child, 6 – 11 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	23.9 kg
	Body weight, toddler, 1 – 2 y (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	10 kg
	Exposure duration (expert judgement)	1 h
	Inhalation rate, adult (short-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m³/h
	Inhalation rate, child, 6 – 11 y (short-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.32 m³/h
	Inhalation rate, toddler, 1 – 2 y (long-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [9]

Inhalation exposure is calculated according to the following equation:

Inhalation exposure = aerial concentration x inhalation rate x exposure duration x inhalation absorption / body weight

9a. Adults

Inhalation exposure = 37.1 mg/m³ x 1.25 m³/h x 1 h x 100 % /60 kg

0.77 mg/kg bw/d

9b. Children

Inhalation exposure = 37.1 mg/m³ x 1.32 m³/h x 1 h x 100 % /23.9 kg

2.05 mg/kg bw/d

9c. Toddlers

Inhalation exposure = 37.1 mg/m³ x 1.26 m³/h x 1 h x 100 % /10 kg

4.67 mg/kg bw/d

Table 76

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1a]	1	6.39	-	-	6.39
Scenario [1b]	1	12.03	-	-	12.03
Scenario [7c]	1	19.16	-	-	19.16
Scenario [7a]	2	0.41	-	-	0.41
Scenario [7b]	2	0.77	-	-	0.77
Scenario [8c]	2	1.23	-	-	1-23
Scenario [8a]	1	2.49	-	-	2.49
Scenario [8b]	1	4.69	-	-	4.69
Scenario [8c]	1	7.48	-	-	7.48
Scenario [9a]	1	0.77	-	-	0.77
Scenario [9b]	1	2.05	-	-	2.05

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9c]	1	4.67	-	-	4.67

- **Combined scenarios**

Combination of scenarios secondary exposure of the general public is considered not relevant. These scenarios are very specific and it is very unlikely that they will occur on the same day.

3.6.3.2 Dietary exposure

The intended use descriptions of the propan-2-ol-containing biocidal product 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 animals. Even so, use as a professional hand disinfectant or as surface disinfectant 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 product, 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.

3.6.3.3 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.

3.6.3.4 Aggregated exposure

Not applicable.

3.6.3.5 Summary of exposure assessment

Table 77

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1	Professional ;Hand disinfection – hygienic[1)]	Tier 1[2)] (no PPE)	16.28
2a	Professional; Small surface disinfection - in between disinfection in medical practices [1)]	Tier 1[2)] (no PPE)	26.00
		Tier 2[2)]) (Improved ventilation / air exchange rate of 5/h; Protective gloves [3)])	17.05
2b	Professional; Small surface disinfection - in between disinfection in hospitals [1)]	Tier 1[2)] (no PPE)	7.07
3	Professional; Small surface disinfection in laboratory[1)]	Tier 1[2)] (no PPE)	14.70
4	Professional; Refilling[1)]	Tier 1[2)] (no PPE)	0.16
5	Professional; Small surface disinfection in kitchens and canteens[1)]	Tier 1[2)] (no PPE)	6.55
6	Professional; Disinfection of food processing machinery[1)]	Tier 1[2)] (no PPE)	3.77
7a.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (adult)	Tier 1	6.39
7b.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child)	Tier 1	12.03
7c.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler)	Tier 1	19.16
7a.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (adult)	Tier 2	0.41
7b.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child)	Tier 2	0.77

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
7c.	PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler)	Tier 2	1.23
8a.	PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals (adult)	Tier 1	2.49
8b.	PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (child)	Tier 1	4.69
8c.	PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (toddler)	Tier 1	7.48
9a.	PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens, (adult)	Tier 1	0.77
9b.	PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (child)	Tier 1	2.05
9c.	PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (toddler)	Tier 1	4.67

1) For secondary exposure of the scenarios it is assumed that inhalation exposure is in the same order of magnitude, dermal exposure is not expected
2) The tier for which a safe use is observed is listed in the table above
3) For a safe use the improved ventilation / air exchange rate of 5/h is necessary.

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 35 and Table 43 in chapter 3.6.1.

Table 78

Reference values of the active substance Propan-2- ol					
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
$AEL_{short\text{-}term,\ medium\text{-}term,\ long\text{-}term}$	Sethre et al. 2000a	68.5 mg/kg bw/d	6.4	-	10.7 mg/kg bw/d
ARfD	Not necessary, no residues in food expected				
ADI	Not necessary, no residues in food expected				

3.6.4.2 Maximum residue limits or equivalent

MRLs are not required.

3.6.4.3 Specific reference value for groundwater

No specific reference value for groundwater was derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

General considerations

The biocidal product family orochemie hand- and surface disinfectants comprises five meta SPCs. An overview of the applications applied for the five meta SPCs are given in Table 59 and Table 65 in chapter

3.6.3.1.1. All members of the biocidal product family orochemie hand- and surface disinfectants contain propan-2-ol (CAS No.: 67-63-0) as active substance.

Risk characterisation for professional users for meta SPC 1 to 3:

The systemic risk assessment for professional users for biocidal products of meta SPCs 2 and 3 is covered by the risk assessment for biocidal products in meta SPC 1. For details refer to sections 3.6.3.1.1.

Systemic effects – quantitative

The primary toxic effect of the active substance propan-2-ol is acute CNS depression (central nervous system depression) and results in the classification of the biocidal product orochemie hand- and surface disinfectants 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 biocidal products in meta SPC 1.

Details of risk characterisation

Reference value

For the purpose of risk characterisation resulting from exposure of professional users to propan-2-ol from biocidal products covered by meta SPC 1, inhalation and dermal exposure to propan-2-ol is assessed. As reference value the $AEC_{long\text{-}term}$ of 52.6 ppm propan-2-ol is used. This external reference value corresponds to a systemic $AEL_{long\text{-}term}$ of 17.9 mg propan-2-ol/kg bw/d.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance propan-2-ol.

Dermal uptake

Due to rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm^2/h) instead of data on percentage of dermal absorption is used for the calculation of the dermal uptake.

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

The inhalation and dermal uptake referring to the active substance propan-2-ol resulting from use of 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 for professional users referring to the active substance propan-2-ol resulting from the use of 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 79 give a detailed overview of the risk assessment results referring to the active substance propan-2-ol for biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 79. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 79, the scenario hand disinfection - hygienic yields an exposure-to-AEL ratio of less than 100 % already in TIER 1.

Risk assessment results for the scenario that are shown in Table 79 are regarded as worst case assumptions for risk assessment of the respective secondary exposure.

As mentioned in chapter 3.6.3.1.1 dermal exposure of the bystander, i.e. secondary dermal exposure, is not expected for the following scenario: hand disinfection – hygienic.
Inhalation exposure of the bystander, i.e. secondary inhalation exposure, is assumed to be in the same order of magnitude or lower than exposure of the operator for the aforementioned scenario in meta SPC 1.

Table 79: Overview of detailed risk assessment results referring to the active substance propan-2-ol for biocidal products covered by meta SPC 1

Scenario		$AEL_{long\text{-}term}$	Estimated inhalation uptake[1]	Estimated dermal uptake[2]	Estimated total uptake	Exposure-to-AEL ratio	Acceptable
		mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%	(yes/no)
Hand disinfection - hygienic	Tier 1	17.9	4.69	11.59	16.28	90.94	yes
Refilling		**For results of the risk assessment, please refer to** Table 83**.**					

Tier 1: no PPE (Hand disinfection - hygienic)
[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100 % absorption by inhalation
[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60 kg, application time/day and exposed skin area see table Table 60 (chapter 3.6.3.1.1).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the intended use hand disinfection - hygienic is unlikely since the respective risk characterisation yields an exposure-to-AEL ratio of less than 100 % already in Tier 1. The risk characterisation for the scenario hand disinfection - hygienic is regarded as worst case assumption for the respective secondary exposure scenarios. Therefore, a risk for professional users resulting from secondary exposure is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % already in TIER 1.

Regarding occupational safety, there are no objections against the use as well as secondary exposure taking into account the provisions described in chapter 2.3.1.5.2 of this PAR.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product family is not required as the products covered by meta SPC 1 contains only the active substance propan-2-ol and no substances of concern.
Nevertheless, a risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described in chapters 3.6.3.1.1 3.6.4.5.

A risk for professional users referring to the active substance propan-2-ol resulting from the combined uses of 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 80 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 80. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 80, the combined scenario considered (refilling + hand disinfection - hygienic) yields an exposure-to-AEL ratio of less than 100 % already in TIER 1.

Table 80: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenarios for biocidal products covered by meta SPC 1

Combined Scenario		$AEL_{long\text{-}term}$ mg/kg bw/d	Estimated inhalation uptake[1] mg/kg bw/d	Estimated dermal uptake[2] mg/kg bw/d	Estimated total uptake mg/kg bw/d	Exposure-to-AEL-ratio %	Acceptable (yes/no)
Refilling + hand disinfection - hygienic	Tier 1	17.9	4.82	11.61	16.43	91.81	yes

Tier 1: no PPE (refilling + hand disinfection - hygienic)

[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100 % absorption by inhalation

[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60 kg, application time/day and exposed skin area see table Table 60 (chapter 3.6.3.1.1).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the combined scenario refilling + hand disinfection – hygienic is unlikely since the respective risk characterisation yields exposure-to-AEL ratios of less than 100 % already in TIER 1. Regarding occupational safety, there are no objections against the combined scenario taking into account the provisions described in chapter 2.3.1.5.2 of this PAR.

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 (2017) is “low” (Table 81).

Table 81: Relevant classification and resulting hazard categories

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015)
RTU (63.1 % (w/w) a.s.)	Eye Irrit. 2, (H319) EUH066	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 (2017) Table 82 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of the biocidal products covered by meta SPC 1 for the intended use hand disinfection - hygienic. With the proposed protection measures the reduction of dermal and eye contact minimizes the anticipated health risk to an acceptable level for the intended use.

Table 82: Summary of qualitative conclusions for local risk assessment for biocidal products covered by meta SPC 1

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
Hand disinfection - hygienic	RTU (63,1 % (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.	**Yes**

Conclusion

Concerning the local eye and skin effects of biocidal products covered by meta SPC 1, the intended use hand disinfection - hygienic does not lead to concern for professional users. This is also applicable for products of meta-SPC 2 and 3.

Overall conclusion

In summary, a risk for professional users resulting from the intended use and from secondary exposure of the biocidal products covered by meta SPC 1 is unlikely. Risk reduction measures described in chapter 2.3.1.5.2 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. This also applies for products in meta SPC 2 and 3.

Risk characterisation for professional users for meta SPC 4 to 5:

The systemic risk assessment for professional users for biocidal products of meta SPC 5 is covered by the risk assessment for biocidal products of meta SPC 4. For details refer to sections 3.6.3.1.1 .

For details of risk assessment for local and systemic effects for professional users please refer to chapters 3.6.3.1.1 and 3.6.4.5.

A risk for professional users referring to the active substance propan-2-ol resulting from the use of biocidal products covered by meta SPC 4 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 83 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for biocidal products covered by meta SPC 4. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 83. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 83, the scenarios small surface disinfection - in between disinfection in hospitals, small surface disinfection in laboratory, refilling, small surface disinfection in kitchen and canteens and disinfection of food processing machinery yield an exposure-to-AEL ratio of less than 100 % already in TIER 1.

By contrast, the exposure-to-AEL ratio of the scenario small surface disinfection – in between disinfection in medical practices exceeds the value of 100 % after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However when risk reduction measures are implemented the risk characterisation results yield an exposure-to-AEL ratio of less than 100 % in TIER 2.

Risk assessment results for the scenarios that are shown in Table 83 are regarded as worst case assumptions for risk assessment of the respective secondary exposure.

As mentioned in chapter 3.6.3.1.1 dermal exposure of the bystander, i.e. secondary dermal exposure, is not expected for the following scenarios: small surface disinfection - in between disinfection in medical practices, small surface disinfection – in between disinfection in hospitals, small surface disinfection in laboratory, refilling and small surface disinfection in kitchen and canteens.
Inhalation exposure of the bystander, i.e. secondary inhalation exposure, is assumed to be in the same order of magnitude or lower than exposure of the operator for the aforementioned scenarios in meta SPC 4.

Table 83: Overview of detailed risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 4

Scenario		$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake[1] mg/kg bw/d	Estimated dermal uptake[2] mg/kg bw/d	Estimated total uptake mg/kg bw/d	Exposure-to-AEL ratio %	Acceptable (yes/no)
Small surface disinfection - in between disinfection in medical practices	Tier 1	17.9	25.61	0.39	26.00	145.24	no
	Tier 2	17.9	16.67	0.39	17.05	95.27	yes
Small surface disinfection – in between disinfection in hospitals	Tier 1	17.9	6.68	0.39	7.07	39.48	yes
Small surface disinfection in laboratory	Tier 1	17.9	14.22	0.48	14.70	82.14	yes
Refilling	Tier 1	17.9	0.13	0.02	0.16	0.87	yes
Small surface disinfection in kitchen and canteens	Tier 1	17.9	6.17	0.39	6.55	36.61	yes
Disinfection of food processing machinery	Tier 1	17.9	1.83	1.94	3.77	21.06	yes

Tier 1: no PPE (small surface disinfection – in between disinfection in hospitals; small surface disinfection in laboratory, refilling, small surface disinfection in kitchens and canteens, disinfection of food processing machinery,)

Tier 2: improved ventilation (cross ventilation providing an air exchange rat of 5/h) (small surface disinfection – in between disinfection in medical practices)

[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100 % absorption by inhalation

[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60 kg, application time/day and exposed skin area see Table 71 (chapter 3.6.3.1.1).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the intended uses surface small surface disinfection - in between disinfection in medical practices, small surface disinfection – in between disinfection in hospitals, small surface disinfection in laboratory, refilling, small surface disinfection in kitchen and canteens and disinfection of food processing machinery is unlikely since the respective risk characterisation yields exposure-to-AEL ratios of less than 100 % at least in TIER 1. The risk characterisation for the scenarios small surface disinfection - in between disinfection in medical practices, small surface disinfection – in between disinfection in hospitals, small surface disinfection in laboratory, refilling and small surface disinfection in kitchens and canteens is regarded as worst case assumption for the respective secondary exposure scenarios. Therefore, a risk for professional users resulting from secondary exposure is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less thann 100 % at least in TIER 2 consideration.
Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.3.1.5.2 of this PAR.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product family is not required as the products covered by meta SPC 4 contains only the active substance propan-2-ol and no substances of concern.
Nevertheless, a risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described in chapters 3.6.3.1.1 .

A risk for professional users referring to the active substance propan-2-ol resulting from the combined uses of the biocidal products covered by meta SPC 4 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100 %. Table 84 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 4. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 84. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 84, the combined scenario considered (refilling + small surface disinfection - in between disinfection in medical practices, refilling + small surface disinfection in hospitals, refilling + small surface disinfection in laboratory and biotechnology, refilling + small surface disinfection in kitchens and canteens and refilling + disinfection of food processing machinery) yield an exposure-to-AEL ratio of less than 100 % at least in TIER 2.

Table 84: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol regarding combined scenarios for the biocidal products covered by meta SPC 4

Combined Scenario		**$AEL_{long-term}$** mg/kg bw/d	**Estimated inhalation uptake[1]** mg/kg bw/d	**Estimated dermal uptake[2]** mg/kg bw/d	**Estimated total uptake** mg/kg bw/d	**Exposure-to-AEL-ratio** %	**Acceptable** (yes/no)
Refilling + Small surface disinfection - in between disinfection in medical practices	Tier 1	17.9	1.61	0.51	2.11	11.81	yes
	Tier 2	17.9	16.80	0.41	17.21	96.14	yes
Refilling + Small surface disinfection – in between disinfection in hospitals	Tier 1	17.9	6.81	0.41	7.22	40.35	yes
Refilling + Small surface disinfection in laboratory	Tier 1	17.9	14.354	0.51	14.86	83.01	yes
Refilling + Small surface disinfection in kitchens and canteens	Tier 1	17.9	6.30	0.41	6.71	37.49	yes
Refilling + Disinfection of food processing machinery	Tier 1	17.9	1.97	1.96	3.93	21.93	yes

Tier 1: no PPE (refilling + small surface disinfection - in between disinfection in hospitals, refilling + small surface disinfection in laboratory, refilling + small surface disinfection in kitchens and canteens, refilling + disinfection of food processing machinery)

Tier 2: improved ventilation (cross ventilation providing an air exchange rat of 5/h) (refilling + small surface disinfection – in between disinfection in medical practices)

[1]Shift average concentration mg/m^3 multiplied with the breathing volume of 10 m^3 per shift, divided by 60 kg body weight and the assumption of 100 % absorption by inhalation

[2]Based on a dermal flux rate of 0.85 mg/cm^2/h and body weight of 60 kg, application time/day and exposed skin area see table Table 71 (chapter 3.6.3.1.1).

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the combined scenario refilling + small surface disinfection - in between disinfection in medical practices, refilling + small surface disinfection in hospitals refilling + small surface disinfection in laboratory, refilling + small surface disinfection in kitchens and canteens, refilling + disinfection of food processing machinery is unlikely since the respective risk characterisation yields exposure-to-AEL ratios of less than 100 % at least in TIER 2. Regarding occupational safety, there are no objections against the combined scenarios taking into account the provisions described in chapter 2.3.1.5.2of this PAR.

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 biocidal products covered by meta SPC 4 with H319 (Causes serious eye irritation). In addition, biocidal products covered by meta SPC 4 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 (2017) is “low” (Table 85).

Table 85: Relevant classification and resulting hazard categories

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015)
RTU (63.1 % (w/w) a.s.)	Eye Irrit. 2, (H319) EUH066	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 (2017) Table 86 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of the biocidal products covered by meta SPC 4 for the intended uses small surface disinfection - in between disinfection in medical practices, small surface disinfection in hospitals, small surface disinfection in laboratory, refilling, small surface disinfection in kitchen and canteens and disinfection of food processing machinery. With the proposed protection measures the reduction of dermal and eye contact minimizes the anticipated health risk to an acceptable level for the intended uses.

Table 86: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 4

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
Small surface disinfection - in between disinfection in medical practices/hospitals	RTU (63,1 % (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.	**Yes**
Small surface disinfection in laboratory	RTU (63,1 % (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.	**Yes**
Refilling	RTU (63,1 % (w/w) a.s.)	Eye Irrit. 2, H319 EUH066	Low	1 task per day, dermal exposure, contact time: 0.5 min	incidental eye contact expected, dermal exposure expected	Eye protection. Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**
Small surface disinfection in kitchens and canteens	RTU (63,1 % (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.	**Yes**
Disinfection of food processing machinery	RTU (63,1 % (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 expected, dermal exposure expected	Eye protection. Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**

Conclusion

Concerning the local eye and skin effects of biocidal products covered by meta SPC 4, the intended uses small surface disinfection - in between disinfection in medical practices, small surface disinfection – in between disinfection in hospitals, small surface disinfection in laboratory, refilling, small surface disinfection in kitchen and canteens and disinfection of food processing machinery do not lead to concern for professional users. The same applies also for meta SPC 5.

Overall conclusion

In summary, a risk for professional users resulting from the intended uses and from secondary exposure of biocidal products covered by meta SPC 4 is unlikely. Risk reduction measures described in chapter 2.3.1.5.2 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 4.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation. The same applies also for meta SPC 5.

3.6.4.6 Risk for non-professional users

Not relevant. The biocidal products are for professional use only.

3.6.4.7 Risk for the general public

Table 87: Systemic effects

Task/ Scenario	Tier	Systemic NO-AEL (mg/kg bw/d)	AEL (mg/kgbw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [7a], PT1; Secondary bystander expoure from professional hand disinfection, e.g. in hospitals (adult)	1	68.5	10.7	6.39	60	yes
Scenario [7b], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child)	1	68.5	10.7	12.03	112	no
Scenario [7c], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler)	1	68.5	10.7	19.16	179	no
Scenario [7a], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (adult)	2	68.5	10.7	0.41	3.8	yes
Scenario [7b], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child)	2	68.5	10.7	0.77	7.2	yes

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kgbw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [7c], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler)	2	68.5	10.7	1.23	11	yes
Scenario [8a], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals (adult)	1	68.5	10.7	2.49	23	yes
Scenario [8b], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (child)	1	68.5	10.7	4.69	44	yes
Scenario [8c], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (toddler)	1	68.5	10.7	7.48	70	yes
Scenario [9a], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens, (adult)	1	68.5	10.7	0.77	7.2	yes
Scenario [9b], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (child)	1	68.5	10.7	2.05	19	yes

Task/ Scenario	Tier	Systemic NO-AEL (mg/kg bw/d)	AEL (mg/kgbw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [9c], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (toddler)	1	68.5	10.7	4.67	44	yes

- **Local effects**

Specific local effects for bystanders (general public) are not expected.
The biocidal products can produce local effects on skin and eyes. However, dermal or eye contact with the biocidal product is not expected for the general public (bystander).

Conclusion

No human health risk was identified for secondary exposure of the general public resulting from professional and non-professional use of the biocidal product.
Specific risk mitigation measures are not required.

3.6.4.8 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.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product family is not required as the products contain only the active substance 2-propanol and no substances of concern.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

Not applicable

3.6.4.10.2 Summary of risk characterisation for professional user

Please refer to Table 79 and Table 80 for meta SPC 1-3.
Please refer to Table 83 and Table 84 for meta SPC 4-5.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant.

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 88

Scenario, Tier	**Relevant reference value (mg kg bw/d)**	**Estimated uptake (mg/kg bw/d)**	**Estimated uptake/ reference value (%)**	**Acceptable** (yes/no)
Scenario [7a], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (adult), Tier 1	10.7	6.39	60	yes
Scenario [7b], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child), Tier 1	10.7	12.03	112	no
Scenario [7c], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler), Tier 2	10.7	19.16	179	no
Scenario [7a], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (adult), Tier 2	10.7	0.41	3.8	yes

Scenario, Tier	Relevant reference value (mg kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario [7b], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (child), Tier 2	10.7	0.77	7.2	yes
Scenario [7c], PT1; Secondary bystander exposure from professional hand disinfection, e.g. in hospitals (toddler), Tier 2	10.7	1.23	11	yes
Scenario [8a], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals (adult), Tier 1	10.7	2.49	23	yes
Scenario [8b], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (child) , Tier 1	10.7	4.69	44	yes
Scenario [8c], PT2: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in patient rooms of hospitals, (toddler), Tier 1	10.7	7.48	70	yes
Scenario [9a], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/ kitchens, (adult) , Tier 1	10.7	0.77	7.2	yes
Scenario [9b], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens /kitchens (child) , Tier 1	10.7	2.05	19	yes

Scenario, Tier	Relevant reference value (mg kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ reference value (%)	Acceptable (yes/no)
Scenario [9c], PT4: Secondary bystander exposure from professional disinfection of small surfaces, e.g. in canteens/kitchens (toddler), Tier 1	10.7	4.67	44	yes

3.7 Risk assessment for animal health

There is no toxicological information available implying that pets or domestic animals a 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 risk is identified and no specific risk mitigation measures are required.

3.8 Risk assessment for the environment

3.8.1 General information

The BPF “orochemie hand- and surface disinfectants” is intended to be used in product type 1, 2, and 4 for hand disinfection (professional), disinfection of surfaces in health-care industry and institutions, as well as in food preparation and handling (kitchen, restaurants, grocery shops, butcher, etc.) and in food production facilities (dairy, non-alcoholic beverages, processed food (meat, deli, vegetables, fruits, etc.). For a detailed description of the single uses, see Chapter 3.8.4.
In the course of the product authorisation process, the applicant submitted an alternative dossier for the evaluation of the active substance propan-2-ol. According to CG-17 document No. AP 13.1-CG-17-2016-13 “Evaluation of alternative dossiers during product authorisation”, “the latest LoEP agreed by the BPC in the context of the (initial or reviewed) approval of the active substance should be taken into account for the product authorisation, regardless of the availability of new relevant data”, unless the data provided by the applicant would “significantly modify the conclusions of the hazard or risk assessment of the active substance”. Since this does not apply to the data provided in the alternative dossier, the evaluation of the BPF “orochemie hand- and surface disinfectants” is based on data that were agreed during the approval of the active substance propan-2-ol.

3.8.2 Effects assessment

The effects assessment for the BPF “orochemie hand- and surface disinfectants” is performed using the ecotoxicity endpoints (PNEC values) for the active substance Propan-2-ol. For the active substance propan-2-ol, as well as its metabolites, the effect assessment is based on the following Assessment reports (AR):

- AR 2014 in PT1 (Human hygiene biocidal products); Rapporteur: Germany
- AR 2014 in PT2 (Private area and public health area disinfectants and other biocidal products); Rapporteur: Germany
- AR 2014 in PT4 (Food and feed area disinfectants); Rapporteur: Germany.

The Assessment Reports of the active substance propan-2-ol provide detailed information on ecotoxicity data, the PNEC derivation and PNEC values and the environmental risk assessment. A summary is included in the chapters below.

3.8.2.1 Mixture toxicity

The BPF “orochemie hand-and surface disinfectants biocidal product family” does not contain substances of concern for the environment and a mixture toxicity assessment is not considered necessary

The BPF “orochemie hand-and surface disinfectants biocidal product family” contains 5 Meta SPC with different compositions.

1) **Meta SPC 2 to 5:** The environmental risk assessment for the product in Meta SPC 2 to 5 can be based on the active substance propan-2-ol. The products in Meta SPC 2 to 5 do not contain substances of concern for the environment.
2) **Meta SPC 1**: Products in Meta SPC1 contain thickeners composed of several co-formulants, which were evaluated regards their potential to be a substance of concern.
   Please refer to Confidential Annex in chapter 5 for more detailed information.

3.8.2.2 Aquatic compartment (including sediment and STP)

Detailed data on the environmental effect assessment and PNEC derivation of the active substance propan-2-ol can be found in the AR for PT1, PT2 and PT4 (2014).

- **Aquatic toxicity**

The lowest chronic effect value (NOEC = 141 mg a.s./L) was derived from a study with *Daphnia magna*. Based on the 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.
For risk assessment a **$PNEC_{surfacewater}$ = 2.82 mg/L** was concluded.

Studies on sediment dwelling organisms are not available and are not necessarily required for the intended uses. Hence, the equilibrium partitioning method (EPM) was applied to estimate a PNECsediment of 2.41 mg a.s./kg ww (Eq. 70; Guidance on the BPR: Volume IV Part B Risk Assessment, 2015).
For risk assessment a **$PNEC_{sediment}$ = 2.41 mg/kg wwt** was concluded.

- **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 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.

3.8.2.3 Terrestrial compartment (including groundwater)

Since direct exposure of the active substance to the soil compartment related to the intended use indoor must not be expected, the provision of experimentally derived data on the toxicity of the propan-2-ol to terrestrial organisms is not required. The toxicity of the active substance propan-2-ol and the co-formulants is known and no synergistic effects are expected. Hence, the risk assessment for the BPF "orochemie hand-and surface disinfectants biocidal product family" can be based on data of the active substance. The PNEC values for propan-2-ol were used according to the Assessment Reports for PT1, 2 and 4 and are summarized below:
For the effect assessment a $PNEC_{soil}$ was determined by using the equilibrium partitioning method and the $PNEC_{water}$ as described in equation 72 of the Guidance on the BPR: Volume IV Part B Risk Assessment (EU, 2015).
For risk assessment a **$PNEC_{soil}$ = 0.496 mg/kg wwt** was concluded.

3.8.2.4 Atmosphere

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

3.8.2.5 Non-compartment specific effects

Due to a $logK_{OW}$ of 0.5, propan-2-ol is not expected to accumulate in the environment. Hence, the risk of non-compartment specific effects can be assumed to be negligible related to the use of the products of the BPF.

3.8.2.6 Summary of effects assessment

Table 89 Summary table on calculated PNEC values

Summary table on calculated PNEC values	
Compartment	**PNEC**
Surface water	2.82 mg a.s./L
Sediment	2.41 mg a.s./kg ww
STP	10 mg a.s./L
Soil	0.496 mg a.s./kg ww

3.8.3 Fate and behaviour

Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and, therefore, is resistant to hydrolysis. Furthermore, no absorption between 290 nm and 750 nm 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 0.82 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 a half-life of 3.1 days can be estimated. Based on a log P_{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.

3.8.3.1 Bioconcentration

The physicochemical properties of propan-2-ol do no indicate an intrinsic potential for bioconcentration (AR 2014 for PT1, 2 and PT4):

- The reported Log K_{ow} values for propan-2-ol is 0.05 indicating it is not a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms).
- The calculated BCF_{fish} = 0.22 L/kg ww and the calculated $BCF_{earthworm}$ = 0.85 L/kg ww
- The surface tension is 70.7 mN/m and thus, lies above the trigger value of ≤ 50 mN/m for surface-active substances.

Table 90

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF_{fish} = 0.22 L/kg ww $BCF_{earthworm}$ = 0.85 L/kg wwt
Justification for the value/conclusion	The physicochemical properties of Propan-2-ol does not indicate an intrinsic potential for bioconcentration (AR 2014 for PT1, 2 and PT4) :

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product family (BPF) “orochemie hand- and surface disinfectants” is used in product type 1, 2 and 4 for disinfection by professional users. The ready-to-use products of the BPF contain 70% v/v (63.1 % w/w equivalent) of the active substance propan-2-ol and are available as gels, solutions, sprays and wipes. The following exposure scenarios are assessed:

Table 91 Intended use of PT 1

Assessed PT	PT 1
Assessed Intended uses	Meta SPC 1, Use 1: hand disinfection (professional) Meta SPC 2, Use 1: hand disinfection (professional) Meta SPC 2, Use 2: hand disinfection (professional) Meta SPC 3, Use 1: hand disinfection (professional)
ESD(s) used	Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1; Royal Haskoning, January 2004)
Approach	Meta SPC 1, Use 1: Average consumption/ tonnage approach Meta SPC 2, Use 1: Average consumption/ tonnage approach Meta SPC 2, Use 2: Average consumption/ tonnage approach Meta SPC 3, Use 1: Average consumption/ tonnage approach
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	NO
Confidential Annexes	YES: In the confidential Annex (chapter 5) the tonnage based approach is provided
Life cycle steps assessed	All meta SPC’s: Production: No Formulation No Use: Yes Service life: No
Remarks	-/-

Table 92 Intended use of PT 2

Assessed PT	PT 2
Assessed Intended uses	Meta SPC 4, Use 1+2, Scenario 1: surface disinfection with ready-to-use solution in industrial areas – professional Meta SPC 4, Use 1+2, Scenario 2: surface disinfection with ready-to-use solution in institutional areas – professional Meta SPC 5, Use 1, Scenario 5: surface disinfection with ready-to-use wipes in industrial areas – professional Meta SPC 5, Use 1, Scenario 6: surface disinfection with ready-to-use wipes in institutional areas – professional

ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), van der Poel, 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC, 2011
Approach	Scenario 1: average consumption Scenario 2: average consumption/tonnage Scenario 5: average consumption Scenario 6: average consumption/tonnage
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	NO
Confidential Annexes	YES: In the confidential Annex 5 the tonnage based local emissions for use 6 and 8 are provided.
Life cycle steps assessed	All meta SPC's: Production: No Formulation No Use: Yes Service life: No
Remarks	-/-

Table 93 Intended use of PT 4

Assessed PT	PT 4
Assessed Intended uses	Meta SPC 4, Use 3+4, Scenario 3: surface disinfection with ready-to-use solution in large-scale kitchen and canteens – professional Meta SPC 4, Use 3+4, Scenario 4: surface disinfection with ready-to-use solution in slaughterhouses and butcheries – professional Meta SPC 5, Use 2, Scenario 7: surface disinfection with ready-to-use wipes in large-scale kitchen and canteens – professional Meta SPC 5, Use 2, Scenario 8: surface disinfection with ready-to-use wipes in slaughterhouses and butcheries – professional
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (JRC, 2011)
Approach	Scenario 3: average consumption Scenario 4: average consumption Scenario 7: average consumption Scenario 8: average consumption
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	NO
Confidential Annexes	NO
Life cycle steps assessed	All meta SPC's: Production: No

	Formulation No Use: Yes Service life: No
Remarks	-/-

3.8.4.2 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 “orochemie hand- and surface disinfectants” containing 63.1% 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 “orochemie hand- and surface disinfectants”, 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.

The products in the BPF “orochemie hand- and surface disinfectants” may be applied by spraying or pouring techniques and wiping or by wipes pre-soaked with the disinfectant. The liquid products are usually applied in an application rate of max. 50 mL/m^2. Using pre-soaked wipes the application rate is lower. According to the applicant, pre-soaked wipes release 7.01 g of product per wipe and a single wipe is used to disinfect 0.5 m^2. The application rate was calculated as max. 16 mL/m^2. The application of the BPF “orochemie hand- and surface disinfectants” as spray or pour application describes an application rate of 50 ml/m^2. This amount also covers the application rate of BPF “orochemie hand- and surface disinfectants” pre-soaked wipes. The application as spray or pour application is therefore the worst-case application.

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.

- Tropospherical 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 94: 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	0.80	Pa/m^3/mol	
Biodegradability			a.s. is readily biodegradable
Rate constant for STP	1	h^{-1}	
DT_{50} for degradation in soil	30	d	

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 %. As the distribution in sewage sludge for propan-2-ol is < 0.1 % further environmental exposure assess-ment via sludge application on agricultural land was considered not relevant for several biocidal prod-ucts containing propan-2-ol as a.s.

3.8.4.3 Local emission estimation for relevant environmental compartments

3.8.4.3.1 Meta SPC 1 (PT1)

Use 1: PT1 - professional hand disinfection via hand gel

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) based tonnage approach

a) <u>Consumption based approach</u>

Table 95: 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)

b) <u>Tonnage based approach:</u>

The resulting local emission of propan-2-ol to the wastewater and air from the application of PT1 products of the BPF “orochemie hand- and surface disinfectants” based on tonnage is given in the Confidential Annex (Chapter 5).

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

3.8.4.3.2 Meta SPC 2 (PT1)

Use 1: PT1 - professional hand disinfection via hand solution

The emission estimation for use 1 is equivalent to the calculations for use 1 in meta SPC 1 (see above), since the scenarios on emission estimation in PT1 are based on default values, irrespective of the mode of application. Following emissions to wastewater and air were derived:

Table 96: Emission rates to the environment for PT1, use 1

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

Use 2: PT1 - professional hand disinfection via hand spray

The emission estimation for use 1 is equivalent to the calculations for use 1 in meta SPC 1 (see above), since the scenarios on emission estimation in PT1 are based on default values, irrespective of the mode of application. The following emissions to wastewater and air were derived:

Table 97: Emission rates to the environment for PT1, use 2

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

3.8.4.3.3 Meta SPC 3 (PT1)

Use 1: PT1 - professional hand disinfection via hand wipes

The emission estimation for use 1 is equivalent to the calculations for use 1 in meta SPC 1 (see above), since the scenarios on emission estimation in PT1 are based on default values, irrespective of the mode of application. The following emissions to wastewater and air were derived:

Table 98: Emission rates to the environment for PT1, use 1

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

3.8.4.3.4 Meta SPC 4 (PT2, PT4)

Meta SPC 4 contains the uses 1 and 2 both with the following scenarios:

- Scenario 1: PT2 – surface disinfection with ready-to-use solution in industrial areas – professional
- Scenario 2: PT2 – surface disinfection with ready-to-use solution in institutional areas – professional

Meta SPC 4 contains the uses 3 and 4 both with the following scenarios:

- Scenario 3: PT 4 – surface disinfection with ready-to-use solution in large-scale kitchen and canteens – professional

- Scenario 4: PT 4 – surface disinfection with ready-to-use solution in slaughterhouses and butcheries – professional

Scenario 1: PT2 – surface disinfection with ready-to-use solution in industrial areas – professional

The emission scenario for disinfectants used in industrial areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2010). The scenario provided in the ESD PT2 (JRC, 2010) 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 max. 50 mL/m^2 represents a worst-case application of the RTU solutions. It was decided at the WG ENV I 2017 that the default surface area treated in industrial areas for RTU products in PT2 is 25m^2. According to applicant, max. every 45 minutes an applications is foreseen. Since the treated surface area (25 m^2) represents 5 applications (WG I 2017 survey), the number of applications per day was set to 2. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF "orochemie hand- and surface disinfectants" is given in Table 99.

Table 99: Emission scenario for surface disinfection with RTU solution in industrial areas (professional users)

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2010)	**Value**
Application rate of b.p. (S)	50 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Surface area treated (WG ENV I 2017)	25 m^2
Number of applications per day (S)	2
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 release to waste water	0.14 kg/d
Local release to air	1.24 kg/d

(S) – Provided by applicant, (D) – Default (ESD PT2, JRC, 2010), (CAR) – CAR Propan-2-ol (2014)

Scenario 2: PT2 – surface disinfection with ready-to-use solution in institutional areas – professional

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

approached 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, 2010). It can be assumed that in institutional and private health care areas disinfection takes place only during the working week. The 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 a product in the BPF “orochemie hand- and surface disinfectants” based on tonnage is given in Annex 5.

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, 2010). It can be assumed that in institutional and private health care areas disinfection takes place only during the working week (260 days per year). The default consumption per capita of the b.p for general purpose and lavatory is 7 mL/d. The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF “orochemie hand- and surface disinfectants” is given in Table 100.

Table 100: 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, 2010)	**Value**
Number of inhabitants feeding one STP (D)	10000
Active substance in product (S)	0.553 kg/L
Consumption per capita (D)	0.007 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	1.16 kg/d
Local release to air	10.45 kg/d

(S) – Provided by applicant, (D) – Default (ESD PT2, JRC, 2010), (CAR) – CAR Propan-2-ol (2014)

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 “orochemie hand- and surface disinfectants”, the environmental exposure and risk assessment is based on consumption.

Scenario 3: PT 4 – surface disinfection with ready-to-use solution in large-scale kitchen and canteens – professional

The emission scenario for surface disinfection in large-scale kitchens and canteens is described in Chapter 2.2 of the ESD for PT 4 (JRC, 2011). It was decided at the WG ENV I 2017 that the default surface area treated in large-scale kitchens and canteens by RTU products is 50 m^2. According to applicant, max. 4 applications per day are foreseen. Since the treated surface area (50 m^2) represents 2-3 applications (WG I 2017 survey), the number of applications per day was set to 2. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF “orochemie hand- and surface disinfectants” is given in Table 101.

Table 101: Emission scenario for surface disinfection with RTU solutions in large scale catering kitchens and canteens (IHO, 2006)

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 b.p. (S)	50 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	27.64 g/m^2
Surface area to be disinfected (WG ENV I 2017) Large scale catering kitchens	50 m^2
Number of applications per day(S)	2
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	0.28 kg/d
Local release to air	2.49 kg/d

(S) – Provided by applicant, (D) – Default (JRC, 2011), (CAR) – CAR Propan-2-ol (2014)

Scenario 4: PT 4 – surface disinfection with ready-to-use solution in slaughterhouses and butcheries – professional

The emission scenario for surface disinfection in slaughterhouses and butcheries is described in Chapter 2.2 of the ESD for PT 4 (JRC, 2011). It was decided at the WG ENV I 2017 that the default surface area treated in slaughterhouses and butcheries by RTU products is 10m^2. According to applicant, max. 4 applications per day are foreseen. The results from the WG I 2017 survey showed that in slaughterhouses RTU products are not routinely used. We therefore keep the default 1 application per day. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF "orochemie hand- and surface disinfectants" is given in Table 102.

Table 102: Emission scenario for surface disinfection with RTU solutions in slaughterhouses and butcheries (IHO, 2006)

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 b.p. (S)	50 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	27.64 g/m^2
Surface area to be disinfected (WG ENV I 2017) Slaughterhouses and butcheries	10 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	0.03 kg/d
Local release to air	0.25 kg/d

(S) – Provided by applicant; (D) – Default (JRC, 2011); (CAR) – CAR Propan-2-ol (2014)

3.8.4.3.5 Meta SPC 5 (PT2, PT4)

Meta SPC 5 contains use 1 with the following scenarios:

- Scenario 5: PT2 – surface disinfection with ready-to-use wipes in industrial areas – professional
- Scenario 6: PT2 – surface disinfection with ready-to-use wipes in institutional areas – professional

Meta SPC 5 contains use 2 with the following scenarios:

- Scenario 7: PT 4 – surface disinfection with ready-to-use wipes in kitchen and canteens – professional
- Scenario 8: PT 4 – surface disinfection with ready-to-use wipes in slaughterhouses and butcheries – professional

•Scenario 5: PT2 – surface disinfection with ready-to-use wipes in industrial areas – professional

The emission scenario for disinfectants used in industrial areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2010). The scenario provided in the ESD PT2 (JRC, 2010) 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. According to the applicant, pre-soaked wipes release 7.01 g of product per wipe and a single wipe is used to disinfect 0.5 m^2. The application rate of pre-soaked wipes was calculated as max. 16 mL/m^2. The application of the BPF "orochemie hand- and surface disinfectants" as spray or pour application describes an application rate of max. 50 ml/m^2 (see scenario 1). This amount also covers the application rate of BPF "orochemie hand- and surface disinfectants" with pre-soaked wipes. The application as spray or pour application (scenario 1) is therefore the worst-case application.

The application as spray or pour application is therefore the worst-case application. It was decided at the WG ENV I 2017 that the default surface area treated in industrial areas for RTU products in PT2 is 25 m^2. According to applicant, max. every 45 minutes an applications is foreseen. Since the treated surface area (25 m^2) represents 5 applications (WG I 2017 survey), the number of applications per day was set to 2. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF "orochemie hand- and surface disinfectants" is given in Table 103.

Table 103: Emission scenario for surface disinfection with pre-soaked wipes in industrial areas (professional users)

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2010)	**Value**
Application rate of b.p. (S)	16 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Surface area treated (WG ENV I 2017)	25 m^2
Number of applications per day (S)	2
Fraction of a.s. disintegration (D)	0
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9

Determinants of the local emission according to Chapter 2.1, Table 2; Environmental Emission Scenarios for PT 2 (JRC, 2010)	Value
Calculation Results	**Value**
Local release to waste water	0.04 kg/d
Local release to air	0.40 kg/d

(S) – Provided by applicant, (D) – Default (ESD PT2, JRC, 2010), (CAR) – CAR Propan-2-ol (2014)

Scenario 6: PT2 – surface disinfection with ready-to-use wipes in institutional areas – professional

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 approached 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, 2010). It can be assumed that in institutional and private health care areas disinfection takes place only during the working week. The 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 a product in the BPF “orochemie hand- and surface disinfectants” based on tonnage is given in Annex 5.

Consumption based approach

The emission estimation based on consumption for scenario 6 is equivalent to the calculations for use scenario 2, since the emission scenarios for surface disinfection in institutional areas in PT2 are based on default values, irrespective of the mode of application. The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF “orochemie hand- and surface disinfectants” is given in Table 104.

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 “orochemie hand- and surface disinfectants”, the environmental exposure and risk assessment is based on consumption.

Table 104: Emission scenario for surface disinfection in institutional areas (professional users) based on consumption

Calculation Results	Value
Local release to waste water	1.16 kg/d
Local release to air	10.45 kg/d

Scenario 7: PT 4 – surface disinfection with ready-to-use wipes in kitchen and canteens – professional

The emission scenario for surface disinfection in large-scale kitchens and canteens is described in Chapter 2.2 of the ESD for PT 4 (JRC, 2011). According to the applicant, pre-soaked wipes release 7.01 g of product per wipe and a single wipe is used to disinfect 0.5 m^2. The application rate of pre-soaked wipes was calculated as max. 16 mL/m^2. The application of the BPF "orochemie hand- and surface disinfectants" as spray or pour application describes an application rate of max. 50 ml/m^2 (see scenario 3). This amount also covers the application rate of BPF "orochemie hand- and surface disinfectants" pre-soaked wipes. The application as spray or pour application (scenario 3) is therefore the worst-case application.

It was decided at the WG ENV I 2017 that the default surface area treated in large-scale kitchens and canteens by RTU products is 50 m^2. According to applicant, max. 4 applications per day are foreseen. Since the treated surface area (50 m^2) represents 2-3 applications (WG I 2017 survey), the number of applications per day was set to 2. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF "orochemie hand- and surface disinfectants" is given in Table 105.

Table 105: Emission scenario for surface disinfection with pre-soaked wipes in large scale catering kitchens and canteens (IHO, 2006)

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 b.p. (S)	16 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	8.85 g/m^2
Surface area to be disinfected (WG ENV I 2017) Large scale catering kitchens	50 m^2
Number of applications per day(S)	2
Fraction of substance disintegrated during or after application (before release to the sewer system)(D)	0

Determinants of the emission scenario according to chapter 2.2.4, table 10; Environmental Emission Scenarios for PT 4 (JRC, 2011)	Value
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	0.09 kg/d
Local release to air	0.80 kg/d

(S) – Provided by applicant, (D) – Default (JRC, 2011), (CAR) – CAR Propan-2-ol (2014)

Scenario 8: PT 4 – surface disinfection with ready-to-use wipes in slaughterhouses and butcheries – professional

The emission scenario for surface disinfection in slaughterhouses and butcheries is described in Chapter 2.2 of the ESD for PT4 (JRC, 2011). According to the applicant, pre-soaked wipes release 7.01 g of product per wipe and a single wipe is used to disinfect 0.5 m^2. The application rate of pre-soaked wipes was calculated as max. 16 mL/m^2. The application of the BPF "orochemie hand- and surface disinfectants" as spray or pour application describes an application rate of max. 50 ml/m^2 (see scenario 4). This amount also covers the application rate of BPF "orochemie hand- and surface disinfectants" pre-soaked wipes. The application as spray or pour application (scenario 4) is therefore the worst-case application.

It was decided at the WG ENV I 2017 that the default surface area treated in slaughterhouses and butcheries by RTU products is $10m^2$. According to applicant, max. 4 applications per day are foreseen. The results from the WG I 2017 survey showed that in slaughterhouses RTU products are not routinely used. We therefore keep the default 1 application per day. The resulting local emission of propan-2-ol to the wastewater and air from the application of a product in the BPF "orochemie hand- and surface disinfectants" is given in Table 106.

Table 106: Emission scenario for surface disinfection with pre-soaked wipes in slaughterhouses and butcheries (IHO, 2006)

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 b.p. (S)	16 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	8.85 g/m^2

Determinants of the emission scenario according to chapter 2.2.4, table 10; Environmental Emission Scenarios for PT 4 (JRC, 2011)	Value
Surface area to be disinfected (WG ENV I 2017) Slaughterhouses and butcheries	10 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	8.85E-3 kg/d
Local release to air	0.08 kg/d

(S) – Provided by applicant, (D) – Default (JRC, 2011), (CAR) – CAR Propan-2-ol (2014)

3.8.4.4 Non-compartment specific effects

- **Primary poisoning**

  Not relevant for considered uses.

- **Secondary poisoning**

  According to the BPR guidance Vol IV part B (2015) for substances with a log K_{ow} < 4.5, the primary uptake route is direct uptake from the water phase and an uptake through the food chains eventually leading to secondary poisoning must not be considered. The biocidal product "orochemie hand-and surface disinfectants biocidal product family" contains the active substance propan-2-ol, which has a log K_{OW} of 0.05. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals (AR for PT1, 2, and PT4, 2014).

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

The application of the BPF "orochemie hand- and surface disinfectants" used for disinfection results in indirect exposure of the environment via the air (wet and dry deposition) and to a lesser extent via STP.

Table 107: Identification of relevant receiving compartments based on the exposure pathway

Meta SPC	Use	Sce-nario	PT	Wastewater (STP)	Surface water and Sedi-ment	Soil and Groundwa-ter	Air
1	1		1	yes	yes (indirect)	not relevant	yes
2	1		1	yes	yes (indirect)	not relevant	yes
	2		1	yes	yes (indirect)	not relevant	yes
3	1		1	yes	yes (indirect)	not relevant	yes
4	1 + 2	1	2	yes	yes (indirect)	not relevant	yes
		2	2	yes	yes (indirect)	not relevant	yes
	3 +4	3	4	yes	yes (indirect)	not relevant	yes
		4	4	yes	yes (indirect)	not relevant	yes
5	1	5	2	yes	yes (indirect)	not relevant	yes
		6	2	yes	yes (indirect)	not relevant	yes
	2	7	4	yes	yes (indirect)	not relevant	yes
		8	4	yes	yes (indirect)	not relevant	yes

3.8.4.6 Calculated PEC values

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols used in small-scale applications, there is no need for a risk assessment of the subsequent environmental compartments following the release path via air (see also TAB v. 2.1, ENV-A5, 2019). As the distribution in sewage sludge for propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant as well. Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product family “orochemie hand- and surface disinfectants”.

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 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

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. Thus,

- PEC_{STP} = $Clocal_{eff}$ referring to equation 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015).

The local PEC values from all intended uses are presented in the following table and are used for the environmental risk assessment.

Table 108: Summary table of calculated PEClocal values from intended uses of the BPF "orochemie hand- and surface disinfectants"

Summary table on calculated PEC values										
Meta SPC	**Use**	**Scenario**	**PT**	**PEC-STP**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**	**$DEPtotal_{ann}$**
				[µg/L]	[µg/L]	[µg/kg_{wwt}]	[µg/kg_{wwt}]	[µg/L]	[mg/m^3]	[mg/(m^2 d)]
1	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
2	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
	2		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
3	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
4	1 + 2	1	2	8.63	0.86	0.73	3.44E-3	0.02	2.73E-5	4.04E-5
		2	2	72.56	7.26	6.19	0.25	1.44	2.08E-3	2.98E-3
	3 +4	3	4	17.25	1.72	1.47	0.06	0.34	4.93E-4	7.09E-4
		4	4	1.75	0.17	0.15	6.05E-3	0.03	4.93E-5	7.10E-5
5	1	5	2	2.75	0.27	0.23	9.66E-3	0.05	7.88E-5	1.13E-4
		6	2	72.56	7.26	6.19	0.25	1.44	2.07E-3	2.98E-3
	2	7	4	5.5	0.55	0.47	0.02	0.11	1.58E-4	2.27E-4
		8	4	0.55	5.53E-2	0.05	1.94E-3	0.01	1.58E-5	2.28E-5

Based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in negligible concentration of propan-2-ol in the sewage sludge. However, because propan-2-ol is highly volatile it will be emitted to soil indirectly by wet and dry deposition ($DEPTtotal_{ann}$), which is calculated according to the OPS model in the Guidance BPR IV ENV B (2015). The groundwater exposure occurs after wet and dry aerial deposition on soil. In accordance to WG ENV IV 2019 and TAB 2.1 ENV A-5, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product family "orochemie hand- and surface disinfectants".

3.8.4.7 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 biocidial 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 B (2015)) shown in Figure 1, it is checked if aggregated exposure estimations are required for the biocidal products of the BPF "orochemie hand and surface disinfectants" containing propan-2-ol as active substance.

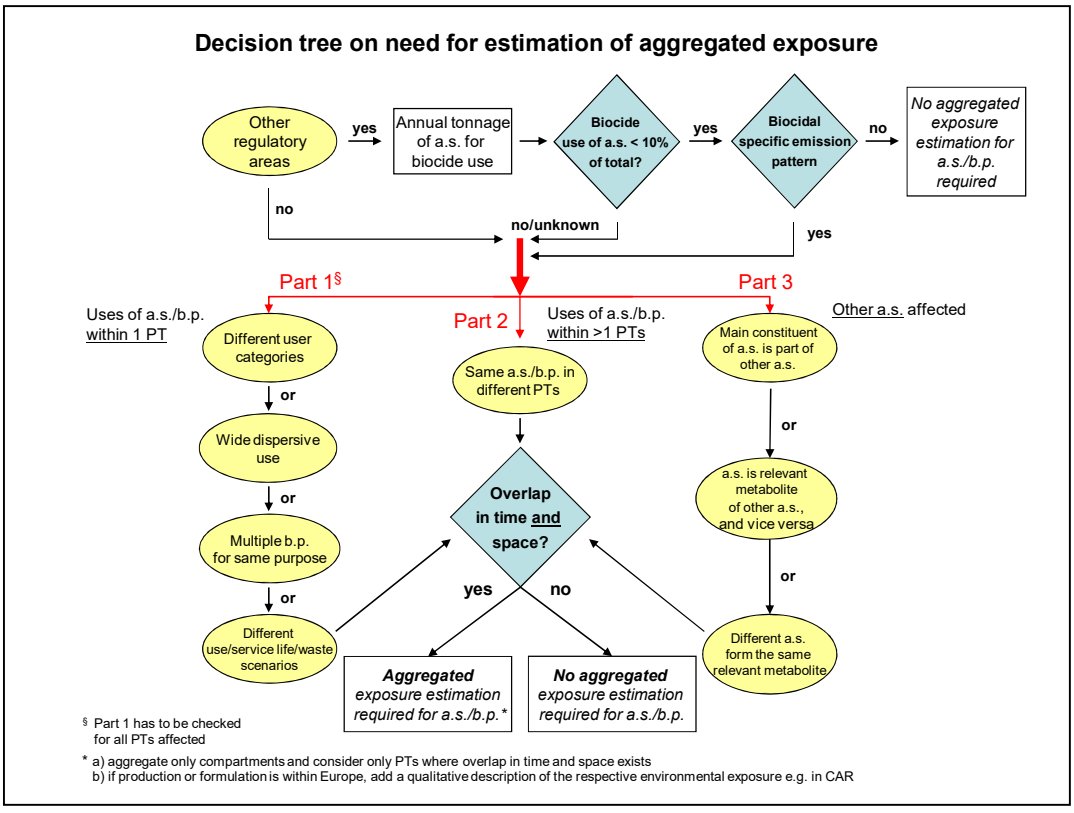

Figure 1: Decision tree on the need for estimation of aggregated exposure

Upper part of the decision tree: Relevance of aggregated exposure for the biocidal sector

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 biocidal products part of the BPF "orochemie hand and surface disinfectants" cannot be identified. The occurring emissions in PT1, 2, and 4 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 phar-maceuticals. Consequently, no aggregated exposure is required for propan-2-ol released due to the use of biocidal products part of the BPF "orochemie hand and surface disinfectants".

3.8.5 Risk characterisation for meta SPC 1 to 5

The biocidal product family (BPF) "orochemie hand- and surface disinfectants" is used in product type 1, 2 and 4 for disinfection by professional users. The biocidal product family (BPF) comprises ten uses in 5 Meta SPCs that need to be assessed in the risk characterisation for the environment: The ready-to-use products of the BPF contain 63.1 (w/w) of the active substance propan-2-ol and are available as gels, solutions, sprays and wipes.

The application of the BPF "orochemie hand- and surface disinfectants" used for disinfection results in indirect exposure of the environment via the air (wet deposition) and to a lesser extent via STP. The local emission estimation for relevant environmental compartments are presented in detail in chapter 3.8.4. The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment. The PECs are presented in detail in chapter 3.8.4.

3.8.5.1 Aquatic compartment (sediment and STP)

The risk assessment for the aquatic compartment compares the predicted environmental concentrations (PECs) of i) an indirect release via STP into the surface water and sediment and ii) a direct release to the sewage treatment plant (STP) with the relevant PNEC values presented in chapter 3.8.2.

Summary table on calculated PEC values

Summary table on calculated PEC values										
Meta SPC	Use	Scenario	PT	**PEC-STP**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**	**$DEPtotal_{ann}$**

				[µg/L]	[µg/L]	[µg/kg$_{wwt}$]	[µg/kg$_{wwt}$]	[µg/L]	[mg/m^3]	[mg/(m^2 d)]
1	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
2	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
	2		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
3	1		1	37.5	3.75	3.2	0.18	1.05	0.0015	0.0022
4	1 +2	1	2	8.63	0.86	0.73	3.44E-3	0.02	2.73E-5	4.04E-5
		2	2	72.56	7.26	6.19	0.25	1.44	2.08E-3	2.98E-3
	3 + 4	3	4	17.25	1.72	1.47	0.06	0.34	4.93E-4	7.09E-4
		4	4	1.75	0.17	0.15	6.05E-3	0.03	4.93E-5	7.10E-5
5	1	5	2	2.75	0.27	0.23	9.66E-3	0.05	7.88E-5	1.13E-4
		6	2	72.56	7.26	6.19	0.25	1.44	2.07E-3	2.98E-3
	2	7	4	5.5	0.55	0.47	0.02	0.11	1.58E-4	2.27E-4
		8	4	0.55	5.53E-2	0.05	1.94E-3	0.01	1.58E-5	2.28E-5

Summary table of PNEC

Table 109 Summary table on calculated PNEC values

Summary table on calculated PNEC values	
Compartment	**PNEC**
Surface water	2.82 mg a.s./L
Sediment	2.41 mg a.s./kg ww
STP	10 mg a.s./L
Soil	0.496 mg a.s./kg ww

3.8.5.1.1 Surface water and sediment

Table 110 Summary table on calculated PEC/PNEC values for surface water

Meta SPC	Intended use	PT	Scenario	Expo-sure	PEC [µg/L]	PNEC [µg/L]	PEC/PNEC
Meta SPC 1	Use1: hand gel	1	-/-	via STP in surface water	3.75	2820	1.00E-03
Meta SPC 2	Use 1:spray Use 2: solution						
Meta SPC 3	Use 1: wipes for hands						
Meta SPC 4	Use 1: surface solution Use 2: surface spray	2	1		0.86		3.05E-04
			2		7.26		2.57E-03
	Use 3: surface solution Use 4: surface spray	4	3		1.72		6.10E-04
			4		0.17		6.03E-05
Meta SPC 5	Use 1: wipes	2	5		0.27		9.57E-05
			6		7.26		2.57E-03
	Use 2: wipes	4	7		0.55		1.95E-04
			8		5.53E-2		1.96E-05

Conclusion

PEC/PNEC-ratios were less than 1 for all intended uses of the BPF “orochemie hand- and surface disinfectants” and thus indicate an acceptable risk for the surface water compartment, if the products belonging to Meta SPC 1 - 5 are used according to the label. It can therefore be concluded that the use of the products of Meta SPC 1 - 5 do not pose an unacceptable risk to the surface water compartment.

Table 111 Summary table on calculated PEC/PNEC values for sediment

Meta SPC	Intended use	PT	Sce-nario	Expo-sure	PEC [µg/kg$_{wwt}$]	PNEC [µg/kg wwt]	PEC/PNEC
Meta SPC 1	Use1: hand gel	1	-/-	via STP in sedi-ment	3.2	2410	1.33E-03
Meta SPC 2	Use 1:spray Use 2: solution						
Meta SPC 3	Use 1: wipes for hands						
Meta SPC 4	Use 1: surface solu-tion Use 2: surface spray	2	1		0.73		3.03E-04
			2		6.19		2.57E-03
	Use 3: surface solu-tion Use 4: surface spray	4	3		1.47		6.10E-04
			4		0.15		6.22E-05
Meta SPC 5	Use 1: wipes	2	5		0.23		9.54E-05
			6		6.19		2.57E-03
	Use 2: wipes	4	7		0.47		1.95E-04
			8		0.05		2.07E-05

3.8.5.1.2 STP

Table 112 Risk characterisation for the STP

Meta SPC	Intended use	PT	Scenario	Expo-sure	PEC [µg/L]	PNEC [µg/L]	PEC/PNEC
Meta SPC 1	Use1: hand gel	1	-/-	STP	37.5	10,000	3.0E-03
Meta SPC 2	Use 1:spray Use 2: solution						
Meta SPC 3	Use 1: wipes for hands						
Meta SPC 4	Use 1: surface solution Use 2: surface spray	2	1		8.63		8.60E-04
			2		72.56		7.26E-03
	Use 3: surface solution Use 4: surface spray	4	3		17.25		1.72E-03
			4		1.75		1.70E-04
Meta SPC 5	Use 1: wipes	2	5		2.75		2.70E-04
			6		72.56		7.26E-03
	Use 2: wipes	4	7		5.5		5.50E-04
			8		0.55		5.53E-05

Conclusion

The PEC/PNEC-ratio for the STP was found to be less than 1 for all intended uses of the BPF “orochemie hand- and surface disinfectants” and thus not indicating an unacceptable risk to the STP, if the products belonging to Meta SPC 1 - 5 are used according to the label.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols used in small-scale applications, there is no need for a risk assessment of the subsequent environmental compartments following the release path via air (see also TAB v.2.1, ENV-A5, 2019). As the distribution in sewage sludge for propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant as well. Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product family “orochemie hand- and surface disinfectants”. As a consequence, no $PEC_{soil}/PNEC_{soil}$ was calculated and PEC_{GW} was not compared to the groundwater trigger value.

3.8.5.3 Atmosphere

No ecotoxicological data on animal species for the air compartment available and therefore a quantitative risk characterisation by comparison of the PECair to PNECair is not possible. For further details please refer to AR 2014.

3.8.5.4 Non-compartment specific

Non-compartment-specific effects are not to be expected.

3.8.5.5 PBT assessment

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 fulfil the PBT- nor the vP/vB-criteria.

3.8.5.6 Endocrine disrupting properties

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

The full composition of the BPF " (BPF)-orochemie hand- and surface disinfectants" is listed in the Confidential Annex in chapter 4. There are no indications that a non-active substance of the product may have

endocrine disrupting properties based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.8.5.7 Summary of risk characterisation

Table 113 Summary table on calculated PEC/PNEC values

Meta SPC	Intended use	PT	Scenario	PEC/PNEC			
				STP	Water	Sediment	Soil
Meta SPC 1	Use1: hand gel	1	-/-	3.0E-03	1.00E-03	1.33E-03	3.6E-4
Meta SPC 2	Use 1: spray Use 2: solution						
Meta SPC 3	Use 1: wipes for hands						
Meta SPC 4	Use 1: surface solution Use 2: surface spray	2	1	8.60E-04	3.05E-04	3.03E-04	6.94E-06
			2	7.26E-03	2.57E-03	2.57E-03	5.04E-04
	Use 3: surface solution Use4: surface spray	4	3	1.72E-03	6.10E-04	6.10E-04	1.21E-04
			4	1.70E-04	6.03E-05	6.22E-05	1.22E-05
Meta SPC 5	Use 1: wipes	2	5	2.70E-04	9.57E-05	9.54E-05	1.95E-05
			6	7.26E-03	2.57E-03	2.57E-03	5.04E-04
	Use 2: wipes	4	7	5.50E-04	1.95E-04	1.95E-04	4.03E-05
			8	5.53E-05	1.96E-05	2.07E-05	3.91E-06

No unacceptable risks for the environment have been identified in the environmental risk assessment by the use of the BPF “orochemie hand- and surface disinfectants”.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

4.1.1 List of studies for the products in meta SPC No

Table 114

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1.1.; 3.1.2.; 3.1.3; 3.3	C20/HD 412 essential	Winkens J.	2014	Orochemie GmbH + Co. KG.
2	For meta SPC 1: 3.1.1.; 3.1.2. ; 3.3	C25 Händedesinfektionsgel	Winkens J.	2016	Orochemie GmbH + Co. KG.
3	3.2	C20/HD 412 essential	Winkens J.	2016a	Orochemie GmbH + Co. KG.
4	For meta SPC 1: 3.2	C25 Händedesinfektionsgel	Winkens J.	2016b	Orochemie GmbH + Co. KG.
5	3.2	Validierungsbericht pH Wert Messung	Winkens J.	2009	Orochemie GmbH + Co. KG.
6	3.2	PH-WERT-MESSUNGEN SAA_PH	Mundil, U.	2016	
7	3.2	Determination of the pH value of C 20 hand disinfection	Trillen, J.	2017	Orochemie GmbH + Co. KG.
8	For meta SPC 1: 3.3	C25 Händedesinfektionsgel	Trillen, J.	2017	Orochemie GmbH + Co. KG.
9	3.3, 3.4.1; 3.4.1.3.	Relative density Ph.Eur. 2.2.5	Anonymous	N.A.	Published

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
10	3.3, 3.4.1.1; 3.4.1.3.	Bestimmung der Dichte - SAA_002	Winkens J.	2016	Orochemie GmbH + Co. KG.
11	3.3; 3.4.1; 3.4.1.3.	Geruch Ph.Eur.2.3.4	Anonymous	N.A.	Published
12	3.3	GC-Alkoholbestimmungen (Arzneimittel)	Biemel, W.	2015	Orochemie GmbH + Co. KG.
13	3.3	Mikrobiologische Prüfung von Arzneimitteln	Winkens J.	2015	Orochemie GmbH + Co. KG.
14	3.3	Prüfung der Sporenfilter für Händedesinfektionsmittel (Integritätstest)	Gehring, E.	2015	Orochemie GmbH + Co. KG.
15	3.3	Mikrobiologische Prüfung nicht steriler Produkte: Zählung der vermehrungsfähigen Mikroorganismen	Anonymous	N.A.	Published
16	3.3; 3.4.1.1; 3.4.1.3.	pH-Wert-Messungen	Mundl, U.	2014	Orochemie GmbH + Co. KG.
17	3.3; 3.4.1.1; 3.4.1.3.	Messungen am Rheometer RheoLab QC	Biemel, W.	2016	Orochemie GmbH + Co. KG.
18	3.3; 3.4.1.1; 3.4.1.3.; 5.1	GC-Alkoholbestimmungen	Winkens J.	2015	Orochemie GmbH + Co. KG.
19	3.3; 3.4.1.1; 3.4.1.3	Geruchsprüfung	Trillen, J.	2015	Orochemie GmbH + Co. KG.
20	3.4.1.1/01	Haltbarkeitprüfung der arzneilich wirksamen Bestandteile	Biemel, W.	2003c	Orochemie GmbH + Co. KG.
21	3.4.1.1/02 und 3.1.1/05	Stability test C 20 Batch C20_226 Loss of weight for 1L, 10L, 125ml, 400ml	Biemel, W.	2003d	Orochemie GmbH + Co. KG.
22	3.4.1.1/03	Stability test C 20 Batch C20_226, 125 mL, Storage at 25C / 60% RH and at 40C / 75% RH	Schneider, A,	2016	Orochemie GmbH + Co. KG.
23	3.4.1.1/04	Stability test C 20 Batch C20_226, 400 ml, storage at 25C / 60% RH and 40C / 75% RH	Schneider, A,	2016	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
24	3.4.1.1/06	Stability test C 20 Batch C20_226, 10 L, storage at 25C / 60% RH and 40C / 75% RH	Schneider, A,	2016	Orochemie GmbH + Co. KG.
25	3.4.1.1/07	Stability Test with C20, solution, in the 125-ml bottle with spray nozzle, batch No. 1513717, accelerated storage test.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
26	3.4.1.1/08	Stability Test with C25, gel, in the 100-ml bottle with screw cap, batch No. 1605215, accelerated storage test.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
27	3.4.1.1/09	Stability Test with C20, solution, in the 1 litre bottle with screw cap, batch No. 1514217, accelerated storage test.	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
28	3.4.1.1/10	Stability Test with C20, solution, in the 125-ml bottle with flip-top cap, batch No. 1519726, accelerated storage test.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
29	3.4.1.1/11	Stability test with C 25 gel in the 1-litre bottle with screw cap, batch No. 160632,a ccelerated storage test	Schneider, A,	2016	Orochemie GmbH + Co. KG.
30	3.4.1.1	Storage stability est of C20 wipes hand disinfection at 54°C +/-2°C for two weeks	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
31	3.4.1.1; 3.4.1.3.	Prüfung der Sporenfilter für Händedesinfektionsmittel (Integritätstest)	Gehring, E.	2015	
32	3.4.1.1; 3.4.1.3.	Mikrobiologische Prüfung von Arzneimitteln	Winkens J.	2015	
33	3.4.1.2	Haltbarkeitprüfung der arzneilich wirksamen Bestandteile	Anonymous	N.A.	
34	3.4.1.2	Stability test C 20 Batch C20_226 Loss of weight for 1L, 10L, 125ml, 400ml	Biemel, W.	2003	Orochemie GmbH + Co. KG.
35	3.4.1.2	Stability test C 20 Batch 85301 Loss of weight for 1L, 10L, 125ml, 400ml,2.5L and 50 mL	Biemel, W.	2003	Orochemie GmbH + Co. KG.
36	3.4.1.2	Opinion on the correlation between relative density and active substance content	Fridrich, D.	2017	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
37	For meta SPC 1: 3.4.1.2	Statement on different versions of the standard operating procedures SAA_ALGN and SAA_025	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
38	For meta SPC 1: 3.4.1.2	Long-term storage test at ambient temperature with C 25	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
39	For meta SPC 3 and 5	Long-term storage test at ambient temperature with wipes hand disinfection	Schneider, A,	2019	Orochemie GmbH + Co. KG.
40	For meta SPC 2-5: 3.4.1.3.	Stability Test with C20, solution, in the 125-ml bottle with spray nozzle, batch No. 1315034, stability below 0ºC.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
41	For meta SPC 1: 3.4.1.3.	Stability Test with C25, gel, in the 1-litre bottle with screw cap, batch No. 1606302, stability below 0ºC.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
42	For meta SPC 1: 3.4.1.3.	Stability Test with C25, gel, in the 100-ml bottle with screw cap, batch No. 1605215, stability below 0ºC.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
43	For meta SPC 2-5: 3.4.1.3.	Stability Test with C20, solution, in the 2.5-litre bottle with screw cap, batch No. 1215033, stability below 0ºC.	Schneider, A,	2016	Orochemie GmbH + Co. KG.
44	3.4.1.3	"Mikrobiologische Prüfung nicht steriler Produkte: Zählung der vermehrungsfähigen Mikroorganismen"	Anonymous	N.A.	
45	3.4.2.1	Photostability of C 20 Hand + Skin Disinfectant	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
46	3.4.2.1	Photostability of C 25 hand disinfection gel	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
47	3.5.6.	Determination Particle Size distribution on the Sample C 20 Hand + Skin Disinfectant - 125 ml	Mazzei, A.	2019	Orochemie GmbH + Co. KG.
48	3.5.6.	Determination Particle Size distribution on the Sample C 20 Hand + Skin Disinfectant - 1 L	Mazzei, A.	2019	Orochemie GmbH + Co. KG.
49	3.5.12.	Spray diameter of C 20 hand + skin disinfectant	Schneider, A.	2017	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
50	3.8	Surface Tension of C 20 Hand + Skin Disinfectant	Schneider, A.	2017	Orochemie GmbH + Co. KG.
51	3.8	Surface tension of C 25 hand disinfection gel	Schneider, A.	2017	Orochemie GmbH + Co. KG.
52	3.9	C25 Händedesinfektionsgel	Winkens J.	2016	Orochemie GmbH + Co. KG.
53	3.9	Messungen am Rheometer RheoLab QC - SAA_025	Biemel, W.	2016	Orochemie GmbH + Co. KG.
54	3.9	Viscosity of C20 at 20°C and 40°C	Trillen, J.	2016a	Orochemie GmbH + Co. KG.
55	3.9	VISCOSITY OF C25 AT 20°C AND 40°C	Trillen, J.	2016b	Orochemie GmbH + Co. KG.
56	4.6	Analysenzertifikat Flammpunkt C25	Mehlis, D.	2013	Orochemie GmbH + Co. KG.
57	4.6	Analysenzertifikat Flammpunkt C20	Mehlis, D.	2016	Orochemie GmbH + Co. KG.
58	4.6. (meta-01 to 03)	C 25, Händedesinfektionsgel; Flammpunkt (AP)	Neger, E.	2013	Orochemie GmbH + Co. KG.
59	4.6. (meta-01 to 03)	C 20; Flammpunkt (AP)	Büchel, D.	2016	Orochemie GmbH + Co. KG.
60	5.1	Validierungsbericht: Gehaltsbestimung von Wirkstoffe: 1-Propanol, 2-Propanol, PRODUKT: C20 HÄNDEDESINFEKTION	Winkens J.		
61	5.1	GC-Alkoholbestimmungen (Arzneimittel)	Biemel, W.	2016	
62	5.1	Statement on different Versions of teh standard operating procedures SAA_ALGA and SAA_ALGN for the description of analytical methods	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
63	5.1	Validation Report - Alcohols in raw material and formulations - basic method	Winkens, J., Trillen, J.	2017	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
64	5.1	Validation report - Quantitative determination of propan-2-ol in C 20 solution	Winkens, J., Trillen, J.	2017	Orochemie GmbH + Co. KG.
65	5.1	Quantitative Determination of Propan-2-ol in finished product C20 wipes	Winkens, J., Trillen, J.	2017	Orochemie GmbH + Co. KG.
66	5.1	Quantitative Determination of Propan-2-ol in Finished Product C 25 Hand Disinfection Gel	Winkens, J., Trillen, J.	2017	Orochemie GmbH + Co. KG.
67	For meta SPC: 1-3: 6.1	EMPFEHLUNGEN ZUR AUSWAHL VIRUZIDER DESINFEKTIONSMITTEL - EINEN NEUE STELLUNGNAHME DES ARBEITSKREISES VIRUZIDE BEIM RKI	Schwebke, I. Et al	2016	published
68	For meta SPC 2-5: 6.7	Efficacy of C20 Hände + Haut Desinfektion for Skin Disinfection (German Original, English Translation)	Brilll, F.H.H.	2012	Orochemie GmbH + Co. KG.
69	For meta SPC 2-5: 6.7	C20 Hand Disinfection (German Original, English Translation)	Marth, E.	2002	Orochemie GmbH + Co. KG.
70	For meta SPC 2-5: 6.7	C20 Hand Disinfection Suitability for Hygienic Hand Disinfection (German original, English translation)	Werner, H.P.	2002	Orochemie GmbH + Co. KG.
71	For meta SPC 2-5: 6.7	C 20 Händedesinfektion Tuberculocidal efficacy quantitative suspension test (German original, English translation)	Werner, H.P.	2002	Orochemie GmbH + Co. KG.
72	For meta SPC 2-5: 6.7	C20 Surgical hand disinfection according to DIN EN 12791 (2005) and pre test according to "Standard Methods" (German Original, English translation) (90 s contact)	Werner, H.P.	2009	Orochemie GmbH + Co. KG.
73	For meta SPC 2-3: 6.7	C20 Surgical hand disinfection according to DIN EN 12791 (2005) and pre test according to "Standard Methods" (German Original, English translation) (3 min contact)	Werner, H.P.	2009	Orochemie GmbH + Co. KG.
74	For meta SPC 1: 6.7	OC-20C-01 / C 20 EN 1500 Hygienic Handrub (phase 2, step2)	Werner, H.P.	2017a	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
75	For meta SPC 1: 6.7	C20 / OC-20C-01 EN12791 Surgical hand disinfection (phase 2, step 2)	Werner, H.P.	2017b	Orochemie GmbH + Co. KG.
76	For meta SPC 1-5: 6.7	OC-20C-01 EN 13727 Quantitative suspension test - bactericidal activity (phase 2, step 1)	Werner, H.P.	2017c	Orochemie GmbH + Co. KG.
77	For meta SPC 1-5: 6.7	OC-20C-01 EN 13624 Quantitative suspension test - yeasticidal activity (phase 2, step 1)	Werner, H.P.	2017d	Orochemie GmbH + Co. KG.
78	For meta SPC 2-5: 6.7	OC-20C-01 EN 14348 Tubercolicidal (M. terrae) activity (phase 2, step 1)	Werner, H.P.	2017e	Orochemie GmbH + Co. KG.
79	For meta SPC 2-5: 6.7	OC-20C-01 / C20 Wipes EN 16615 (2015) with a ready-to-use system bactericidal (E. hirae, P. aeruginosa) activity (phase 2, step 2)	Werner, H.P.	2017f	Orochemie GmbH + Co. KG.
80	For meta SPC 2-5: 6.7	OC-20C-01 / C20 Wipes EN 16615 (2015) with a ready-to-use system bactericidal (E. hirae, P. aeruginosa) activity (phase 2, step 2). Test after storage period of 28 days.	Werner, H.P.	2017g. 1	Orochemie GmbH + Co. KG.
81	For meta SPC 2-5: 6.7	OC-20C-01 / C20 Wipes EN 16615 (2015) with a ready-to-use wipe system bactericidal (E. hirae, P. aeruginosa) activity (phase 2, step 2). Test after storage period of 12 weeks.	Werner, H.P.	2017g. 2	Orochemie GmbH + Co. KG.
82	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) with a standardised wipe material tubercolocidal activity (phase 2, step 2)	Werner, H.P.	2017h	Orochemie GmbH + Co. KG.
83	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 with a standardised wipe material tubercolocidal activity (phase 2, step 2). 3rd test run	Werner, H.P.	2017i	Orochemie GmbH + Co. KG.
84	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) with a standardised wipe material bactericidal and yeasticidal activity (phase 2, step 2), clean conditions	Werner, H.P.	2017j	Orochemie GmbH + Co. KG.
85	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) with a standardised wipe material bactericidal and yeasticidal activity (phase 2, step 2), dirty conditions	Werner, H.P.	2017k	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
86	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) in combination with FD multi wipes with a specified cloth material, bactericidal and yeasticidal activity (phase 2, step 2)	Werner, H.P.	2017l	Orochemie GmbH + Co. KG.
87	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) in combination with FD multi wipes with a specified cloth material, bactericidal and yeasticidal activity (phase 2, step 2)	Werner, H.P.	2017m	Orochemie GmbH + Co. KG.
88	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) in combination with FD multi wipes with a specified cloth material in a wipe dispenser system, bactericidal and yeasticidal activity (phase 2, step 2). Test after storage period of 28 days. 3rd test run VAH.	Werner, H.P.	2017n	Orochemie GmbH + Co. KG.
89	For meta SPC 2-5: 6.7	OC-20C-01 EN 16615 (2015) in combination with FD multi wipes with a specified cloth material in a wipe dispenser system, bactericidal and yeasticidal activity (phase 2, step 2). Test after storage period of 8 weeks.	Werner, H.P.	2017o	Orochemie GmbH + Co. KG.
90	For meta SPC 2-5: 6.7	OC-20C-01 EN 1276 Quantitative Suspension test - bactericidal activity (phase 2, step 1)	Werner, H.P.	2017p	Orochemie GmbH + Co. KG.
91	For meta SPC 2-5: 6.7	0C-20C-01 EN 13697 Quantitative non-porous surface test – bactericidal and yeasticidal activity (phase 2, step 2)	Werner, H.P.	2017q	Orochemie GmbH + Co. KG.
92	For meta SPC 2-5: 6.7	OC-20C-01 EN 1650 Quantitative suspension test - yeasticidal activity (phase 2, step 1).	Werner, H.P.	2017r	Orochemie GmbH + Co. KG.
93	For meta SPC 3: 6.7	C20 wipes hand disinfection	Fridrich, D.	2017	Orochemie GmbH + Co. KG.
94	For meta SPC 4: 6.7	OC-20C-01 Surface disinfection without mechanical action- bactericidal and yeasticidal activity (phase 2, step 2), clean and dirty conditions	Werner, H.P.	2017s	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
95	For meta SPC 4: 6.7	OC-20C-01, Surface disinfection without mechanical action - bactericidal and yeasticidal activity (phase 2, step 2), 2nd test run VAH method 14.1, clean and dirty conditions	Werner, H.P.	2017t	Orochemie GmbH + Co. KG.
96	For meta SPC 4: 6.7	OC-20C-01, EN 13697, Bactericidal and yeasticidal activity, clean and dirty conditons (Medical area)	Werner, H.P.	2018a	Orochemie GmbH + Co. KG.
97	For meta SPC 4: 6.7	OC-20C-01 Surface disinfection without mechanical action- bactericidal and yeasticidal activity, clean and dirty conditions	Werner, H.P.	2018c	Orochemie GmbH + Co. KG.
98	For meta SPC 3: 6.7	OC-20C-01 wipes EN 1500, Hygienic handrub (Phase 2, step 2) modified	Werner, H.P.	2018b	Orochemie GmbH + Co. KG.
99	For meta SPC 2-5: 6.7	Vaccinia virus efficacy of C20 in a quantitative suspension test at 20°C according to the guideline of DVV/RKI dated 1.8.2008	Steinmann, J.	2010a	Orochemie GmbH + Co. KG.
100	For meta SPC 2-5: 6.7	BVDV efficacy of C20 in a quantitative suspension test at 20°C according to the guideline of DVV/RKI dated 1.8.2008	Steinmann, J.	2010b	Orochemie GmbH + Co. KG.
101	For meta SPC 2-5: 6.7	Activity of C 20 Händedesinfektion against bovine corona virus following the Guideline of DVV/RKI dating 01.12.2014	Steinmann, J.	2016a	Orochemie GmbH + Co. KG.
102	For meta SPC 2-5: 6.7	Activity of C20 Händedesinfektion against rotavirus strain Wa following the guideline of DVV/RKI dating 1.12.2014	Steinmann, J.	2016b	Orochemie GmbH + Co. KG.
103	For meta SPC 2-5: 6.7	C 20 Hände- und Hautdesinfektion Virucidal effectivity of C20 Hände- und Hautdesinfektion against Murine Norovirus MNV according to EN 14476 (German original, English translation)	Werner H.P.	2012a	Orochemie GmbH + Co. KG.
104	For meta SPC 1-5: 6.7	C 20 Händedesinfektion Virucidal effectivity of C20 HändeDesinfektion against Murine Norovirus MNV according to EN 14476	Werner, H.P.	2017u	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
105	For meta SPC 1-5: 6.7	Activity of C 20 Händedesinfektion against modified vaccinia virus Ankara (MVA) in a quantitative suspension test according to EN 14476:2013+A1:2015	Steinmann, J.	2016c	Orochemie GmbH + Co. KG.
106	For meta SPC 1-5: 6.7	Activity of C 20 Händedesinfektion against adenovirus type 5 in a quantitative suspension test according to the EN 14476:2013+A1:2015	Steinmann, J.	2016d	Orochemie GmbH + Co. KG.
107	For meta SPC 1-5: 6.7	Vaccinia Virus efficacy of C20 in a quantitative suspension test at 20°C according to the guideline of DVV/RKI	Steinmann, J.	2016e	Orochemie GmbH + Co. KG.
108	For meta SPC 1-5: 6.7	BVDV efficacy of C20 in a quantitative suspension test at 20°C according to the Guideline of DVV/RKI	Steinmann, J.	2016f	Orochemie GmbH + Co. KG.
109	For meta SPC 1-5: 6.7	Virucidal efficacy of OC-20C-01 against Murine Norovirus according to the quantitative Suspensiontest EN 14476:2016/prA2:2016 - Judgement and Test report - clean conditions	Werner, H.P.	2017v	Orochemie GmbH + Co. KG.
110	For meta SPC 1-5: 6.7	Virucidal efficacy of OC-20C-01 against Murine Norovirus according to the quantitative Suspensiontest EN 14476:2016/prA2:2016 - Judgement and test report-dirty conditions	Werner, H.P.	2017w	Orochemie GmbH + Co. KG.
111	For meta SPC 1-5: 6.7	Expert opinion - Activity of C 20 Händedesinfektion against modified vaccinia Virus Ankara (MVA) in a quantitative Suspension test according to EN 14476:2013+A1:2015 under dirty conditions	Steinmann, J.	2017a	Orochemie GmbH + Co. KG.
112	For meta SPC 1-5: 6.7	Expert opinion - Activity of C 20 Händedesinfektion against adenovirus type 5 in a quantitative Suspension test according to the EN 14476:2013+A1:2015 under dirty conditions	Steinmann, J.	2017a	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
113	For meta SPC 1: 6.7	Prüfbericht C 20 Hände- und Hautdesinfektion C 25 Händedesinfektionsgel; Bakterizide (S. aureus, P. aeruginsa)und levurozide (C. albicans) Wirksamkeit; Hohe Belastung	Werner, H.P.	2013	Orochemie GmbH + Co. KG.
114	For meta SPC 1: 6.7	OC-20C-01 - C25 - EN 13624 - Quantitative suspension test - yeasticidal activity - equivalence test	Werner, H.P.	2017x	Orochemie GmbH + Co. KG.
115	For meta SPC 1: 6.7	C25 (Händedesinfektionsgel) - EN 1500 - Hygienic handrub (phase 2, step 2)	Werner, H.P.	2017y	Orochemie GmbH + Co. KG.
116	For meta SPC 1: 6.7	Virucidal efficacy of C25 Händedesinfektionsgel against Murine Norovirus according to the quantitative Suspensiontest EN 14476:2016/prA2:2016	Werner, H.P.	2018d	Orochemie GmbH + Co. KG.
117	For meta SPC 1: 6.7	Activity of C 25 Händedesinfektionsgel against Adenovirus type 5 in a quantitative suspension test according to the EN 14476:2013+A1:2015 u	Steinmann, J.	2016g	Orochemie GmbH + Co. KG.
118	For meta SPC 1: 6.7	Activity of C 25 Händedesinfektionsmittel against modified vaccinia virus Ankara (MVA) in a quantitative suspension test according to EN 14476:2013 + A1:2015	Steinmann, J.	2016h	Orochemie GmbH + Co. KG.
119	For meta SPC 2-5: 6.7	C20 Händedesinfektion PrEN 12054 (Juli 2001) bactericidal Activity - phase 2/step 1 Hygienic handrub (German Original, English Translation)	Werner, H.P.	2002	Orochemie GmbH + Co. KG.
120	For meta SPC 2-5: 6.7	C20 Händedesinfektion prEN 12054 (July 2001) bactericidal activity - phase 2/step 1 Hygienic handrub (German original, English translation)	Werner, H.P.	2002	Orochemie GmbH + Co. KG.
121	For meta SPC 2-3: 6.7	C20 Skin disinfection - test under practical conditions with 20 volunteers (German Original, English Translation)	Werner H.P.	2012	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
122	For meta SPC 1-5: 6.7	Prüfung und Deklaration der Wirksamkeit von Desinfektionsmitteln gegen Viren zur Anwendung im human-medizinischen Bereich	Schwebke	2017	Published
123	6.8.1	Epidemiologic Background of Hand Hygiene and Evaluation of the Most Important Agents for Scrubs and Rubs	Kampf, G., Kramer, A.	2004	Published
124	6.8.1	Antiseptics and Disinfectants: Activity, Action, and Resistance	McDonnel, G., Rusell, D.	1998	Published
125	6.8.2	BUS-Modell: Hautverträglichkeit: Händedesinfektionsmittel / Waschlotionen	Pittermann, W.	2014	
126	10.2	Orochemie hand-and surface disinfectants - Emission scenarios for calculating the release of Propan-2-ol based on the annual tonnage	Bradatsch, C.	2016	Orochemie GmbH + Co. KG.
127	For meta SPC 1: 11	Sicherheitsdatenblatt: C 25 Händedesinfektiogel	Anonymous	2016a	Orochemie GmbH + Co. KG.
128	For meta SPC 1: 11	Safty Data Sheet: C25 Disinfection Hand Gel	Anonymous	2014	Orochemie GmbH + Co. KG.
129	For meta SPC 4: 11	Sicherheitsdatenblatt: B 35 Schnelldesinfektion	Anonymous	2016b	Orochemie GmbH + Co. KG.
130	5	Sicherheitsdatenblatt: B 35 Desinfektionstücher	Anonymous	2016c	Orochemie GmbH + Co. KG.
131	For meta SPC 4: 11	Sicherheitsdatenblatt: B 38 Schnelldesinfektion	Anonymous	2016d	Orochemie GmbH + Co. KG.
132	For meta SPC 5: 11	Sicherheitsdatenblatt B 38 Desinfektionstücher	Anonymous	2016e	Orochemie GmbH + Co. KG.
133	For meta SPC 2: 11	Sicherheitsdatenblatt: C 20 Hände + Haut Desinfektion	Anonymous	2016f	Orochemie GmbH + Co. KG.
134	For meta SPC 2: 11	Sicherheitsdatenblatt: C 22 Händedesinfektion	Anonymous	2016g	Orochemie GmbH + Co. KG.
135	For meta SPC 1: 11	Sicherheitsdatenblatt: C 22 Händedesinfektionsgel	Anonymous	2016h	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
136	For meta SPC 3: 11	Sicherheitsdatenblatt: C 22 wipes Händedesinfektion	Anonymous	2016i	Orochemie GmbH + Co. KG.
137	For meta SPC 2: 11	Sicherheitsdatenblatt: C 25 Händedesinfektion	Anonymous	2016j	Orochemie GmbH + Co. KG.
138	For meta SPC 3: 11	Sicherheitsdatenblatt: C 25 wipes Händedesinfektion	Anonymous	2016k	Orochemie GmbH + Co. KG.
139	For meta SPC 4: 11	Sicherheitsdatenblatt: FD 335 Schnelldesinfektion	Anonymous	2016	Orochemie GmbH + Co. KG.
140	For meta SPC 5: 11	Sicherheitsdatenblatt: FD 335 wipes Schnelldesinfektion	Anonymous	2016l	Orochemie GmbH + Co. KG.
141	For meta SPC 4: 11	Sicherheitsdateblatt: FD 338 Schnelldesinfektion	Anonymous	2016m	Orochemie GmbH + Co. KG.
142	For meta SPC 5: 11	Sicherheitsdatenblatt: FD 338 wipes Schnelldesinfektion	Anonymous	2016n	Orochemie GmbH + Co. KG.
143	For meta SPC 2: 11	Sicherheitsdatenblatt: HD 415 Händedesinfektion	Anonymous	2016o	Orochemie GmbH + Co. KG.
144	For meta SPC 1: 11	Sicherheitsdatenblatt: HD 415 Händedesinfektionsgel	Anonymous	2016p	Orochemie GmbH + Co. KG.
145	For meta SPC 3: 11	Sicherheitsdatenblatt: HD 415 wipes Händedesinfektion	Anonymous	2016q	Orochemie GmbH + Co. KG.
146	For meta SPC 2: 11	Safety Data Sheet according to Regulation EC No. 1907/2006 (REACH), C 20 Hand + Skin Disinfectant	Anonymous	2016r	Orochemie GmbH + Co. KG.
147	For meta SPC 2: 11	Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH), HD 412 essential Hand disinfection	Anonymous	2015	Orochemie GmbH + Co. KG.
148	For meta SPC 2: 11	SICHERHEITSDATENBLATT C 20 LIQUID HÄNDE + HAUT DESINFEKTION	Anonymous	2016t	Orochemie GmbH + Co. KG.
149	For meta SPC 3: 11	SICHERHEITSDATENBLATT C 20 WIPES HÄNDEDESINFEKTION	Anonymous	2016u	Orochemie GmbH + Co. KG.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
150	2 For meta SPC 2: 11	SICHERHEITSDATENBLATT HD 412 LIQUID HÄNDEDESINFEKTION	Anonymous	2016v	Orochemie GmbH + Co. KG.
151	For meta SPC 1: 11	SICHERHEITSDATENBLATT HD 412 HÄNDE-DESINFEKTIONSGEL	Anonymous	2016w	Orochemie GmbH + Co. KG.
152	For meta SPC 3: 11	Sicherheitsdatenblatt HD 412 wipes Hände-desinfektion	Anonymous	2016x	Orochemie GmbH + Co. KG.
153	For meta SPC 1-5: 11	Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) - C 20 Hand + Skin Disinfectant	Wolf K.M., Gehring E.	2015	Orochemie GmbH + Co. KG.
154	12.1	Safety data sheet C 20 spray solution	Wolf K.M., Gehring E.	2015	Orochemie GmbH + Co. KG.
155	For meta SPC 2-3: 12.7	Verpackungsmaterial (Primärpackmittel) / Pack-aging material (primary material)	Anonymous	N.A.	
156	For meta SPC 1,2,4: 12.7	10-l-Kanister / 10-litre-canister	Anonymous	2016a	
157	For meta SPC 1,2,4: 12.7	5-L-Kanister / 5-liter-canister	Anonymous	2016b	
158	For meta SPC 1,2,4: 12.7	2,5-L-Flasche / 2,5-litre-bottle	Anonymous	2016c	
159	For meta SPC 1,2,4: 12.7	1-L-Vierkantflasche / 1-litre-rectangular bottle	Anonymous	2016d	
160	For meta SPC 1,2,4: 12.7	0,5-l-Vierkantflasche / 0,5-litre rectangular bottle	Anonymous	2016	
161	For meta SPC 2,4: 12.7	125 ml-Flasche / 125 ml-bottle	Anonymous	2016e	
162	For meta SPC 1: 12.7	100 ml-Flasche (oval) / 100-ml bottle (oval)	Anonymous	2016f	
163	For meta SPC 1: 12.7	100 ml-Flasche (rund) / 100-ml bottle (round)	Anonymous	2016f	
164	For meta SPC 1: 12.7	C 25 Händedesinfektionsgel - Produktinfor-mation	Anonymous	2016g	

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
165	For meta SPC 5: 12.7	Getränkte Tücher für die Flächendesinfektion, 100 Stück / wet wipes for surface disinfection, 100 pieces	Anonymous	2016h	
166	For meta SPC 1, 3: 12.7	Getränkte Tücher 110 Stück / wet wipes, 110 pieces	Anonymous	2015	
167	For meta SPC 1: 12.7	Packaging specification Wet wipes for hand disinfection; Getränktes Einzeltuch für Händedesinfektion, 1 Stück	Anonymous	N.A.	
168	For meta SPC 2: 12.7	C 20 Hände + Haut Desinfektion PRODUKTINFORMATION	Anonymous	2016i	
169	For meta SPC 2: 12.7	HD 412 essential Hände-Desinfektion, Produktinformation	Anonymous	2015	
170	For meta SPC 2-5: 6.7	Test report 2020-3193	Werner, S.	2021	Orochemie GmbH + Co. KG.
171	For meta SPC 2-5: 6.7	Study report 2020-3194	Werner, S.	2021	Orochemie GmbH + Co. KG.

4.2 New information on the active substance propan-2-ol

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).

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

Overview of professional exposure and risk characterisation

Output_tables_occu
pational_exposure.pc

Risk characterisation
for professionals

4.3.2 Safety for the general public

Consexpo Reports

1. Scenario 7 (general public), estimation of the aerial concentration Tier 2

ConsExpo 4.1 report

Product

Orochemie

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		gram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	63.1	%
exposure duration	24	hour
room volume	80	m3
ventilation rate	1.5	1/hr
applied amount	7.02	gram
release duration	2.01	minute

Uptake model: Fraction

uptake fraction	100	%

Output

Inhalation (point estimates)

inhalation mean event concentration :	1.54	mg/m3
inhalation mean concentration on day of exposure:	1.54	mg/m3