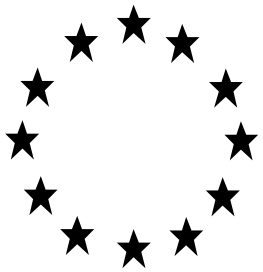
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



Product family identifier in R4BP	perform-IPA
Product type(s):	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-AB023095-72
Asset/Authorisation No. in R4BP	EU-0023656-0000
Evaluating Competent Authority	Germany (DE; BAuA)
Internal registration/file no	5.0-710 31/01.00001 710-31-01-00001-00-00-00-0000
Date	20.03.2020 (initial assessment)

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1 Overall Conclusion

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product/biocidal product family.

General

The biocidal product family consists of products containing the active substance Propan-2-ol (63.1% w/w; 70% v/v) for disinfection of clean non-pourous surfaces, which are not used for direct contact with food or feeding stuffs (PT 02) and for disinfection of clean non porous-surfaces in food and feed area (PT 04). No substances of concern are identified. For a co-formulant concerns were identified with respect to its endocrine-disrupting properties.

The biocidal product family consists of eight meta SPCs with ready-to-use liquids (meta SPCs 1, 3, 7) and ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8). The user categories are professional (including industrial) user (meta SPCs 1 - 8) and non-professional user (meta SPC 6).

The following uses have been assessed:

***meta* SPC 1 :**

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 2 :**

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 3 :**

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 4 :**

- Use 1: Disinfection of surfaces – wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 5 :**

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 6 :**

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 7 :**

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

***meta* SPC 8 :**

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact – wiping

Physico-chemical properties

The products within the family are colourless and have an alcoholic odour. The pH of the products within the family ranges from approximately 7.2 to 7.7, the density is around 0.876 g/cm³.
The products (ready-to-use liquids) of meta SPC 1, 3 and 7 have a shelf-life of 36 months, whereas products (ready-to-use wipes) of meta SPC 2, 4, 5, 6 and 8 have a shelf-life of 24 months.

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

The analytical methods for detection and identification for the BPF are deemed acceptable.

Efficacy

Proven efficacy for disinfection of non-porous surfaces by spraying with ready-to-use liquids (meta SPCs 1, 3, 7):

- PT2 and PT4: bactericidal (including tuberculocidal) and yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C
- PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C

Proven efficacy for disinfection of non-porous surfaces by wiping with ready-to-use liquids (meta SPCs 1, 3, 7) or ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8):

- PT2 and PT4: bactericidal (including tuberculocidal) efficacy within a contact time of 5 minutes under clean conditions at 20°C
- PT2 and PT4: yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C
- PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C

It can be concluded that products of the BPF show sufficient bactericidal and yeasticidal activity as substantiated according to European Standards (EN) in PT2 and PT4. Furthermore, the products show sufficient 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 have been met.

To ensure the efficacy of the products, the following instructions for use are defined in the SPC:

- Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate.
- Make sure to wet surfaces completely.

Human health

Professional user/ industrial user

Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6, 7 and 8 (wipes). The exposure assessment for professional/industrial users for biocidal products of meta SPC 2, 5, 6, 7 and 8 is covered by the exposure assessment for biocidal products of meta SPC 1.
Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). The exposure assessment for professional / industrial users for biocidal products of meta SPC 4 is covered by the exposure assessment for biocidal products of meta SPC 3.

Meta SPC 1

The exposure assessments are based on model assumptions.
Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional/industrial users resulting from the intended uses 'Small surface disinfection in patient rooms (PT02)', 'Small surface disinfection in laboratory and biotechnology (PT02), 'Small surface disinfection in kitchens and canteens (PT04)' as wells as 'Disinfection of food processing machinery (PT04)' and secondary exposure with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100% after TIER 1 consideration.

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 has 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 (2015) is "low".

Based on the systemic and qualitative risk assessment for local effects regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the restriction of the application rate to 25 ml/m² and the use only for disinfection of small surfaces. Based on the local effects to eyes it is recommended to use eye protection for refilling and for disinfection of food processing machinery for ready-to-use liquids only. For ready-to-use wipes a labelling advice to avoid contact to eyes is required.

Meta SPC 3

The exposure assessments are based on model assumptions.
Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional/industrial users resulting from the intended uses 'Small surface disinfection in patient rooms (PT02)', 'Small surface disinfection in laboratory and biotechnology (PT02), 'Small surface disinfection in kitchens and canteens (PT04)' as wells as 'Disinfection of food processing machinery (PT04)' and secondary exposure with the biocidal products covered by meta SPC 3 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100% after TIER 1 consideration. Based on the systemic and qualitative risk assessment for local effects regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the restriction of the application rate to 25 ml/m and the use only for disinfection of small surfaces. Based on the local effects to eyes it is recommended to use eye protection for refilling and for disinfection of food processing machinery for ready-to-use liquids only. For ready-to-use wipes a labelling advice to avoid contact to eyes is required.

Non-Professional user and general public

No human health risk from use of biocidal products for Meta-SPC 6 by non-professional users was identified if the biocidal products are used as intended. To avoid excessive use the typical application rate in a simple form easily understandable for the non-professional user has to appear on the label (e.g. Use one wipe per m^2 surface). In addition, the biocidal product has to be stored out of the reach of children since the unattended use/misuse of the biocidal product by smaller children may result in human health hazards.

Human health hazard based on the classification of the biocidal product as Eye Irrit. 2, H319 and STOT SE 3, H336 can be sufficiently controlled by the corresponding precautionary statements. In addition, a labelling advice to avoid contact to eyes is required.

No human health risk was identified for secondary exposure of the general public (adults and older children) resulting from professional and non-professional use of the biocidal product family. This includes combined exposure to PT02 and PT04. However, for smaller children (toddlers) a risk was identified, if they enter treated areas immediately after application. Safe re-entry is only possible after adequate ventilation. An appropriate labelling is required. The following labelling has to be included which contains also measures to avoid potential risks for children and pets: “Keep children and pets away from rooms where disinfection is taking place.” and “Provide adequate ventilation before children and pets enter treated rooms”.

Dietary exposure/ Consumer risk assessment

For the intended uses of the BPF, due to its high vapour pressure, dietary exposure to humans can be excluded.

Environment

As concluded in the product assessment report no unacceptable risks for the environment are to be expected from the use of the biocidal products in the meta-SPCs of the biocidal product family “Perform-IPA”, the conditions for granting a union authorisation are formally met.

The products in the biocidal product family “Perform-IPA” containing Propan-2-ol are intended for disinfection of non-porous surfaces indoor only, therefore there will be no direct exposure of the environment. However, the application of products part of the BPF “Perform-IPA” used for disinfection can result in indirect exposure via STP. The assessment demonstrated an acceptable risk for all environmental compartments. No risk mitigation measures are necessary.

b) Presentation of the biocidal product/biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product (family) according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

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

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product/biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product family in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

perform-IPA

2.1.2 Product type(s)

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

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	Schülke und Mayr GmbH
Address of manufacturer	Robert-Koch-Str. 2 22851 Norderstedt Germany
Location of manufacturing sites	Robert-Koch-Str. 2 22851 Norderstedt Germany

Name of manufacturer	BOCHEMIE a.s.
Address of manufacturer	Lidická 326 735 95 Bohumín Czech Republic
Location of manufacturing sites	Lidická 326 735 95 Bohumín Czech Republic

Name of manufacturer	Imeco
Address of manufacturer	Boschstr. 5 63768 Hösbach Germany
Location of manufacturing sites	Boschstr. 5 63768 Hösbach Germany
	Neue Straße 2-4 09471 Königswalde Germany

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

Name of manufacturer	Techtex
Address of manufacturer	Units 7&8 Rhodes Bus. Park Silburn Way Middleton M24 4NE United Kingdom
Location of manufacturing sites	Units 7&8 Rhodes Bus. Park Silburn Way Middleton M24 4NE United Kingdom

Name of manufacturer	A.F.P. GmbH
Address of manufacturer	Otto Brenner Straße 16 21337 Lüneburg Germany
Location of manufacturing sites	Otto Brenner Straße 16 21337 Lüneburg Germany

Name of manufacturer	Innovate GmbH
Address of manufacturer	Am Hohen Stein 11 06618 Naumburg (Saale) Germany
Location of manufacturing sites	Am Hohen Stein 11 06618 Naumburg (Saale) Germany

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH
Address of manufacturer	Kaiser-Wilhelm-Straße 133 12247 Berlin Germany
Location of manufacturing sites	Kaiser-Wilhelm-Straße 133 12247 Berlin Germany

Name of manufacturer	Sterisol AB
Address of manufacturer	Kronoängsgatan 3 592 23 Vadstena Sweden

Location of manufacturing sites	Kronoängsgatan 3 592 23 Vadstena Sweden

Name of manufacturer	Rudolf Dankwardt GmbH
Address of manufacturer	Gutenbergring 50-52 22848 Norderstedt Germany
Location of manufacturing sites	Gutenbergring 50-52 22848 Norderstedt Germany
	Lagerstr. 15 19249 Jessenitz - Werk / Lübtheen Germany

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

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
	Shamrockstr. 88 44643 Herne Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334 3000 CH Rotterdam The Netherlands
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam-Pernis The Netherlands

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

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

The given content of 63.1% (w/w) refers to the technical active substance. The pure a.s. content based on the minimum purity of the a.s. is 63.0% (w/w).

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

2.2.2 Information on technical equivalence

The sources of the active substance are the same as the ones evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation No. 528/2012.

2.2.3 Information on endocrine disrupting properties

The BPF is not considered to have endocrine disrupting properties. For further Information, please see chapter 3.6.4.4 and 3.8.5.6 and confidential PAR.

2.2.4 Information on the substance(s) of concern

No substance of concern (SoC) was identified.
None of the co-formulants contained in the BPF triggers the classification of the respective meta SPCs. Thus, none of the co-formulants must be considered as an SoC. For details on the composition refer to the confidential PAR.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type(s) of formulation

meta SPCs 1, 3 and 7: Any other liquid (AL), ready-to-use
meta SPCs 2, 4, 5, 6 and 8: Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The products of meta SPCs 1, 3 and 7 are ready to use products which are amongst others stored with spray heads.
The products of meta SPCs 2, 4, 5, 6 and 8 are wipes impregnated with the disinfectant formulation. The specification of the wipes is given in the confidential annex.

2.3 Meta SPC 1 (second information level)

2.3.1 Administrative Information

2.3.1.1 Meta SPC identifier

meta SPC 1 perform IPA liquid

2.3.1.2 Suffix to the authorisation number

1-1

2.3.1.3 Product type(s)

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

2.3.2 Composition and formulation

2.3.2.1 Qualitative and quantitative information on the composition

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

2.3.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use

2.3.3 Classification and Labelling according to the Regulation (EC) 1272/2008[1]

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPCs.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). In addition, the biocidal product family has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

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

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 + P235	Store in a well-ventilated place. Keep cool.

	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.3.4 Use(s) appropriate for authorisation

2.3.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - spraying

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Spraying (Product will be sprayed directly on the surface)
Application rate(s) and frequency	Ready-to-use Disinfection after each production and cleaning process or when required according to standard operating procedure (SOP) Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: high-density polyethylene (HDPE), surlyn/polypropylene (PP) closure material is either: PP, polyoxymethylene (POM), low-density polyethylene (LDPE), HDPE, polyethylene (PE), ethylene-vinyl acetate (EVA), stainless steel, polybutylene terephthalate (PBT), (LD)PE, exp. polytetrafluoroethylene (PTFE), linear low density polyethylene (LLDPE), expanded PE (EXPPE), Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

2.3.4.1.1 Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 minute.

2.3.4.1.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.3.4.2 Use 2 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use Disinfection after each production and cleaning process or when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP.

	canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

2.3.4.2.1 Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.3.4.2.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.3.4.3 Use 3 appropriate for authorisation – disinfection of surfaces with food and feed contact - spraying

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)

	Indoor use
Application method(s)	Product will be sprayed directly on the surface
Application rate(s) and frequency	Ready-to-use Disinfection after each production and cleaning process or when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

2.3.4.3.1 Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

2.3.4.3.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.3.4.4 Use 4 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use Disinfection after each production and cleaning process or when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

2.3.4.4.1 Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.3.4.4.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.3.5 General directions for use

2.3.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Do not apply more than 25 ml/m². Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.3.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Apply a funnel for refilling. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid: In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If on skin: Wash with water. If skin irritation occurs: Get medical advice. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.3.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 36 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.3.5.6 Other information

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

2.4 Meta SPC 2 (second information level)

2.4.1 Administrative information

2.4.1.1 Meta SPC identifier

meta SPC 2 perform wipes IPA

2.4.1.2 Suffix to the authorisation number

1-2

2.4.1.3 Product type(s)

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

2.4.2 Composition and formulation

2.4.2.1 Qualitative and quantitative information on the composition

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

2.4.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The specification of the wipes is given in the confidential annex.

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 + P235	Store in a well-ventilated place. Keep cool.

	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.4.4 Use(s) appropriate for authorisation

2.4.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; biaxially oriented polypropylene (BOPP) + cast polypropylene (CPP) Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.4.4.1.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20±2°C).

2.4.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.4.4.2 Use 2 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.4.4.2.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.4.4.2.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.4.5 General directions for use

2.4.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.4.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If on skin: Wash with water. If skin irritation occurs: Get medical advice. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.4.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 24 months Keep container tightly closed. Store in a well-ventilated place. Protect from sunlight. Store at room temperature in the original container.

2.4.5.6 Other information

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

2.5 Meta SPC 3 (second information level)

2.5.1 Administrative information

2.5.1.1 Meta SPC identifier

meta SPC 3 mikrozid liquid

2.5.1.2 Suffix to the authorisation number

1-3

2.5.1.3 Product type(s)

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

2.5.2 Composition and formulation

2.5.2.1 Qualitative and quantitative information on the composition

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

2.5.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 +	Store in a well-ventilated place. Keep cool.

	P235	
	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.5.4 Use(s) appropriate for authorisation

2.5.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - spraying

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Spraying (Product will be sprayed directly on the surface)
Application rate(s) and frequency	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure : PP/Silicone/EVA

2.5.4.1.1 Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 minute.

2.5.4.1.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.5.4.2 Use 2 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP

	canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA

2.5.4.2.1 Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.5.4.2.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.5.4.3 Use 3 appropriate for authorisation – disinfection of surfaces with food and feed contact - spraying

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast, viruses

Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Spraying (Product will be sprayed directly on the surface)
Application rate(s) and frequency	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure : PP/Silicone/EVA

2.5.4.3.1 Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

2.5.4.3.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.5.4.4 Use 4 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on surface.
Application rate(s) and frequency	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA.

2.5.4.4.1 Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.5.4.4.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.5.5 General directions for use

2.5.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Do not apply more than 25 ml/m². Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.5.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Apply a funnel for refilling. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid: In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.5.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 36 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.5.5.6 Other information

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

2.6 Meta SPC 4 (second information level)

2.6.1 Administrative information

2.6.1.1 Meta SPC identifier

meta SPC 4 mikrozid wipes

2.6.1.2 Suffix to the authorisation number

1-4

2.6.1.3 Product type(s)

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

2.6.2 Composition and formulation

2.6.2.1 Qualitative and quantitative information on the composition

Table 1

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

2.6.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The specification of the wipes is given in the confidential annex.

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.

	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.6.4 Use(s) appropriate for authorisation

2.6.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection when required according to SOP
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.6.4.1.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.6.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.6.4.2 Use 2 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection when required according to SOP
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.6.4.2.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.6.4.2.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.6.5 General directions for use

2.6.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.6.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid: In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.6.5.4 Instructions for safe disposal of the product and its packaging

-

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

Shelf-life: 24 months Keep container tightly closed. Store in a well-ventilated place. Protect from sunlight. Store at room temperature in the original container.

2.6.5.6 Other information

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

2.7 Meta SPC 5 (second information level)

2.7.1 Administrative information

2.7.1.1 Meta SPC identifier

meta SPC 5 kodan wipes IPA pro

2.7.1.2 Suffix to the authorisation number

1-5

2.7.1.3 Product type(s)

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

2.7.2 Composition and formulation

2.7.2.1 Qualitative and quantitative information on the composition

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

2.7.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The specification of the wipes is given in the confidential annex.

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 + P235	Store in a well-ventilated place. Keep cool.

	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.7.4 Use(s) appropriate for authorisation

2.7.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.7.4.1.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.7.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.7.4.2 Use 2 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.7.4.2.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.7.4.2.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.7.5 General directions for use

2.7.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.7.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid: In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.7.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 24 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.7.5.6 Other information

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

2.8 Meta SPC 6 (second information level)

2.8.1 Administrative information

2.8.1.1 Meta SPC identifier

meta SPC 6 kodan wipes IPA

2.8.1.1.1 Suffix to the authorisation number

1-6

2.8.1.2 Product type(s)

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

2.8.2 Composition and formulation

2.8.2.1 Qualitative and quantitative information on the composition

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

2.8.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The specification of the wipes is given in the confidential annex.

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.

	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

For non-professional user the following has to be considered:
In fact H319 would trigger P280 (Wear eye protection/face protection.). However, for non-professional use correct use of personal protective equipment cannot be assumed. Based on a qualitative risk assessment an additional advice (labelling) with “Avoid contact with eyes” and the other precautionary statements P305 + P351 + P338 and P337 + P313 are considered sufficient to protect the non-professional user from the corresponding risk. H319 also trigger P264 (Wash … thoroughly after handling.). This precautionary statement is also not required since the biocidal product is also intended for use on hands and other body parts. If it is washed away efficacy might not be sufficient. In addition, propan-2-ol is very volatile and will be evaporate from contaminated skin rapidly. Thus, washing of hands or other body parts is not necessary.

For professional user the following has to be considered:
In fact H319 would trigger P280 (Wear eye protection/face protection.). However, the product in meta-SPC 6 consists only of RTU wipes, the WG V-2019 agreed that P280 can be removed as there is no risk of eye contact.

2.8.4 Use(s) appropriate for authorisation

2.8.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user non-professional user

Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.8.4.1.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.8.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.8.4.2 Use 2 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	bacteria including Mycobacterium tuberculosis, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping

	Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user non-professional user
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2.8.4.2.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

2.8.4.2.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.8.5 General directions for use

2.8.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.
Used wipes must be disposed in a closed container.

2.8.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces.
Ensure adequate ventilation to prevent the formation of explosive atmospheres.
Avoid contact with eyes.
Keep out of the reach of children and pets.
Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:
In case of accident: Call a poison centre or a doctor.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If on skin: Wash with water. If skin irritation occurs: Get medical advice.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.8.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 24 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.8.5.6 Other information

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

2.9 Meta SPC 7 (second information level)

2.9.1 Administrative information

2.9.1.1 Meta SPC identifier

meta SPC 7 AntiLy SD

2.9.1.2 Suffix to the authorisation number

1-7

2.9.1.3 Product type(s)

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

2.9.2 Composition and formulation

2.9.2.1 Qualitative and quantitative information on the composition

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

2.9.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	P403 + P235	Store in a well-ventilated place. Keep cool.

	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.9.4 Use(s) appropriate for authorisation

2.9.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - spraying

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Spraying (Product will be sprayed directly on the surface)
Application rate(s) and frequency	Ready-to-use Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

2.9.4.1.1 Use-specific instructions for use

Spray the ready-to-use product onto the surfaces and allow to take effect for at least 1 minute at room temperature (20±2 °C).

2.9.4.1.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.9.4.2 Use 2 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).
Application rate(s) and frequency	Ready-to-use Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

2.9.4.2.1 Use-specific instructions for use

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20±2 °C).

2.9.4.2.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.9.4.3 Use 3 appropriate for authorisation – disinfection of surfaces with food and feed contact - spraying

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Spraying (Product will be sprayed directly on the surface).
Application rate(s) and frequency	Ready-to-use Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

2.9.4.3.1 Use-specific instructions for use

Spray ready-to-use product onto the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

2.9.4.3.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.9.4.4 Use 4 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).
Application rate(s) and frequency	Ready-to-use Do not apply more than 25 ml/m².
Category(ies) of users	industrial user professional user

Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

2.9.4.4.1 Use-specific instructions for use

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20 ±2°C).

2.9.4.4.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.9.5 General directions for use

2.9.5.1 Instructions for use

Clean the surface carefully before use.
Remove excess water from the surface before disinfection, if appropriate.
Do not apply more than 25 ml/m².
Make sure to wet surfaces completely.
Used wipes must be disposed in a closed container.

2.9.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces.
Ensure adequate ventilation to prevent the formation of explosive atmospheres.
Avoid contact with eyes.
Apply a funnel for refilling.Keep out of reach of children and pets.
Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:
In case of accident: Call a poison centre or a doctor.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If on skin: Wash with water. If skin irritation occurs: Get medical advice.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.9.5.4 Instructions for safe disposal of the product and its packaging

-

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

Shelf-life: 36 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.9.5.6 Other information

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

2.10 Meta SPC 8 (second information level)

2.10.1 Administrative information

2.10.1.1 Meta SPC identifier

meta SPC 8 AntiLy SD wipes

2.10.1.2 Suffix to the authorisation number

1-8

2.10.1.3 Product type(s)

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

2.10.2 Composition and formulation of the products within the meta SPC

2.10.2.1 Qualitative and quantitative information

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

2.10.2.2 Type(s) of formulation

Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

The specification of the wipes is given in the confidential annex.

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

Besides the active substance propan-2-ol, the other components do not affect the classification of the products in the meta SPC.
The current harmonised classification of the active substance propan-2-ol is based on Annex VI of Regulation (EC) No 1272/2008. In addition, the BPF has to be labelled with EUH066 based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.

Classification Hazard classes, Hazard categories	Hazard statements	
Flam. Liq. 2	H225	
Eye Irrit 2	H319	
STOT SE 3	H336	
Labelling		
	Code	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H225	Highly flammable liquid and vapour.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	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.
	P240	Ground/bond container and receiving equipment.
	P241	Use explosion-proof electrical/ventilating/lighting equipment.
	P242	Use only non-sparking tools.
	P243	Take precautionary measures against static discharge.
	P261	Avoid breathing vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
	P312	Call a POISON CENTER/ doctor if you feel unwell.
	P337 + P313	If eye irritation persists get medical advice/attention.
	P370 + P378	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.

	P403 + P235	Store in a well-ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container to an approved waste disposal plant.
Note	-	-

2.10.4 Use(s) appropriate for authorisation

2.10.4.1 Use 1 appropriate for authorisation – disinfection of surfaces - wiping

Product Type(s)	02
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

2.10.4.1.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ±2°C).

2.10.4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.10.4.2 Use 2 appropriate for authorisation – disinfection of surfaces with food and feed contact - wiping

Product Type(s)	04
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria, yeast, viruses
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B) Indoor use
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	industrial user professional user
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

2.10.4.2.1 Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ±2°C).

2.10.4.2.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.10.5 General directions for use

2.10.5.1 Instructions for use

Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate. Make sure to wet surfaces completely. Used wipes must be disposed in a closed container.

2.10.5.2 Risk mitigation measures

The product must only be applied for disinfection of small surfaces. Ensure adequate ventilation to prevent the formation of explosive atmospheres. Avoid contact with eyes. Keep out of reach of children and pets. Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid: In case of accident: Call a poison centre or a doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If on skin: Wash with water. If skin irritation occurs: Get medical advice. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.10.5.4 Instructions for safe disposal of the product and its packaging

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

Shelf-life: 24 months
Keep container tightly closed.
Store in a well-ventilated place.
Protect from sunlight.
Store at room temperature in the original container.

2.10.5.6 Other information

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

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

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

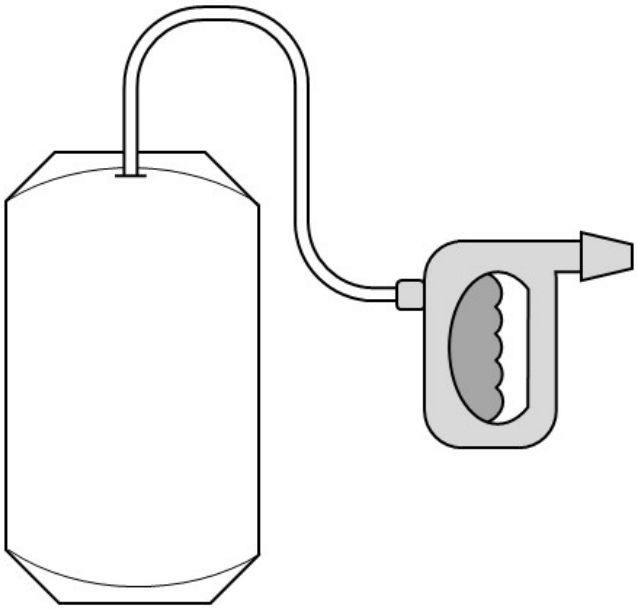
2.12 Packaging

Table 2 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Bottle	250 ml – 1000 ml	HDPE, surlyn/PP	PP Pump device: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP	professional, industrial	Yes
Canister	5 -10 l	HDPE	HDPE/LDPE	professional, industrial	Yes
Soft Pack	1-200 wipes	LDPE/PET, BOPP+CPP, LDPE/Alu/PET	-	professional, industrial, non-professional	Yes
Pouch	10-200 wipes	LDPE/PET	-	professional, industrial, non-professional	Yes
Tube	50-200 wipes	HDPE	PP, PE3385	professional, industrial, non-professional	Yes
Revolver bag*	1 l	EVA	PP/Silicone/EVA	professional, industrial	Yes
Bottle	125 – 1000 ml	HDPE	Clack cap: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray	professional, industrial	yes

			head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)		
Canister	5 – 30 L	HDPE	HDPE	professional, industrial	yes
Drum	220 L	HDPE	PP	professional, industrial	yes
Container	1000 L, IBC	HDPE	HDPE	professional, industrial	yes
Can	100 -150 wipes	HDPE	HDPE	professional, industrial	yes
Refill pack	100- 150 wipes	PET/PE	-	professional, industrial	yes

*__Additional information__: revolver bag



Kind of infusion bag combined with a spray head.

3 Assessment of the biocidal product family

3.1 Intended use(s) as applied for by the applicant[2][3]

[2] With letter of 22.12.2016 the applicant **withdrew the original application** for all uses in product type 01 (human hygiene).

[3] The SPC as applied for contains additional uses which are combinations of the uses listed in chapter 3.1.1 to 3.1.8. The eCA assessed the different uses as listed in this chapter 3.1.1 to 3.1.8 and intended to present additional combinations of the uses appropriate for authorisation in the summary chapter 2 and the SPC. This was discussed with and agreed by the applicant. However, due to different target organisms, risk mitigation measures and instructions for use and due to the agreed SPC structure, **the use combinations applied for are not possible.** A list of the relevant use combinations is given in chapter 3.1.9.

3.1.1 meta SPC 1

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be sprayed directly on the surface	Ready-to-use Disinfection after each production / cleaning process or when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

2	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be sprayed / poured on the surface and wiped afterwards or wipe will be soaked by spraying / pouring with product and wiped on surface	Ready-to-use Disinfection after each production / cleaning process or when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.
3	Contact liquid Water based liquid	4	Food and feed area	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be sprayed directly on the surface	Ready-to-use Disinfection after each production / cleaning process or when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4	Contact liquid Water based liquid	4	Food and feed area	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be sprayed / poured on the surface and wiped afterwards or wipe will be soaked by spraying / pouring with product and wiped on surface	Ready-to-use Disinfection after each production / cleaning process or when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

3.1.2 meta SPC 2

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Wipes impregnated with Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be wiped directly on the surface	Ready-to-use wipes Disinfection after each production / cleaning process or when required according to SOP	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385
2	Wipes impregnated with Contact liquid Water based liquid	4	Food and feed area	bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B) Indoor use	Product will be wiped directly on the surface	Ready-to-use wipes Disinfection after each production / cleaning process or when required according to SOP	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

3.1.3 meta SPC 3

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be sprayed directly on the surface	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA.

2	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be sprayed / poured on the surface and wiped afterwards or wipe will be soaked by spraying / pouring with product and wiped on surface	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA.
3	Contact liquid Water based liquid	4	Food and feed area	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be sprayed directly on the surface	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA.

4	Contact liquid Water based liquid	4	Food and feed area	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be sprayed / poured on the surface and wiped afterwards or wipe will be soaked by spraying / pouring with product and wiped on surface	Ready-to-use Disinfection when required according to SOP Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA, Closure : PP/Silicone/EVA.

3.1.4 meta SPC 4

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Wipes impregnated with Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be wiped directly on the surface	Ready-to-use wipes Disinfection when required according to SOP	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2	Wipes impregnated with Contact liquid Water based liquid	4	Food and feed area	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses)	Disinfection of non-porous surfaces Indoor use	Product will be wiped directly on the surface	Ready-to-use wipes Disinfection when required according to SOP	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

3.1.5 meta SPC 5

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Wipes impregnated with Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses, noroviruses)	Disinfection of non-porous surfaces. Indoor use	Thoroughly wipe the surface with the impregnated wipe and allow to take effect. Make sure to wet surfaces completely and keep them wet for the whole exposure time. Make sure that all visible dirt is removed prior to disinfection.	Ready-to-use wipes If required	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2	Wipes impregnated with Contact liquid Water based liquid	4	Food and feed area	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses, noroviruses)	Disinfection of non-porous surfaces. Indoor use	Thoroughly wipe the surface with the impregnated wipe and allow to take effect. Make sure to wet surfaces completely and keep them wet for the whole exposure time. Make sure that all visible dirt is removed prior to disinfection.	Ready-to-use wipes If required	industrial user professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

3.1.6 meta SPC 6

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Wipes impregnated with Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses, noroviruses)	Disinfection of non-porous surfaces. Indoor use	Thoroughly wipe the surface with the impregnated wipe and allow to take effect. Make sure to wet surfaces completely and keep them wet for the whole exposure time. Make sure that all visible dirt is removed prior to disinfection.	Ready-to-use wipes If required	industrial user professional user non-professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

2	Wipes impregnated with Contact liquid Water based liquid	4	Food and feed area	bacteria incl. Tb, fungi (Candida albicans), limited spectrum virucidal activity (incl. HIV, HBV, HCV, herpes simplex viruses, influenza viruses, rotaviruses, adenoviruses, noroviruses)	Disinfection of non-porous surfaces. Indoor use	Thoroughly wipe the surface with the impregnated wipe and allow to take effect. Make sure to wet surfaces completely and keep them wet for the whole exposure time. Make sure that all visible dirt is removed prior to disinfection.	Ready-to-use wipes If required	industrial user professional user non-professional user	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP; Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

3.1.7 meta SPC 7

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	Bacteria, yeast, limited spectrum virucidal activity (incl. HIV, HBV, HCV and non-enveloped virus, rotavirus)	Disinfection of non-porous surfaces Indoor use	Spray or pour a sufficient amount of the product directly on the surface. Make sure that all visible soiling is removed before disinfection.	Ready-to-use before and after every procedure or if required Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)
2	Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	Bacteria, yeast, limited spectrum virucidal activity (incl. HIV, HBV, HCV and non-enveloped virus, rotavirus)	Disinfection of non-porous surfaces Indoor use	Apply a sufficient amount of the product on wipes by pouring, spraying or soaking and wipe the surface thoroughly (wet-wiping). Make sure that all visible soiling is removed before disinfection.	Ready-to-use before and after every procedure or if required Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

3	Contact liquid Water based liquid	4	Food and feed area	Bacteria, yeast, limited spectrum virucidal activity (incl. HIV, HBV, HCV and non-enveloped virus, rotavirus)	Disinfection of non-porous surfaces Indoor use	Spray or pour a sufficient amount of the product directly on the surface. Make sure that all visible soiling is removed before disinfection.	Ready-to-use Every cleaning or disinfection process or if required Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)
4	Contact liquid Water based liquid	4	Food and feed area	Bacteria, yeast, limited spectrum virucidal activity (incl. HIV, HBV, HCV and non-enveloped virus, rotavirus)	Disinfection of non-porous surfaces Indoor use	Apply a sufficient amount of the product on wipes by pouring, spraying or soaking and wipe the surface thoroughly (wet-wiping). Make sure that all visible soiling is removed before disinfection.	Ready-to-use Every cleaning or disinfection process or if required Do not apply more than 25 ml/m².	industrial user professional user	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

3.1.8 meta SPC 8

Use	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organisms (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1	Wipes impregnated with Contact liquid Water based liquid	2	Disinfectant not intended for direct application to humans or animals	Bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces Indoor use	Product will be wiped directly on the surface. Make sure that all visible soiling is removed before disinfection.	Ready-to-use wipes Every cleaning or disinfection process or if required	industrial user professional user	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE
2	Wipes impregnated with Contact liquid Water based liquid	4	Food and feed area	Bacteria, levurocids, limited spectrum virucidal activity (incl. HIV, HBV, HCV)	Disinfection of non-porous surfaces Indoor use	Product will be wiped directly on the surface. Make sure that all visible soiling is removed before disinfection.	Ready-to-use wipes Every cleaning or disinfection process or if required	industrial user professional user	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

3.1.9 use combinations not assessed[4]

meta SPC	Use name	Combination of the following uses in the meta SPC
Meta 1	disinfection of surfaces – spraying and wiping	Use 1 + 2
	disinfection of surfaces with food and feed contact – spraying and wiping	Use 3 + 4
	disinfection of surfaces with or without food and feed contact - spraying	Use 1 + 3
	disinfection of surfaces with or without food and feed contact - wiping	Use 1 + 2 + 3 + 4
Meta 2	disinfection of surfaces with or without food and feed contact	Use 1 + 2
Meta 3	disinfection of surfaces – spraying and wiping	Use 1 + 2
	disinfection of surfaces with food and feed contact – spraying and wiping	Use 3 + 4
	disinfection of surfaces with or without food and feed contact - spraying	Use 1 + 3
	disinfection of surfaces with or without food and feed contact - wiping	Use 2 + 4
	disinfection of surfaces with or without food and feed contact – spraying and wiping	Use 1 + 2 + 3 + 4
Meta 4	disinfection of surfaces with or without food and feed contact	Use 1 + 2
Meta 5	disinfection of surfaces with or without food and feed contact	Use 1 + 2
Meta 6	disinfection of surfaces with or without food and feed contact	Use 1 + 2
Meta 7	disinfection of surfaces – spraying and wiping	Use 1 + 2
	disinfection of surfaces with food and feed contact – spraying and wiping	Use 3 + 4

4 The SPC as applied for contains additional uses which are combinations of the uses listed in chapter 3.1.1 to 3.1.8. The eCA assessed the different uses as listed in this chapter 3.1.1 to 3.1.8 and intended to present additional combinations of the uses appropriate for authorisation in the summary chapter 2 and the SPC. This was discussed with and agreed by the applicant. However, due to different target organisms, risk mitigation measures and/or instructions for use and due to the agreed SPC structure, **the use combinations applied for are not possible.**

3.2 Physical, chemical and technical properties

Table 3: 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 examination	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1258762, 1255317, 1251260	clear liquid	Heidel, J. (2014): "Appearance of perform sterile alcohol IPA"
		Product: perform sterile wipes IPA (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 1267985, 1266789, 1264960	clear liquid (on soaked tissues)	Heidel, J. (2014): "Appearance of perform sterile wipes IPA"
		Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	clear solution	Cielusek, G. (2016): "Superficid - Specification and measured values"
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	clear solution	Cielusek, G. (2016): "Superficid pure - Specification and measured values"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Colour at 20 °C and 101.3 kPa	visual examination	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1258762, 1255317, 1251260	colourless	Heidel, J. (2014): “Appearance of perform sterile alcohol IPA”
		Product: perform sterile wipes IPA (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 1267985, 1266789, 1264960	colourless liquid (on soaked white tissues)	Heidel, J. (2014): “Appearance of perform sterile wipes IPA”
		Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	colourless	Cielusek, G. (2016): “Superficid - Specification and measured values”
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	colourless	Cielusek, G. (2016): “Superficid pure - Specification and measured values”
Odour at 20 °C and 101.3 kPa	organoleptic examination	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1258762, 1255317, 1251260	alcoholic odour	Heidel, J. (2014): “Appearance of perform sterile alcohol IPA”
		Product: perform sterile wipes IPA (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 1267985, 1266789, 1264960	alcoholic odour	Heidel, J. (2014): “Appearance of perform sterile wipes IPA”

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	characteristic odour	Cielusek, G. (2016): “Superficid - Specification and measured values”
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% Propan-2-ol,Batch: Q-1007-01	characteristic odour	Cielusek, G. (2016): “Superficid pure - Specification and measured values”
Acidity / alkalinity	PharmEU method 2.2.3. based on method CIPAC MT 75.3; Potentiometric determination	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1258762	The pH value of a 1 % solution of perform sterile alcohol IPA at 20-25°C is 7.7.	Heidel, J. (2014): “pH value of Perform sterile alcohol IPA”
	Ph.Eur. 2.2.3.	Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	pH value: 7.2	Cielusek, G. (2016): “Superficid - Specification and measured values”
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	pH value: 7.6	Cielusek, G. (2016): “Superficid pure - Specification and measured values”
Relative density / bulk density	PharmEU 2.2.5. based on EU-method A3; pycnometer method	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1173967; 1180611; 1207731; 1211518	density: 0.8758 g/cm³ (20°C) (specified: 0.870 – 0.881 g/cm³ (20°C))	Heidel, J. (2016): “Density of perform sterile alcohol IPA”

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Product: mikrozid IPA liquid (meta-SPC 3); Batch number: 695/063/002	density: 0.8756 g/cm³ (20°C) (specified: 0.870 – 0.881 g/cm³ (20°C))	Heidel, J. (2016): "Density of mikrozid IPA liquid"
	PharmEU 2.2.5./OECD 109 oscillating densitimeter	Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	density: 0.876 g/cm³	Cielusek, G. (2016): "Superficid - Specification and measured values"
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	density: 0.876 g/cm³	Cielusek, G. (2016): "Superficid pure - Specification and measured values"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1211518	**Appearance:** ▫ The physical state, colour and odour did not change during the storage for 9 months at 40°C. **Density:** ▫ before storage: 0.8757 ▫ after 3 months at 40°C: 0.8750 ▫ after 6 months at 40°C: 0.8740 ▫ after 9 months at 40°C: 0.8736 **Active substance content:** ▫ before storage: 63.1% ▫ after 3 months at 40°C: 63.5% ▫ after 6 months at 40°C: 64.0% ▫ after 9 months at 40°C: 64.0% The product is stable for 9 months at 40°C.	Heidel, J. (2016): “Stability of perform sterile alcohol IPA”
		Product: perform sterile wipes IPA (squeezed solution) (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 9640756	**Appearance:** ▫ The physical state, colour and odour did not change during the storage for 6 months at 40°C. **Density (of the squeezed solution):**	Heidel, J. (2014): “Stability of perform sterile wipes IPA”

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ before storage: 0.8663 ▫ after 3 months at 40°C: 0.8678 ▫ after 6 months at 40°C: 0.8617 **Active substance content (in the squeezed solution):** ▫ before storage: 66.0% ▫ after 3 months at 40°C: 66.5% ▫ after 6 months at 40°C: 68.9% **Additional information:** Although the initial active substance content (66% w/w) of the squeezed solution appears to be outside FAO tolerance limit of ± 25 g/kg for the nominal content of 63.1% w/w the given test was deemed acceptable. Since the squeezed solution is not mandatory identical to the solution used for impregnation of the wipes, the a.s. content may deviate between both solutions (e.g. water may keep rather absorbed to the wipe than the a.s.). The product is stable for 6 months at 40°C.	
Storage stability test – **long term storage at ambient temperature**		Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1211518	**Used packaging:** 500 ml PPC 3660 airless-bottle with PP spray pump (representative for other commercial packaging as a worst case packaging: This packaging system is the worst-case packaging compared to other packaging systems, due to the spray pump, which has an venting insert for vapour exchange. This venting insert is the preferred path of	Heidel, J. (2016): "Stability of perform sterile alcohol IPA"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			migration and not migration through the wall of the bottle.) **Appearance:** ▫ The physical state, colour and odour did not change during the storage for 36 months at 25°C. **Density:** ▫ before storage: 0.8757 ▫ after 3 months at 25°C: 0.8755 ▫ after 6 months at 25°C: 0.8753 ▫ after 9 months at 25°C: 0.8751 ▫ after 12 months at 25°C: 0.8748 ▫ after 18 months at 25°C: 0.8746 ▫ after 24 months at 25°C: 0.8739 ▫ after 30 months at 25°C: 0.8743 ▫ after 36 months at 25°C: 0.8735 **Active substance content:** ▫ before storage: 63.1% ▫ after 3 months at 25°C: 63.1% ▫ after 6 months at 25°C: 63.5% ▫ after 9 months at 25°C: 63.3% ▫ after 12 months at 25°C: 63.1% ▫ after 18 months at 25°C: 63.4% ▫ after 24 months at 25°C: 64.1% ▫ after 30 months at 25°C: 63.7% ▫ after 36 months at 25°C: 64.0% **Weight change:**	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No information on the weight change during storage was provided. Since there was no identifiable decrease in the active substance content in the given long term storage stability studies and since IPA forms an azeotrope mixture with water (boiling at 80.4°C) containing 12.3% w/w water, a weight loss of the product during storage would result in changing IPA content. Therefore, no further data on weight loss were requested. Nevertheless, the applicant provided data from a separate stability/weight loss test, which was performed on another batch (see below). **Stability of the spray pump:** The stability of the spray pump was addressed separately (see below). Furthermore, no complaints from customers were received from any non functioning of the spraying device and also internally no mal functioning was observed. Moreover, considering the composition of the products a blockage of the spray pump is unlikely to occure. The product is stable for 36 months at 25°C.	
		Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1251260	**Weight (mean value of three 500 mL bottles):** ▫ before storage: 539.24 g ▫ after 6 months at 25°C: 537.62 g (-0.30%) ▫ after 12 months at 25°C: 536.35 g (-0.54%) ▫ after 18 months at 25°C: 534.86 g (-0.81%) ▫ after 24 months at 25°C: 533.64 g (-1.04%) ▫ after 30 months at 25°C: 532.11 g (-1.32%)	quality control/screening data **[2014-2017]** (additional data)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No optical changes on the packaging after 30 months at 25°C could be observed. That data indicate that weight losses do not have an impact on the storage stability of the products.	
		Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch numbers: - 1335891 (2017-10), 500 mL bottle with spray pump - 1517360 (2018-10), 500 mL bottle with spray pump - 1315998 (2016-09), 1000 mL bottle with spray pump	**Comparison of the functionality of the spray pump after 12, 24 and 36 months of storage:** **Sprayed quantity per stroke (mean value of 10 strokes):** ▫ after 12 months at 25°C: 0.88 g ▫ after 24 months at 25°C: 0.87 g ▫ after >36 months at 25°C: 0.84 g **Visual control of spray function:** ▫ after 12 months at 25°C: complies ▫ after 24 months at 25°C: complies ▫ after >36 months at 25°C: complies The spray function is not affected by storage.	Reinstorff H. (2019): "Stability of the spray pump for perform sterile alcohol IPA"
		Product: perform sterile wipes IPA (squeezed solution) (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 9640756	**Used packaging:** pouch 260mm x 169mm made of printed film #18373, PET (12µm) / LLDPE (120µm), white); (representative for other commercial packaging as a worst case packaging) **Appearance:** ▫ The physical state, colour and odour did not change during the storage for 24 months at 25°C.	Heidel, J. (2014): "Stability of perform sterile wipes IPA"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Density (of the squeezed solution): ▫ before storage: 0.8663 ▫ after 3 months at 25°C: 0.8693 ▫ after 6 months at 25°C: 0.8724 ▫ after 9 months at 25°C: 0.8657 ▫ after 12 months at 25°C: 0.8650 ▫ after 18 months at 25°C: 0.8608 ▫ after 24 months at 25°C: 0.8610 **Active substance content (in the squeezed solution):** ▫ before storage: 66.0% ▫ after 3 months at 25°C: 66.0% ▫ after 6 months at 25°C: 66.6% ▫ after 9 months at 25°C: 67.5% ▫ after 12 months at 25°C: 67.6% ▫ after 18 months at 25°C: 69.1% ▫ after 24 months at 25°C: 69.3% **Weight change:** No information on the weight change during storage was provided. Since there was no identifiable decrease in the active substance content in the given long term storage stability studies and since IPA forms an azeotrope mixture with water (boiling at 80.4°C) containing 12.3% w/w water, a weight loss of the product during storage would result in a changing IPA content. Therefore, no further data on weight loss were requested.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Nevertheless, the applicant provided data from a separate stability/weight loss test, which was performed on another batch (see below). **Additional information:** Although the initial active substance content (66% w/w) of the squeezed solution appears to be outside FAO tolerance limit of ± 25 g/kg for the nominal content of 63.1% w/w the given test was deemed acceptable. Since the squeezed solution is not mandatory identical to the solution used for impregnation of the wipes, the a.s. content may deviate between both solutions (e.g. water may keep rather absorbed to the wipe than the a.s.). The product is stable for 24 months at 25°C.	
		Product: perform sterile wipes IPA (squeezed solution) (meta-SPC 2), 63.1% (w/w) Propan-2-ol, Batch number: 9645120	**Weight (mean value of three (20 ST BT) pouches):** ▫ before storage: 282.38 g ▫ after 6 months at 25°C: 277.45 g (-1.75%) ▫ after 12 months at 25°C: 273.435 g (-3.17%) ▫ after 18 months at 25°C: 268.64 g (-4.87%) ▫ after 24 months at 25°C: 265.09 g (-6.13%) ▫ after 30 months at 25°C: 260.31 g (-7.82%) No optical changes on the packaging after 30 months at 25°C could be observed. That data indicate that weight losses do not have an impact on the storage stability of the products.	quality control/screening data **[2014-2017]** (additional data)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol, Batch number: 1211518	**Appearance:** ▫ The physical state, colour and odour did not change during the storage for 24 months at -5°C. **Density:** ▫ before storage: 0.8757 ▫ after 3 months at -5°C: 0.8757 ▫ after 6 months at -5°C: 0.8756 ▫ after 9 months at -5°C: 0.8756 ▫ after 12 months at -5°C: 0.8757 ▫ after 18 months at -5°C: 0.8757 ▫ after 24 months at -5°C: 0.8757 **Active substance content:** ▫ before storage: 63.1% ▫ after 3 months at -5°C: 63.1% ▫ after 6 months at -5°C: 63.4% ▫ after 9 months at -5°C: 62.9% ▫ after 12 months at -5°C: 62.8% ▫ after 18 months at -5°C: 62.8% ▫ after 24 months at -5°C: 63.2% The product is stable for 24 months at -5°C.	Heidel, J. (2016): "Stability of perform sterile alcohol IPA"
		Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7)	No precipitation of the ingredients was observed in any of the products after storage for seven days about 0 °C. (only supporting information)	Cielusek, G. (2016): "Study on low-temperature stability of alcoholic disinfectants"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7)	No precipitation of the ingredients was observed in any of the products after storage for seven days about 0 °C. (only supporting information)	Cielusek, G. (2016): "Study on low-temperature stability of alcoholic disinfectants"
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			For propan-2-ol no absorption between 290 nm and 750 nm is expected. Therefore, it is not scientifically necessary to determine the effect of light. It is recommended to store the product within the original container and keep it closed and away from direct sunlight and heat (label claim).	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			It is recommended to store the products within the original container and keep it closed and away from direct sunlight and heat (label claim). Please refer to the results of the long term and accelerated storage (at 40°C) stability tests as well.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The in the Meta-SPCs stated packaging materials are suitable, no request for further information.	Dangerous Goods Database
Wettability			Data waiving acceptable (data are only required for solid preparations which are to be dispersed in water).	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability			Data waiving acceptable (data are not required since the biocidal products are ready-to-use products).	
Wet sieve analysis and dry sieve test			Data waiving acceptable (data are only required for solid biocidal products, dispersible concentrates or suspensions).	
Emulsifiability, re-emulsifiability and emulsion stability			Data waiving acceptable (data are not required since the biocidal products are ready-to-use products).	
Disintegration time			Data waiving (based on formulation type) acceptable (data are only required for biocidal products supplied as tablets).	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187 (SOP-PR-051)	Product: perform sterile alcohol IPA (meta-SPC 1), HDPE Trigger Spray Bottle [1 L], 63.1% (w/w) Propan-2-ol, Batch number: 1512707	**MMAD**: 205 µm mean results (3 samples, 5 measurements per sample): 10% of all particles were smaller than 63 µm 50% of all particles were smaller than 205 µm 90% of all particles were smaller than 561 µm	Mack, L. (**2019**): "Determination of the Particle Size Distribution for perform sterile alcohol IPA 70/30 and mikrozid® IPA liquid and Calculation of the Mass Median Aerodynamic Diameter (MMAD)", Study No. Mo6473, Report No. AQ071-19
		Product: mikrozid IPA liquid (meta-SPC 3), HDPE Trigger Spray Bottle [1 L], 63.1% (w/w) Propan-2-ol, Batch number: 733/171/002	**MMAD**: 196 µm mean results (3 samples, 5 measurements per sample): 10% of all particles were smaller than 65 µm 50% of all particles were smaller than 196 µm 90% of all particles were smaller than 519 µm	
		Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7);	**MMAD**: 181 µm mean results (3 samples, 5 measurements per sample):	Mack, L. (**2019**): "Determination of the Particle Size Distribution for

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		HDPE Trigger Spray Bottle [1 L], Batch number: A-02-2022	10% of all particles were smaller than 51 µm, 50% of all particles were smaller than 181 µm 90% of all particles were smaller than 549 µm	Superficid and Calculation of the Mass Median Aerodynamic Diameter (MMAD)", Study No. Mo6473, Report No. AQ077-19
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7)	Read-across to Superficid (As the product Superficid contains only a small amount of perfume in comparison to the product Superficid pure, the product Superficid can be regarded as the worst case. The mean results of the measurements on Superficid show, that only 10% of all particles were smaller than 51 µm. Therefore, less than 10% of particles of the product have an aerodynamic diameter <50 µm. The MMAD of Superficid was 181 µm. Since the influence of the amount of parfume in Superficid can be regarded as negliglibe, comparable results are expected for the product Superficid pure. In summary, the particle size of the product Superficid can be transferred to the product Superficid pure.)	
		Other products of the BPF without spraying device	Data waiving (based on packaging and formulation type: ready-to-use products without spraying device) acceptable.	
Persistent foaming	CIPAC MT 47	Product: mikrozid IPA liquid (meta-SPC 3); Batch number: 695/063/002	A solution of 100 % of mikrozid IPA liquid produced an amount of no foam (30 ml liquid). The amount of foam remained after 10 s was no foam (30 ml liquid).	Heidel, J. (2015): "Persistent Foaming of

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				mikrozid IPA liquid”
Flowability/Pourability/Dustability			Data waiving acceptable (flowability/dustability is not applicable since none of the biocidal products is a solid product like a granular preparation or a dustable powder; pourability is not applicable since none of the biocidal products is a suspension concentrate, capsule suspension or suspoemulsion).	
Burning rate — smoke generators			Data waiving acceptable (not applicable since the biocidal products are not smoke generators).	
Burning completeness — smoke generators			Data waiving acceptable (not applicable since the biocidal products are not smoke generators).	
Composition of smoke — smoke generators			Data waiving acceptable (not applicable since the biocidal products are not smoke generators).	
Spraying pattern — aerosols		products of meta SPC 1, 3 and 7	Data waiving acceptable (Information on the spray pattern is not adequate, because the products (meta SPC 1, 3 and 7) are sprayed without the support of a propellant gas. The spray pattern and the amount of spray delivered by each operation depends on the individual force the operator performed by hand. Therefore, the test results may not reproducible and may have a low significance.). Additionally, the applicant explained that blockage is not expected based on the structure of the spray head. More information is stated in the confidential annex chapter 3.	
		other products of the BPF without spraying device	Data are not required for wipes and products without spray head. .	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical compatibility			Data waiving acceptable: The products are not intended to be used in combination with other substances, mixtures or biocidal or non-biocidal products.	
Chemical compatibility			Data waiving acceptable: The products are not intended to be used in combination with other substances, mixtures or biocidal or non-biocidal products.	
Degree of dissolution and dilution stability			Data waiving acceptable (not applicable since the biocidal products are not water-soluble bags, tablets or water-soluble preparations).	
Surface tension	pendant drop method	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% Propan-2-ol, Batch number: 1211518	26.4 mN/m (20°C)	Heidel, J. (2014): "Surface Tension of perform sterile alcohol IPA"
		Product: mikrozid IPA liquid (meta-SPC 3); Batch number: 695/063/002	27.54 mN/m (20°C)	Heidel, J. (2014): "Surface Tension of mikrozid IPA liquid"
	OECD Test Guideline 115	Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	24.0 mN/m (20°C)	Cielusek, G. (2016): "Superficid - Specification and measured values"
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	24.0 mN/m (20°C)	Cielusek, G. (2016): "Superficid pure - Specification and measured values"
Viscosity	OECD Test Guideline 114;	Product: perform sterile alcohol IPA (meta-SPC 1), 63.1% (w/w) Propan-2-ol,	4 mPa s (dynamic) (20°C) 2.4 mPa s (dynamic) (40°C)	Heidel, J. (2014):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	rotational viscometer	Batch number: 1258762		"Viscosity of perform sterile alcohol IPA"
	OECD Test Guideline 114	Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% (w/w) Propan-2-ol, Batch: Q-1010-01	3.58 mPa s (20°C) 2.35 mPa s (40°C)	Cielusek, G. (2016): "Superficid - Specification and measured values"
		Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% (w/w) Propan-2-ol,Batch: Q-1007-01	3.58 mPa s (20°C) 2.35 mPa s (40°C)	Cielusek, G. (2016): "Superficid pure - Specification and measured values"

Table 4

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. The biocidal product family (BPF) consists of eight meta SPCs with ready-to-use liquids (meta SPCs 1, 3, 7) and ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8) based on the active substance propan-2-ol. The products within the family are colourless and have an alcoholic odour. The pH of the products within the family ranges from approximately 7.2 to 7.7, the density is around 0.876 g/cm³. The main constituents of all meta SPCs are popan-2-ol and water. The BPF has two further components in a low concentration, one of them is a surfactant (used in meta SPC 3/ 4) and the other is a perfume (used in meta SPC 7/ 8). Based on the similar composition it is acceptable that only products of meta SPC 1 and 2 were tested for storage stability, as the low concentrations of the two other components should not influence the stability. In conclusion the products (ready-to-use liquids) of meta SPC 1, 3 and 7 have a shelf-life of 36 months, whereas products (ready-to-use wipes) of meta SPC 2, 4, 5, 6 and 8 have a shelf-life of 24 months.

3.3 Physical hazards and respective characteristics

Table 5: 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			Waiver: The study does not need to be conducted because there are no chemical groups present in the active substance or in any of the co-formulants, which are associated with explosive properties.	IUCLID 4.1[5]
Flammable gases	study scientifically unjustified			Waiver	IUCLID 4.2
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID 4.2
Oxidising gases	study scientifically unjustified			Waiver	IUCLID 4.4
Gases under pressure	study scientifically unjustified			Waiver	IUCLID 4.5
Flammable liquids	Extrapolation	70 % (v/v) propan-2 -ol and 30 % (v/v) water	Flash point: about 20 °C	Flammable liquid, Category 2 based on GHS/CLP criteria	Liaw, H.J.; Chiu, Y.Y., J Hazard Mater. A101 (2003) 83-106

[5] 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
	DIN 51755	Product: [Superficid assigned to] AntiLy 5 (meta-SPC 7) 63.1% Propan-2-ol, Batch: Q-1010-01	Flash point: 21 °C	Flammable liquid, Category 2 based on GHS/CLP criteria	Cielusek, G. (2016): Superficid - Specification and measured values
	DIN 51755	Product: [Superficid pure assigned to] AntiLy 6 (meta-SPC 7) 63.1% Propan-2-ol,Batch: Q-1007-01	Flash point: 21 °C	Flammable liquid, Category 2 based on GHS/CLP criteria	Cielusek, G. (2016): “Superficid pure - Specification and measured values”
Flammable solids	UN Test N.1 (in Part III of the UN-MTC)	Perform sterile wipes IPA (meta-SPC 2) batch 9644780	Burning time: 10 seconds over 100 mm, and the flame passes the wetted zone	Flammable solid, Category 1 based on GHS/CLP criteria	Smeykal, H. (2016) Study No.: CSL-16-0056.01

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID 4.8
Pyrophoric liquids	study scientifically not necessary			Waiver: Based on experience in production and handling it can be concluded that the liquid products of the BPF perform IPA are not pyrophoric.	IUCLID 4.17
Pyrophoric solids	study scientifically not necessary			Waiver: Based on experience in production and handling it can be concluded that the solid products (wipes) of the BPF perform IPA are not pyrophoric.	IUCLID 4.17
Self-heating substances and mixtures	study scientifically not necessary			Waiver: Self-heating properties for the products of the BPF perform IPA are not expected and for liquids the study does not need to be conducted.	IUCLID 4.17
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the product is manufactured with water and does not contain metals or metalloids.	IUCLID 4.17
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the product is classified as a flammable liquid.	IUCLID 4.4
Oxidising solids	study scientifically not necessary			Waiver: The study does not need to be conducted because the product is classified as a flammable solid.	IUCLID 4.4

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Organic peroxides	study scientifically not necessary			The study does not need to be conducted because the products of the BPF perform IPA do not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID 4.15
Corrosive to metals	study scientifically not necessary			Waiver: The biocidal products are alcoholic liquids without basic or acidic properties and do not contain any halogens.	IUCLID 4.16
Auto-ignition temperature (liquids and gases)	study scientifically not necessary	Estimation	Auto-ignition temperature: 425 °C	Waiver: The active substance in the product is propan-2-ol. The concentration of propan-2-ol in the product is 70 % (v/v). The auto-ignition temperature of propan-2-ol is 425 °C and can be used as a worst case.	IUCLID 4.17.1
Relative self-ignition temperature for solids	study scientifically not necessary			Waiver: The endpoint relative self-ignition temperature for solids is assigned to section 2.11 “Self-heating substances and mixtures” to the CLP regulation.	IUCLID 4.17.2
Dust explosion hazard	study scientifically unjustified			Waiver	IUCLID 4.2

Table 6

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. The biocidal product family (BPF) consists of eight meta SPCs with ready-to-use liquids (meta SPCs 1, 3, 7) and ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8) 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 a flashpoint of 21°C according to DIN 51755. The boiling point of propan-2-ol is >35 °C according to CAR. Therefore, all products of the BPF 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 perform IPA as a worst case.
Due to structural reasons explosive and oxidising properties can be excluded for the products of the BPF perform IPA. Based on experience in production and handling it can be concluded that the products of the BPF Perform IPA 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 perform IPA 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.
Flam. Liq. 2; (Flammable liquids, hazard category 2)
H225: Highly flammable liquid and vapour

3.4 Methods for detection and identification

Table 7

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**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Propan-2-ol (Propan-2-ol 70% v/v = 63.1% w/w) and (Propan-2-ol in the biocidal product perform sterile IPA)	GC-FID main method (using Divinylbenzene/ Styrene Polymer as stationary phase)	No interference	[5 points] R^2 = 0.99998; R=0.99999	80 % - 120% (80%, 90%, 100%, 110%, 120%) 6 samples for 100%, 3 samples for each of the other 4 concentrations; each sample measured in duplicate	100.1 – 100.5	100.3	0.15	n.d. (Not relevant; method for determination of active substance in the products.)	Bosnak, M.(2016): “Analytical method for the determination of 2-propanol - „Isopropylalkohol 70%" - Method development and validation”

Table 8

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 PT2, PT4; LoEP (07/2014)
Drinking water	no relevant residues expected	-	AR for PT2, PT4; LoEP (07/2014)
Surface water	no relevant residues expected	-	AR for 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 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 PT2, PT4; LoEP (07/2014)
Food of animal origin	no relevant residues expected	-	AR for PT2, PT4; LoEP (07/2014)

Table 9

Data waiving was acceptable for the following information requirements	
Information requirement	1. For analytical methods for air the applicant refers to the CAR for the active substance propan-2-ol. 2. Soil: Data waving is accepted. 3. Water (including drinking water) and sediment: Data waving is accepted. 4. Animal and human body fluids and tissues: Data waving is accepted. 5. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waving is accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 10

Conclusion on the methods for detection and identification
The methods provided regarding the active substance were acceptable. The methods provided regarding the residues were acceptable. Methods 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) consists of eight meta SPCs with ready-to-use liquids (meta SPCs 1, 3, 7) and ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8) based on the active substance propan-2-ol.
In PT2, the propan-2-ol based disinfectants of the BPF are intended to be used for the disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B).
In PT4, the propan-2-ol based disinfectants of the BPF are intended to be used for the disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B).

The products of the BPF are intended for both professional and industrial use (all meta SPCs) as well as non-professional use (meta SPC 6).

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

The products of the BPF are intended to have bactericidal (all meta SPCs, including tuberculocidal (meta SPCs 3-6)) and yeasticidal activity (all meta SPCs). Furthermore, the applicant claimed limited spectrum virucidal activity for the products of the BPF. However, such a limited spectrum virucidal claim was not acceptable for the intended uses in PT2 and PT4 at the time of evaluation. Therefore, only full virucidal activity for PT 4 has been evaluated.

3.5.3 Effects on target organisms, including unacceptable suffering

Application of the products within the BPF leads to the irreversible inactivation of bacterial cells and yeast (PT2 and PT4) as well as viruses (PT4).

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 leads to a loss of cellular activity resulting in the cell's death.
Propan-2-ol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant). The time required for sufficient inactivation is strongly depending on the formulation, concentrations of propan-2-ol contained in the applied biocidal product, the type of target organisms and on the specific use conditions.

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 (quantitative suspension tests) and phase 2 / step 2 tests (quantitative surface tests) where available. With exception of two studies which have been carried out according to standard methods of the DVV/RKI[6], all studies have been performed based on available EN standards. Experimental data is summarised in table 11.
The biocidal product family (BPF) “perform-IPA” consists of eight 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 ready-to-use liquids are intended to be sprayed onto a surface (disinfection without mechanical action), poured onto a surface and wiped directly afterwards or a wipe will be soaked with the liquid and wiped over a surface (disinfection with mechanical action). The ready-to-use wipes are intended to be used by wiping a surface to be disinfected (disinfection with mechanical action).

Bactericidal efficacy incl. tuberculocidal efficacy
Three phase 2, step 1 tests (EN1276 (1), EN13727 (3), EN14348 (12)) and two phase 2, step 2 tests (EN 13697 (5), EN16615 (7)) have been submitted to prove the bactericidal efficacy of the products. In all studies, efficacy of products consisting of 63.1% (w/w) propan-2-ol and water under clean conditions at 20°C has been assessed. The studies fulfil all validation criteria needed to pass the test according to the relevant standard protocol.
Bactericidal efficacy in phase 2, step 1 tests has been proven at 80% product concentration after 15 seconds (EN13727) or 1 minute (EN 1276; 1 min was the minimum contact time tested). Efficacy against *Mycobacterium terrae* was shown at 80% product concentration after 1 minute and at 97% product concentration after 30 seconds (EN14348).
For disinfection without mechanical action (EN 13697), efficacy has been shown after 1 minute at 100% product concentration. For disinfection with mechanical action (EN16615), efficacy has been shown after 5 min at 100 % product concentration with the standard wipe (55% cellulose, 45% PET). The standard wipe can be considered as a representative worst case for the wipes included in the application according to chapter 5.9.3 of EN16615 in conjunction with the comparably low reactivity of the a.s. as well as the comparably high concentration of a.s. in the liquid (63.1%).

Yeasticidal efficacy
Three phase 2, step 1 tests (EN1650 (8), (9); EN13624 (3)) and three phase 2, step 2 tests (EN 13697 (10), (11); EN16615 (7)) have been submitted to prove the yeasticidal efficacy of the products. In all studies, efficacy of products consisting of 63.1% (w/w) propan-2-ol and water under clean conditions at 20°C has been assessed. With exception of one EN1650 (9) and one EN13697 (10) study, where only one instead of three product concentrations have been tested, the tests on *Candida albicans* fulfil all validation criteria needed to pass the test according to the relevant standard protocol.
Yeasticidal efficacy in phase 2, step 1 tests has been proven at 80% product concentration after 15 seconds (EN13624) or at 50% product concentration after 5 min (EN 1650 (8); 5 min was the minimum contact time tested).

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6 Guideline of “Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V.“ (DVV; German Association for the Control of Virus Diseases) and Robert Koch Institute (RKI; German Federal Health Authority) for testing the virucidal efficacy of chemical disinfectants in the human medical area

For disinfection without mechanical action, efficacy has been shown for 50% product concentration after 5 min which was the minimum contact time (EN13697 (11)). However, study EN 13697 (10) - which failed to pass the test criteria due to testing of only one product concentration (100%) - showed a yeasticidal efficacy of the product after 1 minute. Since one phase 2, step 2 test (EN 13697 (11)) which fulfils all validation criteria (including testing of three different product concentrations) has been submitted and the second phase 2, step 2 test (EN 13697 (10)) fulfils all other validation criteria, an efficacious contact time of 1 minute for yeasticidal activity can be accepted in this case.
For disinfection with mechanical action, yeasticidal efficacy has been shown after 1 min at 100% product concentration (EN16615) with the standard wipe (55% cellulose, 45% PET). The standard wipe can be considered as a representative worst case for the wipes included in the application according to chapter 5.9.3 of EN16615 in conjunction with the comparably low reactivity of the a.s. as well as the comparably high concentration of a.s. in the liquid (63.1%).

Virucidal activity (PT 4)
Five phase 2, step 1 tests (EN 14476 (15), (16), (17) with test organisms Human Rotavirus, Adenovirus, Murine Norovirus; DVV/RKI guideline[7] (13), (14) with test organisms Vaccinia virus, Bovine viral diarrhea virus (BVDV)) and two phase 2, step 2 tests (prEN16777 (18), (19) with test organisms Adenovirus and Murine Norovirus) have been submitted to prove the limited spectrum virucidal efficacy of the products. In all studies, efficacy of products consisting of 63.1% (w/w) propan-2-ol and water at 20°C has been assessed. Except for the tests according to the DVV/RKI guideline where clean and dirty conditions have been tested, all tests have been carried out under clean conditions. The studies fulfil all validation criteria needed to pass the test according to the relevant standard protocol.
Efficacy against Vaccinia virus and BVDV according to the DVV/RKI guideline and against Human Rotavirus according to EN14476 was shown at 80% product concentration after 30 sec under clean conditions[8]. According to EN14476, efficacy against Adenovirus and Murine Norovirus was sufficient at 97% product concentration after 1 min (Murine Norovirus) or 2 min (Adenovirus) under clean conditions.
For disinfection without mechanical action, efficacy has been shown at 100% product concentration after 2 minutes for Adenovirus and Murine Norovirus (prEN16777). No standard test protocol for disinfection of viruses with mechanical action is available at this point.
According to EU guidance, a limited virucidal claim is not possible for surface disinfection in PT 2 and PT 4. Since no efficacy against Poliovirus has been demonstrated in the course of product authorisation, no virucidal claim is possible for surface disinfection in PT 2.
Since according to EU guidance virucidal activity in PT 4 does not require efficacy against Poliovirus, and efficacy against Adenovirus and MNV has been demonstrated, a virucidal claim in PT 4 is acceptable.

Read-across approach: Surfactant / Perfume[9]
Products of the meta-SPCs 1, 2, 5 and 6 solely contain 63.1% (w/w) propan-2-ol and water. In addition to these two components the products of meta-SPCs 3 and 4 contain a surfactant. Products of the meta-SPCs 7 and 8 contain a perfume in addition to propan-2-ol and water.
In order to prove that the surfactant does not influence the efficacy the applicant submitted tests according to EN1276 comparing the efficacy of a product with and without surfactant under clean conditions. Since

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[7] The experiments have been carried out according to the guideline from 2014. An english translation of the guideline from 2008 is available at: http://www.dvv-ev.de/english/DVV-Leitlinie%20Englische%20VersionEndfass7_09Homepage.pdf
[8] For rotavirus it has to be kept in mind that the remaining amount of BSA-soiling in the course of the experiment remains questionable since trypsin has to be added to the samples and trypsin is able to degrade BSA.
[9] For name, composition and concentration of surfactant and perfume please see confidential PAR.

no difference in efficacy after 1 or 5 minutes with a test concentration of the products of 25, 50 and 80% could be observed, it is to be expected that the surfactant does not influence the efficacy of the biocidal products. Thus, the read-across between products without surfactant to products with surfactant is deemed acceptable.
Since the perfume contains potentially active substances, the applicant submitted a test according to EN13727 with *Staphylococcus aureus* showing that in a solution containing the perfume at the same concentration as real products of the family, but without propan-2-ol,no bactericidal efficacy was observable at 80% product dilution under dirty conditions and 30 seconds or 1 minute contact time (log red <2,47 /<2.72; count of cfu per ml >660).
Furthermore, efficacy testing in general has been conducted with a product which does not contain any perfume. These tests clearly demonstrated that the perfume is not required for the efficacy of the products, which is in line with the proposed results of Test 3 of efficacy TAB entry 6 “Co-formulant(s) being a potential active substance in disinfectant products”. According to the table “Schematic overview of possible test results and conclusions” in the TAB, the perfume therefore is not regarded as an additional active substance in perform-IPA.

Read-across approach: Temperature
Generally, products of the BPF are intended to be used at 20°C. However, especially in the area of food and feed processing it is possible that the products will also be used at 10°C. According to the applicant, for application at 10°C only bactericidal and yeasticidal efficacy is claimed.
No efficacy tests showing the bactericidal and yeasticidal efficacy of products containing 63.1% propan-2-ol at 10°C have been submitted. However, in addition to a scientific justification for non-submission of propan-2-ol specific data, the applicant provided phase 2, step 2 tests (EN13697) in which the bactericidal efficacy of products containing 23,5 % (w/w) ethanol and 35 % (w/w) propan-1-ol at 10°C and 20°C was compared. The tested product was efficacious against all standard organisms at both tested temperatures (product concentration of 100%, contact time 1 min). No difference in efficacy at 10°C or 20°C was observed. This result is supported by a report written according to the DVG Guidelines, stating that no error of temperature could be observed for the same product in phase 2, step 2 tests at 10 or 20°C under clean or dirty conditions for bacteria or fungi with a contact time of 5 or 30 minutes. However, since no raw data have been made available with this report, it can only be used as supportive information.

In accordance with the decision of WG EFF V 2019, the read-across based on the studies with Ethanol/Propan-1-ol and the justification between efficacy at 20°C and 10°C cannot be accepted. Therefore, efficacy against bacteria and yeast at 10°C is not proven.

Summary on efficacy
In general, sufficient bactericidal, tuberculocidal and yeasticidal efficacy has been proven for disinfection of clean, non-porous surfaces with and without mechanical action in PT2 and PT4.

Originally, the applicant claimed limited spectrum virucidal efficacy in PT2 and PT4. However, no limited spectrum virucidal claim is possible for surface disinfection in PT2 and PT4. No full virucidal efficacy has been shown for surface disinfection in PT2 (tests with poliovirus are missing). Since proof of efficacy against Adenovirus and Murine Norovirus are sufficient to claim full virucidal efficacy for surface disinfectants in PT4, sufficient virucidal efficacy has been shown for disinfection of clean, non-porous surfaces with and without mechanical action in PT4.
For the conclusion on efficacy, please see Table 13.

Table 11

Experimental data on the efficacy of the biocidal product family against target organism(s)						
Function	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericidal activity	pluradent Händedesinfektion (63.1% (w/w) Propanol in water)	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	DIN EN 1276: 2009: AC2010	Suspension test Interfering substance: 0.3 g/L BSA (clean conditions) Test temperature: 21°C Contact time: 1 and 5 min Test concentrations: 25, 50, 80%	Bactericidal efficacy was shown after 1 min at 80% product concentration.	(1) "DIN EN 1276 (2009:AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1); Steinhauer, Paßvogel, 2017"
Bactericidal activity	mikrozid IPA liquid (63.1% (w/w) propan-2-ol, surfactant)[9]	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 1276: 2009 : AC2010	Suspension test Interfering substance: 0.3 g/L BSA (clean conditions) Test temperature: 20°C Contact time: 1, 5 min Test concentrations: 25, 50, 80%	Bactericidal efficacy was shown after 1 min at 80% product concentration.	(2) "DIN EN 1276 (2009:AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1); Steinhauer, Paßvogel, 2017

Bactericidal and yeasticidal activity	solution for Kodan wipes (63.1% (w/w) Propanol in water)	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae* *Candida albicans, Aspergillus brasiliensis*	DIN EN 13727: 2014 and DIN EN 13624: 2013	Suspension test Interfering substance: 0.3 g/L BSA (clean conditions) Test temperature: 20°C Contact time: 15, 30 and 60 sec (Bacteria and yeast) 1, 5 and 15 min (Fungi) Test concentrations: 20%, 80% and 97%	Bactericidal efficacy was shown after 15 sec at 80% product concentration. Yeasticidal efficacy was shown after 15 sec at 80% product concentration.	(3) “Test report for Kodan wipes pure active substances solution on the basis of DIN EN 13727 and DIN EN 13624 – 2015 and 2017; Sammann, 2017”)
Bactericidal activity	Perfume [9]	*Staphylococcus aureus*	EN 13727	Suspension test Interfering substance: 0.3 g/l BSA and sheep erythrocytes (dirty conditions) Test temperature: 21°C Contact time: 0.5, 1 min Test concentrations: 25, 50, 80%	No bactericidal concentration could be determined.	(4) “Bactericidal efficacy of Superficid: Proof of non-activity of [redacted] (used as perfume); Rödger, 2016” [9]

Bactericidal activity	perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 13697: 2015	Surface test Interfering substance: 0.3 g/L BSA or skim milk for P. aeruginosa (clean conditions) Test temperature: 20°C Contact time: 1, 2 and 5 min Test concentrations: 25, 50, 100%	Bactericidal efficacy was shown after 1min at 50% product concentration for *P. aeruginosa*, *E. coli* and *E. hirae*. Bactericidal efficacy against *S. aureus* was shown after 1 min at 100% product concentration.	(5) "DIN EN 13697:2015, Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2); Steinhauer, Paßvogel, 2017"
Bactericidal activity - Temperature dependance	Product containing 23,5 % (w/w) ethanol and 35% (w/w) propan-1-ol	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae*	EN 13697: 2001	Surface test Interfering substance: 3 g/L BSA (dirty conditions) Test temperature: 20°C Contact time: 1 min Test concentrations: 100%	The product was sufficiently efficacious against all tested standard organisms after 1 min.	(6) "Bakterizide Wirkung auf Oberflächen unter allgemeinen Anwendungsbedingungen (höhere Belastung) gemäß DIN EN 13697 (2001); Goroncy-Bermes, 2004"
Bactericidal and yeasticidal activity	Pluradent Händedesinfektion (63.1% (w/w) Propanol in water)	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae* *Candida albicans*	DIN EN 16615: 2015	4-field test Interfering substance: 0.3 g/L BSA (clean conditions) Test material: standard wipe (55%	Bactericidal efficacy against *S. aureus* was shown after 5 min at 100% product concentration.	(7) "DIN EN 16615:2015 Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in

				cellulose, 45% PET) Test temperature: 20°C Contact time: 1, 2, 5 min Test concentrations: 100 %	Bactericidal efficacy against *P. aeruginosa*, *E. hirae* and *C. albicans* was shown after 1 minute at 100% product concentration.	the medical area (4-field test). (phase 2, step 2); Steinhauer, Hofmann; 2016"
Yeasticidal activity	Perform classic alcohol IPA (63.1% (w/w) Propanol in water)	*Candida albicans*	DIN EN 1650: 2013	Suspension test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperature: 20°C Contact time: 5, 15 min Test concentrations: 25, 50, 80%	Yeasticidal efficacy was shown after 5 min at 50% product concentration.	(8) "Report A15193-1, Perform Classic Alcohol IPA, Yeasticidal Efficacy (EN 1650); Koburger-Janssen, Kramer, 2015"
Yeasticidal activity	Perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Candida albicans*, *Aspergillus brasiliensis*	DIN EN 1650: 1998	Suspension test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperature: 20°C Contact time: 1, 2, 5, 10 min	Yeasticidal efficacy was shown after 1 min at 100% product concentration.	(9) "DIN EN 1650 (1998) Quantitative suspension test for the determination of fungicidal efficacy of chemical disinfectants and antiseptics for the area of food, industry, household and public domain.; Steinhauer, 2009"

				for *C. albicans* and 15, 30 min for *A. brasiliensis* Test concentration: 100%		
Yeasticidal activity	perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Candida albicans* *Aspergillus brasiliensis*	EN 13697: 2001	Surface test Interfering substance: 0.3 g/L BSA (clean conditions) Test temperature: 20°C Contact time: 1, 2, 5 min (*C. albicans*) 15, 30 min (*A. brasiliensis*) Test concentrations: 100%	Yeasticidal efficacy was shown after 1 min at 100% product concentration.	(10) "DIN EN 13697:2001, Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2); Steinhauer, 2009"
Yeasticidal activity	perform classic alcohol IPA (63.1% (w/w) Propanol in water)	*Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae* *Candida albicans*	EN 13697: 2015	Surface test Interfering substance: 0.3 g/L BSA or skim milk for *P. aeruginosa* (clean conditions) Test temperature: 20°C Contact time: 5 and 15 min Test concentrati	Yeasticidal efficacy was shown after 5 min at 50% product concentration.	(11) "Report A 15193-3 Perform Classic Alcohol IPA – Bactericidal and yeasticidal activity (13697); Koburger-Janssen and Kramer, 2015"

				ons: 25, 50, 100%		
Tubercoluc idal activity	Perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Mycobacteri um terrae*	EN 14348: 2005	Suspension test Interfering substance: 0.3 g/L BSA Test temperatur e: 20°C Contact time: 15, 30, 60 sec Test concentrati ons: 10, 80, 97%	Tuberculoc idal efficacy was shown after 30 sec at 97% product concentrati on and after 60 sec at 80% product concentrati on.	(12) “DIN EN 14348 (2005): Chemical disinfectants and antiseptic – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2/ step 2); Radischat, 2015”
Virucidal activity	perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Vaccinia Virus strain Elstree*	Guidelin e of RKI and DVV	Suspension test Interfering substance: A. dest (clean conditions) 10% FCS (dirty conditions) Test temperatur e: 20°C Contact time: 0.5, 1, 2, 5 min Test concentrati ons: 20, 80%	Sufficient efficacy against Vaccinia virus was shown after 30 sec at 80% product concentrati on.	(13) “The efficacy of perform sterile alcohol IPA against vaccinia virus in the virucidal quantitative suspension test for chemical disinfectants and antiseptics; Enders and Eggers, 2009”
Virucidal activity	perform sterile alcohol IPA	*Bovine viral diarrhea virus (BVDV)*	Guidelin e of RKI and DVV	Suspension test Interfering substance:	Sufficient efficacy against BVDV was shown	(14) “The efficacy of perform sterile alcohol IPA against BVDV in the

	(63.1% (w/w) Propanol in water)			A. dest (clean conditions) 10% FCS (dirty conditions) Test temperatur e: 20°C Contact time: 0.5, 1, 2, 5 min Test concentrati ons: 20, 80%	after 30 sec at 80% product concentrati on.	virucidal quantitative suspension test for chemical disinfectants and antiseptics; Enders, Eggers; 2009”
Virucidal activity	perform sterile alcohol IPA (63.1% (w/w) Propanol in water)	*Human Rota Virus strain Wa*	EN 14476: 2013	Suspension test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperatur e: 20°C Contact time: 0.5, 1 min Test concentrati ons: 10, 50, 80%	Sufficient efficacy against Human Rotavirus was shown after 30 sec at 80% product concentrati on.	(15) “Evaluation of the effectiveness of perform sterile alcohol IPA; Steinmann, 2015”
Virucidal activity	Solution of Kodan wipes pure (63.1% (w/w) Propanol in water)	*Adenovirus type 5*	EN 14476: 2013	Suspension test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperatur e: 20°C	Sufficient efficacy against Adenovirus was shown after 2 min at 97% product concentrati on.	(16) “Evaluation of the effectiveness of Kodan wipes pure (active solution); Steinmann, 2015”

				Contact time: 0.5, 1, 2, 30 min Test concentrations: 10, 50, 80, 97%		
Virucidal activity	Solution of Kodan wipes pure (63.1% (w/w) Propanol in water)	*Murine norovirus strain S99*	EN 14476: 2013 / FprA1:2015	Suspension test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperature: 20°C Contact time: 1, 2, 5 min Test concentrations: 25, 50, 97%	Sufficient efficacy against Murine Norovirus was shown after 1 min at 97% product concentration.	(17) “Efficacy of Kodan wipes pure (active solution) against Murine norovirus strain S99 in the virucidal quantitative suspension test for chemical disinfectants and antiseptics; Enders, Eggers, 2016”
Virucidal activity	perform classic alcohol IPA (Propan-2-ol 63.1% (w/w) in water)	*Murine norovirus strain S99*	EN 16777: 2015	Surface test Interfering substance: 0.3 g/l BSA (clean conditions) Test temperature: 18-25°C Contact time: 1, 2, 5 min Test concentrations: 10, 50, 100%	Sufficient efficacy against Murine Norovirus was shown after 2 min at 97% product concentration.	(18) “Efficacy of perform® classic alcohol IPA against Murine norovirus in the quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area (phase2/step2).; Eggers, 2017”

Virucidal activity	Perform classic alcohol IPA (63.1% (w/w) Propanol in water)	*Adenovirus type 5 strain Adenoid 75*	EN 16777: 2015	Surface test Interfering substance: 0.3 g/l BSA Test temperatur e: 18-25°C Contact time: 1, 2, 5 min Test concentrati ons: 10, 50, 100%	Sufficient efficacy against Adenovirus was shown after 2 min at 97% product concentrati on.	(19) “The efficacy of perform® classic alcohol IPA against Adenovirus in the quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area (phase2/step2), Eggers, 2017”

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

No management strategies have been developed since no occurrence of resistance has been observed.

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 disinfectant BPF.

3.5.8 Evaluation of the label claims

The following biocidal label claims are considered to be suitable for product labels of the BPF (non-biocidal label claims have not been evaluated):

All uses:

- For disinfection of non-porous surfaces (including surfaces in cleanrooms class A/B)
- Effective against bacteria (incl. *Mycobacterium tuberculosis*), yeast and viruses[10]
- Effective against bacteria (incl. *Mycobacterium tuberculosis*) and yeast

Spraying:

- Bactericidal (incl. *tuberculocidal*)/Yeasticidal activity (contact time: 1 min at 20°C)
- Virucidal activity (contact time: 2 min at 20°C)[11]

Wiping:

- Bactericidal (incl. tuberculocidal)/Yeasticidal/ Virucidal[16] activity (contact time: 5 min, bactericidal and yeasticidal activity at 20°C, virucidal[16] activity at 20°C)

In general, the required contact times should be mentioned on the product label.

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

- Clean the surface carefully before use.
- Remove excess water from the surface before disinfection, if appropriate.
- Make sure to wet surfaces completely.

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 12

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 surfactant [9]
Justification	The applicant submitted tests according to EN1276 comparing the efficacy of a product with and without surfactant under clean conditions. Since no difference in efficacy after 1 or 5 minutes with a test concentration of the products of 25, 50 and 80% could be observed, it is to be expected that the surfactant does not influence the efficacy of the biocidal products.
Information requirement	6.7 Efficacy data to support these claims: Read-across to support efficacy at 10°C
Justification	No efficacy tests showing the bactericidal and yeasticidal efficacy of products containing 63.1% propan-2-ol at 10°C have been submitted. However, in addition to a scientific justification for non-submission of propan-2-ol specific

10 only for PT4, not possible for PT2
11 only for PT4, not possible for PT2

	data, the applicant provided phase 2, step 2 tests (EN13697) in which the bactericidal efficacy of products containing 23,5 % (w/w) ethanol and 35 % (w/w) propan-1-ol at 10°C and 20°C was compared. This read-across was deemed not acceptable by the WG EFF V 2019. For further information see chapter 3.5.5 Efficacy data.

Table 13

Conclusion on the efficacy
Proven efficacy for disinfection of non-porous surfaces by spraying with ready-to-use liquids (meta SPCs 1, 3, 7): • PT2 and PT4: bactericidal (including tuberculocidal) and yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C • PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C Proven efficacy for disinfection of non-porous surfaces by wiping with ready-to-use liquids (meta SPCs 1, 3, 7) or ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8): • PT2 and PT4: bactericidal (including tuberculocidal) efficacy within a contact time of 5 minutes under clean conditions at 20°C • PT2 and PT4: yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C • PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C It can be concluded that products of the BPF show sufficient bactericidal and yeasticidal activity as substantiated according to European Standards (EN) in PT2 and PT4. Furthermore, the products show sufficient 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 have been met. A maximum volume of 25 ml/m^2 should not be exceeded, since this was claimed by the applicant and therefore assessed in the risk assessment. To ensure the efficacy of the products, the following use conditions have to be indicated on the product label: • Clean the surface carefully before use. • Remove excess water from the surface before disinfection, if appropriate. • Make sure to wet surfaces completely.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 14 Reference values for the Active Substance Propan-2-ol

	Value	Source
AEL acute/medium/long-term General population	10.7 mg/kg bw/d	Assessment-Report (RMS DE (2014))
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d	Assessment-Report (RMS DE (2014))
Inhalative absorption	100 %	Assessment-Report (RMS DE (2014))
Oral absorption	Nearly 100 % within 72 h (presumably much faster)	Assessment-Report (RMS DE (2014))
Dermal absorption	0.85 mg/cm²/h – for biocidal products of the BPF, which do not contain a surfactant. (meta SPC 1, 2, 5, 6, 7, 8) 25 % - for biocidal products of the BPF containing a surfactant (meta SPC 3 and 4)	Assessment-Report (RMS DE (2014)) Default according to the EFSA Guidance on Dermal Absorption (2012)

Table 15 Classification and other toxicological information for the Active Substance Propan-2-ol

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	GHS07 Warning Eye Irrit. 2, H319 STOT SE 3, H336
Proposed, with regard to toxicological data according to the criteria in Reg. 1272/2008, based on Assessment-Report (RMS DE (2014)	GHS07 Warning Eye Irrit. 2, H319 STOT SE 3, H336 EUH066*

*In addition to current classification/labelling of propan-2-ol, classification/labelling as EUH066 is proposed.

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 16

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 product / individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 “Skin irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “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.” For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no indication of synergistic effects between any of the components. 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 themselves is not required. According to the CAR a valid study has shown that propan-2-ol was 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. Other components of the biocidal product classified for skin irritation are considered as not relevant since their concentration is below 0.09 %.

Table 17

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin. However, repeated exposure may cause skin dryness or cracking.
Justification for the value/conclusion	Based on intrinsic properties of components of the biocidal products pertaining to the BPF. However, according to the 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, labelling with EUH066: Repeated exposure may cause skin dryness or cracking is indicated.
Classification of the product according to CLP	No classification for skin corrosion/irritation is required. EUH066 (Repeated exposure may cause skin dryness or cracking.)

3.6.2.2 Eye irritation

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye irritating properties of the biocidal product / individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 “Eye irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “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.” For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the BPF 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 themselves is not required. According to the CAR propan-2-ol was moderately eye irritating in two independent studies with rabbits. However, propan-2-ol has been classified as eye irritating in other assessment procedures (WHO 1990, OECD 1997). Overall, propan-2-ol has eye irritating properties. Other components of the biocidal product classified for eye irritation or eye damage are considered as not relevant since their concentration is not higher than 0.09 %. Classification of the BPF members can be made according to the rules of the Regulation (EC) No 1272/2008. According to the CLP criteria, the individual biocidal products of the BPF, and thus the BPF itself, requires classification as Eye Irrit. 2 (H319).

Table 19

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	May cause eye irritation.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP	Eye Irrit. 2 H319 (Causes serious eye irritation.)

3.6.2.3 Respiratory tract irritation

Table 20

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Inhalation exposure is expected due to propan-2-ol vapour upon volatisation. Propan-2-ol is not classified with respect to this endpoint and further information on the product is not required. Based on the concentration of other potentially relevant components (not higher than 0.09 % for each component) it is not expected that these components affect this endpoint. Classification of the BPF can be made according to the rules of the Regulation (EC) No 1272/2008. According to the CLP criteria, for the individual biocidal products of the BPF, and thus for the BPF itself, classification with respect to respiratory tract irritation is not required.

Table 21

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 of the biocidal products pertaining to the BPF are not irritating to the respiratory tract.
Classification of the product according to CLP	Not irritating to the respiratory tract.

3.6.2.4 Skin sensitization

Table 22

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 product / individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the biocidal products 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.” For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Some biocidal products of the BPF contain a perfume, which is a mixture of numerous substances. Some of these components are classified for skin sensitisation. Several of these components are structurally closely related and at least additive effects cannot be excluded for them. However, even if such

	components are summed up, concentrations are far below the concentration limits for classification or labelling. Consequently, classification of the BPF 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 themselves is not required.

Table 23

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. Some biocidal products of the BPF contain a perfume, which is a mixture of numerous substances. Some of these components are classified for skin sensitisation. Several of these components are structurally closely related and at least additive effects cannot be excluded for them. However, even if such components are summed up, concentrations are far below the concentration limits for classification or labelling. The biocidal products of this family have some similarities to cosmetic products. Therefore, it should be noted that in case of cosmetic products the following substances would be indicated in the list of ingredients for biocidal products of the BPF containing the perfume (Regulation (EC) No 1223/2009): 1,6-Octadien-3-ol, 3,7-dimethyl- (linalool), (R)-p-mentha-1,8-diene (limonene), 2-benzylideneheptanal (amyl cinnamal).
Classification of the product according to CLP	Classification is not required.

3.6.2.5 Respiratory sensitization (ADS)

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Data on respiratory sensitisation for the biocidal products or their components are not available.

Table 25

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

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	Studies on acute oral toxicity of the components and/or of the individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “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.” For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal products of the BPF 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 themselves is not required.

Table 27

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on the oral LD_{50} available for the single components the oral LD_{50} of the biocidal products of this family are estimated as >> 2000 mg/kg bw.
Classification of the product according to CLP	Classification is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on acute inhalation toxicity of the components and/or of the individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “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.”

	For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal products of the BPF 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 themselves is not required.

Table 29

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal products of this family are estimated as >> 5 mg/L. The active substance is classified with STOT SE 3, H336 (May cause drowsiness and dizziness). Based on the high concentration of the active substance this must also be assumed for the biocidal products.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required but with STOT SE 3, H336 (May cause drowsiness and dizziness).

3.6.2.6.3 Acute toxicity by dermal route

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	Studies on acute dermal toxicity of the components and/or of the individual biocidal products of the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “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.” For all products pertaining to the BPF, the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal products of the BPF 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 themselves is not required.

Table 31

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the dermal LD_{50} available for the single components 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 is not required.

3.6.2.7 Information on dermal absorption

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Additional studies on dermal absorption of the components and/or of the individual biocidal products of the biocidal product family (BPF) are not required for biocidal products of the BPF, which do not contain a surfactant. For these biocidal products the absorption/dermal flux rate for propan-2-ol determined in a 70 % (w/w) aqueous dilution on rat skin and estimated as 0.85 mg/cm²/h (Boatman et al. 1998) during active substance evaluation is applicable for the following reasons. The concentration of the active substance in the biocidal product (63.1 % w/w) is comparable to the active substance concentration in the test formulation (70 % w/w). The amount normally applied on skin (3 mL/820 cm² surface of both hands ≙ 0.002 mg a.s./cm² [density: 0.88 g/cm³]) is below the applied amount in the above mentioned study (0.3 mL/4.3 cm² ≙ 0.0352 mg a.s./cm² [density: 0.72 g/cm³]). Since the flux represents the dermally absorbed dose per unit of time, i.e. an absolute rather than a relative value, the value from the dermal absorption study is considered a worst case for all intended application i.e. professional and non-professional. It is assumed that the amount applied by spraying is higher compared to the amount transferred to skin by wipes. Some biocidal products of the BPF (Meta-SPC 7 and 8) may contain a perfume, which could affect dermal absorption due to its skin-irritating and skin-sensitising properties. However, since the concentration of this compound is low and as it does not contribute to the classification of the biocidal products it is considered not relevant for dermal absorption. However, some biocidal products of this BPF (Meta-SPC 3 and 4) may contain a surfactant. Comparable to the perfume this component does not influence dermal absorption due to its classification as skin irritating since the concentration is considerable low. According to EFSA Guidance on Dermal Absorption (2012) and EFSA Panel on Plant Protection Products (PPR, 2011) surfactants increase dermal absorption even at much lower concentration since they optimise the wetting and permeability of the skin. Therefore, additional information on dermal absorption is required for these biocidal products. Otherwise the default value of 25 % according to the EFSA Guidance on Dermal Absorption (2012) has to be applied.

Table 33

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	63.1 % (w/w), no surfactant Dose on skin: > 0.3 mL BP/ 4.3 cm^2	63.1 % (w/w), surfactant Dose on skin: > 0.3 mL BP/ 4.3 cm^2
Value(s)	0.85 $mg/cm^2/h$	25 %
Justification for the selected value(s)	See table above	Default, EFSA Guidance on Dermal Absorption

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 components of the biocidal product, which are classified (Asp. 1; Skin Irrit. 2; Skin Sens. 1, Eye Irrit. 2 and Skin Irrit. 2; Eye Dam. 1) do not contribute to the classification of the biocidal product due to their low concentration.

3.6.2.9 Available toxicological data relating to a mixture

Not required.

3.6.2.10 Other

Not available.

3.6.2.11 Summary of effects assessment

Table 34

Endpoint	Brief description
Skin corrosion and irritation	Not classified for skin corrosion or irritation. Repeated exposure may cause skin dryness or cracking. [EUH066]
Eye irritation	Eye Irrit. 2, H319
Respiratory tract irritation	Not classified for respiratory tract irritation.
Skin sensitisation	Not classified for skin sensitisation. However, biocidal products of this BPF may contain sensitising substances, which would lead to a labelling according to the Cosmetic Regulation (EC) No 1223/2009).
Respiratory sensitization (ADS)	Not classified for respiratory sensitisation.
Acute toxicity by oral route	Not classified for acute oral toxicity. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L However, the biocidal products of this BPF are classified with STOT SE 3, H336 (May cause drowsiness and dizziness).

Acute toxicity by dermal route	Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw
Information on dermal absorption	Biocidal products of this BPF not containing a surfactant: 0.85 mg/cm^2/h (flux rate) Biocidal products of this BPF containing a surfactant: 25 %
Available toxicological data relating to non-active substance(s)	Substances of concern were not identified.
Available toxicological data relating to a mixture	Not required.
Other relevant information	Not available.

3.6.3 Exposure assessment

3.6.3.1 Identification of main paths of human exposure towards active substance and SoC from its use in biocidal product

Table 35

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

List of scenarios

Table 36

			Summary table: scenarios of the BPF (professionals)	
Scenario no.	**Scenario**	**Use no. (PT)**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Small surface disinfection - in-between disinfection	1, 2 (PT2)	Primary exposure of the professional user resulting from application (pouring, spraying and/ or 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. 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 meta SPCs 1, 3 and 7 for RTU solutions and meta SPCs 2, 4, 5, 6 and 8 for wipes**	Professional Industrial
2.	Small surface disinfection in laboratory	1, 2 (PT2)	Primary exposure of the professional user resulting from application (pouring, spraying and/ or wiping) of an alcohol based disinfectant in form of a ready to use product on small surfaces in technically ventilated rooms e.g. a work bench in a laboratory. Secondary exposure of a professional bystander who is present in the laboratory where the surface disinfection is carried out can be expected. **Applies to meta SPCs 1, 3 and 7 for RTU**	Professional Industrial

			solutions and meta SPCs 2, 4, 5, 6 and 8 for wipes	
3.	Small surface disinfection in kitchens and canteens	3, 4 (PT4)	Primary exposure of the professional user resulting from application (pouring, spraying and/ or wiping) of an alcohol based disinfectant in form of a ready to use product on small surfaces in food contact areas e.g. a work bench in a kitchen. Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out can be expected. **Applies to meta SPCs 1, 3 and 7 for RTU solutions and meta SPCs 2, 4, 5, 6 and 8 for wipes**	Professional Industrial
4	Disinfection of food processing machinery	3, 4 (PT4)	Primary exposure of the professional user resulting from application (pouring, spraying and/ or wiping) of an alcohol based disinfectant in form of a ready to use of food processing machinery and its parts in a technically ventilated and cooled production hall of e.g. a meat processing factory. Secondary exposure of a professional bystander who is present in the close to the food processing machinery where the surface disinfection is carried out can be expected. **Applies to meta SPCs 1, 3 and 7 for RTU solutions and meta SPCs 2, 4, 5, 6 and 8 for wipes**	Professional Industrial
5.	Refilling	All uses	Decanting/Refilling of disinfectant from canisters (5 - 10 L) into handy sized packages (manually or with hand pumps). Secondary exposure of a professional bystander is expected.	Professional Industrial

Summary table: scenarios (non-professionals; general public)			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	application	PT2: Disinfection of small surfaces, bath rooms	non-professionals
2	application	PT4: Disinfection of small surfaces, kitchens	non-professionals
3a.	post-application	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult	general public, bystanders
3b.	post-application	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, child	general public, bystanders
3c.	post-application	PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler	general public, bystanders
4a	post-application	PT4: Secondary exposure from disinfection of small surfaces, kitchens, adult	general public, bystanders
4b	post-application	PT4: Secondary exposure from disinfection of small surfaces, kitchens, child	general public, bystanders
4c	post-application	PT4: Secondary exposure from disinfection of small surfaces, kitchens, toddler	general public, bystanders
5	post-application	PT2: Secondary exposure from disinfection of small surfaces, hospital rooms, toddler	general public, bystanders

Note that the exposure assessments for bystanders (scenarios 3 and 4, adults) are essentially identical to the inhalation exposure assessments for non-professional users (scenarios 1 and 2). Hence, these assessments cover both, exposure of bystanders after use and during use.

3.6.3.1.1 Industrial exposure

Scenario 1 Small surface disinfection - in-between disinfection

For a detailed description on this scenario, please see chapter 3.6.3.1.2.

Scenario 2 Small surface disinfection in laboratory

For a detailed description on this scenario, please see chapter 3.6.3.1.2.

Scenario 3 Small surface disinfection in kitchens and canteens

For a detailed description on this scenario, please see chapter 3.6.3.1.2

Scenario 4 Disinfection of food processing machinery

For a detailed description on this scenario, please see chapter 3.6.3.1.2.

Scenario 5 Refilling

For a detailed description on this scenario, please see chapter 3.6.3.1.2.

3.6.3.1.2 Professional exposure

Overview of the intended applications within the eight meta SPCs of the perform-IPA BPF

The “perform-IPA BPF” is a biocidal product family (BPF) of propan-2-ol-based liquid disinfectants consisting of 8 meta SPCs. All members of the eight meta SPCs are ready to use disinfectants containing propan-2-ol (CAS-No.: 67-63-0), 63.1 % (w/w).

All 8 meta SPCs comprise products of PT2 which are used for disinfection of small surfaces in the health and institutional sector. All 8 meta SPCs also contain products of PT4 which are used for disinfection of small surfaces in food contact areas and of food processing machinery.

The **products of meta SPCs 1, 3 and 7 are ready to use solutions** which are poured or sprayed with a hand-held trigger spray bottle on a surface which is then wiped or the ready to use solution is sprayed on the surface which is then left to dry. The products are used for disinfection of small surfaces and for food processing machinery.

The **products of meta SPCs 2, 4, 5, 6 and 8 are ready to use wipes** which are impregnated with the disinfectant solution. They are used for disinfection of small surfaces and food processing machinery by wiping.

For all member of the eight meta SPCs identical applications are requested by the applicant. Therefore is the **exposure assessment in meta SPC 1 valid for meta SPCs 1 to 8**. Moreover, the assessment of the liquid formulation is considered as the worst case assumption for the use of wipes: The application of a ready to use wipe from which the disinfection solution is transferred on the surface to be treated can well be compared to the surface disinfection by pouring or spraying of the ready to use solution and subsequent wiping. The ready to use solution is applied with a use rate of 25 ml per m². According to information from the applicant the use rate for a ready to use wipe is 15.9 ml/m².
The application of the ready to use solution represents a realistic worst case for the exposure scenarios and covers the use of impregnated wipes.

The summary

Table 37 gives an overview of the in use products in meta SPCs 1 to 8 of the BPF.

Table 37

meta SPC	Formulation type
1.	Ready to use solutions (63.1 % active substance)
2	Ready to use wipes (63.1 % active substance)
3	Ready to use solutions (63.1 % active substance)
4	Ready to use wipes (63.1 % active substance)
5	Ready to use wipes (63.1 % active substance)
6	Ready to use wipes (63.1 % active substance)
7	Ready to use solutions (63.1 % active substance)
8	Ready to use wipes (63.1 % active substance)

General Information on meta SPC 1 to 8

The products of meta SPC 1, 3 and 7 are ready to use disinfectant solutions. They are marketed in different package sizes:

- Bottle containing 250 to 1000 ml product
- revolver bag containing 1 L of product
- canister containing 5 to 10 L product

The products of meta SPC 2, 4, 5, 6 and 8 are ready to use wipes which are impregnated with the disinfectant solution. They are marketed in different package sizes:

- soft pack containing 1 to 200 wipes
- pouch containing 10 to 200 wipes
- pouch containing 50 to 200 wipes

The concentration of the active substance propan-2-ol is 63.1 % (w/w).

The exposure assessment is usually based on the harmonised 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 dermal and inhalation exposure to the active substance propan-2-ol are assessed separately for the different application techniques and will thus be described in individual subsections of the current section.
The inhalation exposure to vapours of the active substance propan-2-ol for the exposure scenarios is assessed using the consumer exposure model ConsExpo Web.
The used parameters for calculation are in accordance with information from the applicant and the CAR of propan-2-ol.
Due to local effects of the active substance propan-2-ol a qualitative local risk assessment is performed and described in chapter 3.6.4.6.

The following description of the scenarios 1 - 5 (Table 36) and the related exposure assessment is valid for all eight meta SPCs.

In Annex 4.3 the details of the exposure calculations to the active substance propan-2-ol for the professional user are laid out.

Further information on meta SPC 3 and 4

The external exposure assessment for professional users for biocidal products of meta SPC 3 and 4 is covered by the exposure assessment as presented for biocidal products of meta SPC 1.

The products of meta SPC 3 and 4 contain a surfactant[Fehler! Textmarke nicht definiert. 9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption. Therefore the internal exposure values are different to the internal values for meta SPC 1. The results of the internal exposure are identical for meta SPC 3 and 4.

Since no risk was identified for scenario 1-3 resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For information purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account (see exposure assessment meta SPC 1).

The results of the local risk assessment are the same as described in meta SPC 1.

Scenario 1 Small surface disinfection in-between disinfection

The following scenario covers the disinfection of small surfaces with an alcohol based disinfectant in a naturally ventilated room. This scenario is introduced because the scenarios from the CAR for propan-2-ol consider disinfection in technically ventilated rooms, only. Alcohol based RTU products are used on hospital and care home surfaces which require rapid and effective in-between infection control such as: door handles, cabinets, tables, non-invasive medical equipment (such as wheelchairs, walking frames) and general equipment (e.g. telephones, trolleys).
For the disinfection of small surfaces the ready to use disinfectant solution (meta SPC 1, 3 and 7) is poured or sprayed with a hand-held trigger spray bottle on the surface to be treated which is then wiped. Or a wipe will be soaked by pouring/spraying with liquid product and wiped on surface. Or the liquid product is sprayed on the surface which is then left to dry. To get the alcoholic disinfectant effectively on the surface the spraying is carried out directly from a very short distance.

This scenario also covers the disinfection of small surfaces area with impregnated wipes (meta SPC 2, 4-6, 8).

The eCA assessed based on the decision of Working Group Human Health VII 2018 for a similar product family with the a.s. two different types of professional users:

1: Small surface disinfection – in-between disinfection by nurses or health care worker
and in addition
2: Small surface disinfection – in patient rooms by specialised cleaning personal

The complete exposure assessments of both types of users are available in Annex 4.3. Based on the results the scenario “Small surface disinfection – in-between disinfection by nurses or health care worker” is the worst case. Therefore this scenario is described in more details in the following section and is brought to the risk characterisation.

The perform IPA (meta SPC 1, 3 and 7) disinfectant product is a ready-to-use surface disinfectant solution which may be decanted from a canister into a smaller unit prior to application.
For disinfection of small surfaces

- the application liquid is either poured or sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally the surface to be disinfected is wiped off. Or
- the application liquid is sprayed onto the surface which is then left to dry.

To get the alcoholic disinfectant effectively on the surface, 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.

Based on HEAdhoc recommendation 9, during the working day a nurse/carer is expected to stay 20 minutes in every room to perform their duties. After visiting 4 rooms they are expected to repeat the process throughout the day revisiting each room in turn (therefore, 2 visits per room per day).

Dermal exposure

Dermal exposure can be expected during the wiping procedure of the application phase when the 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 products of meta SPC 3 and 4 contain a surfactant as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption which was calculated based on the model BEAT small scale wiping (CAR Propan-2-ol): 75th percentile values are used (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux.

This assessment is also valid for the ready to use wipes of meta-SPC 4.

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. Calculation of inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation- exposure to vapour- evaporation model” which is applicable to assess the volatile part of the active substance.
Based on HEAdhoc recommendation 9 the inhalation exposure can be estimated from the following outputs in ConsExpo – evaporation model:
Mean air concentration from disinfection (mg/m^3): during 20 minute visit in the room, a small area 0.5 m^2 is disinfected for 1 minute per room.

Remaining air concentration after 240 min: extrapolation from ConsExpo graph plot.

Inhalation exposure =
4 rooms (1st treatment) x mean air conc (xx mg/m3) x 20mins x inhalation rate (1.25m^3/hr) + 4 rooms (2nd treatment) x (mean air conc xx mg/m^3 + residual air conc xx mg/m^3) x 20mins x inhalation rate (1.25m^3/hr)

The above described exposure assessment for a ready to use solution is a worst case for the assessment of the ready to use wipes.

Exposure to the eyes

The product is presented in form of a ready to use solution/wipe. For the treatment of small horizontal surfaces only a small amount of the product is directly applied from a short distance on the surface so that exposure to the eyes is not expected. Moreover propan-2-ol 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 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 38

Details of Scenario 1	
Parameters	**Value**
Concentration of propan-2-ol in biocidal product	63.1 % (w/w)
Density of the biocidal product	0.876 g/cm³
Number of surface disinfections	8
Area of one palm	205 cm²
ConsExpo 4.1 parameters	
Room volume	80 m³
Ventilation rate	1.5 / h
Surface area	0.5 m²
Volume of biocidal product per application	12.5 ml
Application duration	1 min
Product amount	10.9 g
Exposure duration (in one room)	20 min
Frequency of use	4 rooms visited (2 visits per room per day)
Mode of release	Evaporation

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 43 and Table 44.

For details of the calculation of dermal and inhalation exposure and for the ConsExpo Web reports, please refer to Annex 4.3 of this PAR.

For risk characterisation, see chapter 3.6.4.6.

Further information and considerations on scenario 1

Scenario 1, as described for meta SPC 1, applies also to the respective application of meta SPCs 2 to 8.

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 biocidal product requires additional assessment of local risks (see chapter 3.6.4.6). Local risk assessment has indicated a risk for eye irritation. For disinfection of small horizontal 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. Thus, contact with eyes should be avoided.

The scenario 1 “Small surface disinfection – in-between disinfection by nurses or health care worker” represents a realistic worst case scenario and also covers the additional scenario ”Small surface disinfection in patient rooms” performed by specialised cleaning personal. This scenario describes disinfection of small surfaces in hospital rooms where one disinfection of 0.5 m² is carried out by e.g. a specialised cleaning personal who visits 10 different hospital rooms during the shift and stays five min in each room to perform routine cleaning tasks.
For further details please refer to Annex 4.3.

The used paper towel or ready to use wipes has to be discarded into a closed container after use to prevent secondary inhalation exposure to the a.s. which evaporates from the used towel/ready to use wipe.

For refilling of application bottles from larger storage containers, please refer to scenario 5, below.

Scenario 2 Small surface disinfection in laboratory

For the disinfection of small surfaces the ready to use disinfectant solution (meta SPC 1, 3 and 7) is poured or sprayed with a hand-held trigger spray bottle on the surface to be treated which is then wiped. Or the liquid product is sprayed on the surface which is then left to dry. To get the alcoholic disinfectant effectively on the surface the spraying carried out directly from a very short distance.

This scenario also covers the disinfection of small surfaces area with impregnated wipes (meta SPC 2, 4-6, 8).

This scenario is analogous to the respective scenario of the propan-2-ol CAR.

In laboratories, alcoholic disinfection of small surfaces of 0.5 m² is commonly performed prior to every new task to remove potential contamination e.g. of biomaterial from a previous task. As worst case scenario, it is assumed that one person disinfects its working bench every 45 minutes in a small room. This scenario also covers the application of the products of meta SPC 1-8 for disinfection of small surfaces in cleanrooms because it represents a realistic worst case scenario:
The laboratory has a room volume of 25 m³ whereas for a cleanroom a room volume of 55 m³ is assumed. The air exchange rate in the laboratory is 8/h which is similar to the Tier 1 scenario in the cleanroom. In Tier 2 of the cleanroom scenario the air exchange rate of 20/h for a cleanroom (information from the applicant; ISO 14644-1, class 7) is considerably higher.
For more details please refer to the additional scenario “Small surface disinfection in cleanrooms” in Annex 4.3.

Dermal exposure

Dermal exposure can be expected during the wiping procedure of the application phase when the 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 products of meta SPC 3 and 4 contain a surfactant [9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption which was calculated based on the model BEAT small scale wiping (CAR Propan-2-ol): 75th percentile values are used (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux.
This assessment is also valid for the ready to use wipes.

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 of the professional user to the active substance propan-2-ol is carried out using the consumer exposure model ConsExpo web model “Inhalation- exposure to vapour- evaporation model” which is applicable to assess the volatile part of the active substance. The spraying is carried out directly from a very short distance and the disinfectant solution is wiped over the surface. This is not comparable with spraying in a room. Therefore the exposure relevant task is the treatment of the surface by wiping and the resulting evaporation and not the spraying.

The above described exposure assessment for a ready to use solution is a worst case for the assessment of the ready to use wipes.

Exposure to the eyes

The product is presented in form of a ready to use solution/wipe. For the treatment of small horizontal surfaces e. g. work benches the product is directly applied on the surface by pouring or spraying and subsequent wiping so that exposure to the eyes is not expected. Moreover propan-2-ol 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 39

Details of Scenario 2	
Parameters	**Value**
Concentration of propan-2-ol in biocidal product	63.1 % (w/w)
Density of the biocidal product	0.876 g/cm³
Number of surface disinfections	10
Area of one palm	205 cm²
ConsExpo web parameters	
Room volume	25 m3
Ventilation rate	8 / h
Surface area	0.5 m²
Volume of biocidal product. per application	12.5 ml
Application duration	1 min
Product amount	10.9 g
Exposure duration	45 min
Mode of release	Evaporation

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 43 and Table 44.

For details of the calculation of dermal and inhalation exposure and the ConsExpo web reports, please refer to Annex 4.3 of this PAR.

For risk characterisation, see chapter 3.6.4.6.

Further information and considerations on scenario 2

Scenario 2, as described in this meta SPC 1, applies also to the respective application of meta SPCs 2 to 8.
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 biocidal products requires additional assessment of local risks (see chapter 3.6.4.6). Local risk assessment has indicated a risk for eye irritation. For disinfection of small horizontal 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. Thus, contact with eyes should be avoided.
The used paper towel or ready to use wipe has to be discarded into a closed container after use to prevent secondary inhalation exposure to propan-2-ol which evaporates from the used towel/ready to use wipe.

For refilling of application bottles from larger storage containers, please refer to scenario 5, below.

Scenario 3 Small surface disinfection in kitchens and canteens

Description

For the disinfection of small surfaces the ready to use disinfectant solution (meta SPC 1, 3 and 7) is poured or sprayed with a hand-held trigger spray bottle on the surface to be treated which is then wiped. Or the liquid product is sprayed on the surface which is then left to dry. To get the alcoholic disinfectant effectively on the surface the spraying carried out directly from a very short distance.

This scenario also covers the disinfection of small surfaces area with impregnated wipes (meta SPC 2, 4-6, 8).
This scenario is analogous to the respective scenario of the propan-2-ol CAR.

In canteens or kitchens, alcohol-based disinfectant can be used after the finishing of special tasks (e.g. working with eggs or egg-containing substances). For this scenario disinfection of small surfaces of 1 m² is taken into consideration according to the corresponding scenario in the CAR for propan-2-ol which describes a surface area of 1 m² for use in PT4. Four disinfections are carried out during the workday of 8 h. The propan-2-ol concentrations are calculated for a small room of 25 m³ and that the person does not leave the room (worst case assumption).

Dermal exposure

Dermal exposure can be expected during the wiping procedure of the application phase when the 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 products of meta SPC 3 and 4 contain a surfactant [9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption which was calculated based on the model BEAT small scale wiping (CAR Propan-2-ol): 75th percentile values are used (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux.

This assessment is also valid for the ready to use wipes.

Inhalation exposure

Exposure to vapour occurs during the application phase due to the vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure of the professional user to the active substance propan-2-ol is carried out using the consumer exposure model ConsExpo web model “Inhalation- exposure to vapour- evaporation model” which is applicable to assess the volatile part of the active substance. The spraying is carried out directly from a very short distance and the disinfectant solution is wiped over the surface. This is not comparable to spraying in a room. Therefore the exposure relevant task is the treatment of the surface by wiping and the resulting evaporation and not the spraying.

The above described exposure assessment for a ready to use solution is a worst case for the assessment of the ready to use wipes.

Exposure to the eyes

The product is presented in form of a ready to use solution/wipe. For the treatment of small horizontal surfaces the product is directly applied on the surface by pouring or spraying and subsequent wiping so that exposure to the eyes is not expected. Moreover propan-2-ol 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 kitchen 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 40

Details of Scenario 3	
Parameters	**Value**
Concentration of propan-2-ol in biocidal product	63.1 % (w/w)
Density of the biocidal product	0.876 g/cm³
Number of surface disinfections	4 per day
Area of one palm	205 cm²
ConsExpo 4.1 parameters	
Room volume	25 m3
Ventilation rate	15 / h
Surface area	1 m²
Volume of biocidal product per application	25 ml
Application duration	2 min
Product amount	21.9 g
Exposure duration	120 min
Mode of release	Evaporation

Calculations for Scenario 3

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 43 and Table 44.

For details of the calculation of dermal and inhalation exposure and the ConsExpo web reports, please refer to Annex 4.3 of this PAR.

For risk characterisation, see chapter 3.6.4.6.

Further information and considerations on scenario 3

Scenario 3, as described in this meta SPC 1, applies also to the respective application of meta SPCs 2 to 8.

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 biocidal product requires additional assessment of local risks (see chapter 3.6.4.6: Risk for professional users). Local risk assessment has indicated a risk for eye irritation. For disinfection of small horizontal surfaces by professional users the product is usually applied on the surface in downwards direction so that exposure to the eye is not expected. Thus, contact with eyes should be avoided.

This scenario also covers the application of the products of meta SPC 1 for disinfection of small surfaces in e.g. canteens or supermarkets which have a larger room volume but a lower air exchange rate.

The used paper towel and ready to use wipe has to be discarded into a closed container after use to prevent secondary inhalation exposure to the active substance which evaporates from the used towel/ready to use wipe.

For refilling of application bottles from larger storage containers, please refer to scenario 5, below.

Scenario 4 - 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.

For the disinfection of food processing machinery the applicant describes that wipes soaked with ready to use disinfectant solutions (meta SPC 1, 3 and 7) by pouring or spraying are used for rapid surface disinfections of a cutting machine and a packaging machine in the production hall of a food processing factory are performed four times per day.
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, not the spraying (aerosol formation), and wiping.

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

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 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.

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 products of meta SPC 3 and 4 contain a surfactant [9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption which was calculated based on the model BEAT small scale wiping (CAR Propan-2-ol): 75th percentile values are used (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux.

Inhalation exposure

Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol (4260 Pa at 20° C). A calculation of 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 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 (e.g. splashes). 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 production hall is not expected because due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the production hall or canteen where the surface disinfection is carried out. The inhalation exposure will be in the same order of magnitude or lower as for the operator.

This scenario also covers the disinfection of small surfaces area with impregnated wipes (meta SPC 2, 4-6, 8).

Table 41

Details of Scenario 4	
Parameters	**Value**
Concentration of propan-2-ol in biocidal product	63.1 % (w/w)
Density of the biocidal product.	0.876 g/cm³
Number of surface disinfections	4 per day
Area of two palms	410 cm²
ConsExpo web parameters	

Room volume around the machine	300 m3
Temperature	20 °C
Ventilation rate	20/ h
Area to be treated	4.6 m²
Application rate of biocidal product	25 ml/m^2
Application duration	5 min
Exposure duration	120 min

Calculations for Scenario 4

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 43 and Table 44.

For details of the calculation of dermal and inhalation exposure and the ConsExpo 4.1 reports, please refer to Annex 4.3 of this PAR.

For risk characterisation, see chapter 3.6.4.6.

Further information and considerations on scenario 4

Scenario 4, as described in this meta SPC 1, applies also to the respective application of meta SPCs 2 to 8.

Since no risk was identified in meta SPC 1, 2, 5-8 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 application of the products of meta SPC 1 to 8 for disinfection of food processing machinery at room temperature which is applicable e.g. for bakeries: The increase in temperature only triggers a negligible increase in inhalation exposure.

The classification of the biocidal product requires additional assessment of local risks (see chapter 3.6.4.6: Risk for professional users). Local risk assessment has indicated a risk for eye irritation.
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.

The used paper towel and ready to use wipe has to be discarded into a closed container after use to prevent secondary inhalation exposure to the active substance which evaporates from the used towel/ready to use wipe.

For refilling of application bottles from larger storage containers, please refer to scenario 5, below.

Scenario 5 – 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 which requires the use of an adequate funnel. After refilling the person closes the bottles with a screw cap and lifts the bottle to put it aside, which results in dermal exposure of 1 palm.

Dermal exposure

Exposure of the palm of one hand is expected during replacement of refilled bottles, due to spilled quantities on the outside.

The products of meta SPC 3 and 4 contain a surfactant [9] as ingredient. For this reason the dermal risk for the professional user was assessed based on “Mixing and loading model 4” (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG). For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux.

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. The 75th percentile is used instead of the 90th percentile since the scenario is already a worst case assumption using a small room size, low ventilation and the nearfield. Moreover the 75th percentile of an ART model was already agreed for HEADhoc recommendation 3 “Spraying models for assessing exposure to insecticides for low pressure downward uses”.

Exposure of 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

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

Table 42

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.	0.876 g/cm³
Frequency per day	1
Exposed skin area (one palm)	205 cm²
ART 1.5 parameters	
Room volume	Small workroom only
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1 - 1 l/minute
Containment level	Handling that reduces contact between product and adjacent air.
Loading type	Splash loading

Calculations for Scenario 5

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 43 and Table 44.
For details of the calculation of dermal and inhalation exposure and the ConsExpo web reports, please refer to Annex 4.3 of this PAR.
For risk characterisation, see chapter 3.6.4.6.

Further information and considerations on scenario 5

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required.
The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.6: 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.

Summary of professional exposure

The following tables give an overview of the assessed exposure values. In Table 43 the estimated external inhalation exposure and external dermal exposure are listed. In Table 44 the values of the assumed exposed skin area and application time for dermal exposure are summarised.

The dermal exposure values in Table 43 are used for the risk assessment in meta SPCs 3 and 4. The products of meta SPC 3 and 4 contain a surfactant[9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption (see chapter 3.6.4.6).

The values in Table 44 are necessary for the dermal risk assessment based on the dermal flux (see chapter 3.6.4.6).

Table 43

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 Small surface disinfection - in between disinfection	1, 2 (PT2)	Tier 1	20.805	946.32*
		Tier 2 (Protective gloves)	20.805	94.63*
Scenario 2 Small surface disinfection in laboratory	1, 2 (PT2)	Tier 1	42.656	1182.90*
		Tier 2 (Protective gloves)	42.656	118.29*
Scenario 3 Small surface disinfection in kitchens and canteens	3, 4 (PT4)	Tier 1	18.300	946.32*
		Tier 2 (Protective gloves)	18.300	94.63*
Scenario 4 Disinfection of food processing machinery	3, 4 (PT4)	Tier 1	5.240	2365.80*
		Tier 2 (Protective gloves)	5.240	236.58*
Scenario 5 Refilling	All uses	Tier 1	0.950	276.38*
		Tier 2 (Protective gloves)	0.950	27.64*

*) The products of meta SPC 3 and 4 contain a surfactant[9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption calculated from external dermal exposure.
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux. Therefore, the external dermal exposure is only given for purpose of information.

Table 44

Summary table: Exposed skin area and application time for dermal exposure.						
Scenario	**Product type**	**Application time [min]**	**Application frequency/ day**	**Exposed skin area [cm²]**	**Exposed hand (palm) surfaces**	**Application time/day [min]**
Scenario 1 Small surface disinfection– in-between disinfection	PT2	1	8	205	1	8.0

Scenario 2 Small surface disinfection in laboratory	PT2	1	10	205	1	10.0
Scenario 3 Small surface disinfection in kitchens and canteens	PT4	2	4	205	1	8.0
Scenario 4 Disinfection of food processing machinery	PT4	5	4	410	2	20.0
Scenario 5 Refilling	All uses	0.5	1	205	1	0.5

Combined scenarios

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

Table 45

Summary table: combined 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 Exposed propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure* [mg/day]**
Scenario 1: Small surface disinfection - in-between disinfection and Scenario 5: Refilling	1 (PT 02)	Tier 1	21.755	1222.70*
		Tier 2 (Protective gloves)	21.755	122.27*
Scenario 2: Small surface disinfection in laboratory and Scenario 5: Refilling	1 (PT 02)	Tier 1	43.606	1459.28
		Tier 2 (Protective gloves)	43.606	145.93
Scenario 3: Small surface disinfection in kitchens and canteens and Scenario 5: Refilling	2 (PT 04)	Tier 1	19.250	1222.70
		Tier 2 (Protective gloves)	19.250	122.27

Scenario 4: Disinfection of food processing machinery and Scenario 5: Refilling	2 (PT 04)	Tier 1	6.190	2642.17
		Tier 2 (Protective gloves)	6.190	264.22

*) The products of meta SPC 3 and 4 contain a surfactant[9] as ingredient. For this reason the dermal risk for the professional user was assessed based on the dermal absorption calculated from external dermal exposure.
For the products of meta-SPCs 1, 2, 5, 6, 7, 8 the risk assessment is based on the use of dermal flux. Therefore, the external dermal exposure is only given for purpose of information.

3.6.3.1.3 Non-professional exposure

The exposure assessments for non-professional users according to the CAR are based on the TNsG models/defaults and Consexpo 4. Although 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 non-professional users are amended accordingly.
Exposure and risk assessment is based on the reference product Perform IPA directly applied as a liquid in accordance to the corresponding CARs for propan-2-ol (PT 2 and 4). For non-professionals only the use of wipes is relevant (Meta-SPC 6). It is assumed that direct use of liquids represent a worst case for wipe application. More details are given in the Description of Scenarios in Table 46 and Table 47.
The applications assessed according to the listed scenarios are considered to represent also a realistic worst case for all other potential applications.

- **Scenario [1]**

Table 46

Description of Scenario [1]
PT2: Primary exposure, disinfection of small surfaces, bath rooms: The biocidal product family (for non-professional use only products of meta SPC 6) is used by non-professionals to disinfect surfaces for household cleaning. Usually this may occur once per week. The biocidal products are used as wipes. Exposure by wiping is considered to be lower or in maximum in the same range than exposure by direct application of the liquid and has hence not been assessed separately. Exposure by direct application of the liquid represents a worst case. Furthermore, due to the high vapour pressure of the active substance inhalation exposure may occur if the person stays in the room after application. It is expected that non-professional exposure is limited to a short time interval, usually one day. Even if applied regularly, e.g. for household cleaning, time intervals between exposures are expected to be sufficiently long to assume acute exposure. Therefore, only acute exposure is assessed. It is further assumed that disinfection is performed after regular cleaning and that the person cleaning the surface in bathrooms, for example, will leave the room shortly after disinfection. The applicant informed in its application that the amount that is set free during wiping is 5.3 g biocidal product/m^2 or 3.3 g active substance/m^2. The amount, which is set free to the surface from the wipe and which is available for disinfection is about 75 %. The applicant also submitted the information that a standard wipe of 17.5 cm x 28 cm is sufficient to disinfect a surface of 1.8 m^2. It should also be noted that the applicant specified the application rate for ready-to-use wipes used by professionals with 15.9 mL biocidal product. However, the amounts of product used for the exposure assessment in the CAR (inhalation exposure: 25 mL/m^2, dermal exposure 8.2 mL per application) represents a worst case for both application rates of biocidal products from meta SPC 6.

Inhalation

For a single application it was assumed that 25 mL (corresponding to 21.9 g with a density of 0.88 g/mL) will be used. This corresponds to a surface of 1 m^2 if 25 mL of the biocidal product are used per m^2. This is half of the maximum amount that should be used in hospitals according to German TRGS 525 (Technical regulation for the handling of hazardous substances in medical care facilities, 2014) and is considered to represent maximum conditions for the private area. It is assumed that the biocidal product is applied to a total surface of 1 m^2 within 2.5 minutes. A small room volume of 10 m^3 and a ventilation rate of 2.0/h (default value for bathrooms) have been chosen for calculations according to the General Fact Sheet for Consexpo (2014). The mass transfer rate from the surface to the room volume has been assumed as 10 m/h = 0.167 m/min (= 10 m/h) according to RIVM Overarching issues – ConsExpo Web and fact sheets, 2018) As a worst case it is assumed that application is performed 5 times a day.

Dermal exposure

For non-professional users only the application of wipes is relevant (meta SPC 6). Non-professional users are normally less experienced in the use of these wipes. Therefore, it must be assumed that in contrast to professional user both hands will be used and exposed during application. Hence, for dermal exposure as a worst case scenario it is assumed that the biocidal product covers completely the surface of both hand palms (410 cm^2) with a thin liquid layer of 0.01 cm (according to TGD on Risk Assessment, 2003) resulting in 4.1 mL biocidal product (equivalent to 3.6 g biocidal product and 2277 mg propan-2-ol; taken into account a density of 0.88 g/cm^3). For a worst case scenario it is assumed that the time for evaporation is about 130 s and that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70 % aqueous dilution (w/w) on rat skin has been estimated as 0.85 mg/cm^2/h (Boatman et al. 1998).

	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	5/d
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Weight fraction compound (applicant)	63.1 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	5 min
	Room volume (CAR, propan-2-ol, 2014 Consexpo General Fact Sheet, 2014)	10 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.0/h

	Applied amount (German TRGS 525, 2014)	21.9 g (25 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mol weight matrix (water)	18 g/mol
	Mass transfer rate (Overarching issues – ConsExpo Web and fact sheets, 2018)	10 m/h = 0.167 m/min
	Inhalation rate, adult (short- term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m^3/h (0.021 m^3/min)
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	
	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	130 s per application/event (rounded)
	Frequency (CAR, propan-2-ol, 2014)	5/d
	Exposed area (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	410 cm^2 (two hand palms)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 mg/cm^2/h

Calculations for Scenario [1]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

Inhalation exposure = 1.88 mg/kg bw/d (1 application)
= 9.39 mg/kg bw/d (5 applications)

For dermal exposure the evaporation time is calculated according to the following equation:

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 127 s

t: time [s]
m: mass of propan-2-ol on surface: 2277 mg
R: gas constant: 8.314 J/K/mol
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g/mol
β: mass transfer coefficient, for calculation see TGD: 8.7 m/h
p: vapour pressure of the pure substance: 7600 Pa (30 °C)
A: surface area (hands): 410 cm^2
K: conversion factor: 36000

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

Dermal exposure = dermal flux rate x evaporation time x hand surface / body weight
= 0.85 mg/cm^2/h x 0.0361 h x 410 cm^2 / 60 kg
= 0.21 mg/kg bw/d (1 application)
= 1.05 mg/kg bw/d (5 applications)

- **Scenario [2]**

Table 47

Description of Scenario [2]
PT4: Primary exposure, disinfection of small surfaces, kitchens: The biocidal product family (for non-professional use only products of meta SPC 6) is used by non-professionals to disinfect surfaces in kitchens. Usually this may occur once per week. The biocidal products are used as wipes. Exposure by wiping is considered to be lower or in maximum in the same range than exposure by direct application of the liquid and has hence not been assessed separately. Exposure by direct application of the liquid represents a worst case. Furthermore, due to the high vapour pressure of the active substance inhalation exposure may occur if the person stays in the room after application. Disinfection is usually performed after conventional cleaning of the kitchen. Thus, it is assumed that persons will leave the kitchen briefly after use within 15 min. Dermal exposure is expected in the moment when the operator applies the spray. It is assumed that the total surface of the hands will be covered with the biocidal product for a short time interval until the active substance is evaporated. Dermal exposure because of contact to treated surfaces is considered negligible due to rapid evaporation. The applicant informed in its application that the amount that is set free during wiping is 5.3 g biocidal product/m^2 or 3.3 g active substance/m^2. The amount, which is set free from the wipe and which is available for disinfection is about 75 %. The applicant also submitted the information that a standard wipe of 17.5 cm x 28 cm is sufficient to disinfect a surface of 1.8 m^2. It should also be noted that the applicant specified the application rate for ready-to-use wipes used by professionals with 15.9 mL biocidal product. However, the amounts of product used for the exposure assessment in the CAR (inhalation exposure: 25 mL/m^2, dermal exposure 8.2 mL per application) represents a worst case for both application rates of biocidal products from meta SPC 6. <u>Inhalation</u> For a single application it was assumed that 25 mL (corresponding to 21.9 g with a density of 0.88 g/mL) will be used. This corresponds to a surface of 1 m^2 if 25 mL of the biocidal product are used per m^2. This is half of the maximum amount that should be used in hospitals according to German TRGS 525 (Technical regulation for the handling of hazardous substances in medical care facilities, 2014) and is considered to represent maximum conditions for the private area. It is assumed that the biocidal product is applied to a total surface of 1 m^2 for 5 min (application duration) and that the user leaves the kitchen after 15 minutes (exposure duration). A room volume of 15 m^3 and a ventilation rate of 2.5/h have been chosen for calculations as default values for kitchens according to the General Fact Sheet for Consexpo (2014). The mass transfer rate from the surface to the room volume has been assumed as 10 m/h = 0.167 m/min (= 10 m/h) according to RIVM Overarching issues – ConsExpo Web and fact sheets, 2018). <u>Dermal exposure</u> For non-professional users only the application of wipes is relevant (meta SPC 6). Non-professional users are normally less experienced in the use of these wipes. Therefore, it must be assumed that in contrast to professional user both hands will be used and exposed during application. Hence, or dermal

exposure as a worst case scenario it is assumed that the biocidal product covers completely the surface of both hand palms (410 cm^2) with a thin liquid layer of 0.01 cm (according to TGD on risk assessment) resulting in 4.1 mL biocidal product (equivalent to 3.6 g biocidal product and 2277 mg propan-2-ol; taken into account a density of 0.88 g/cm^3). For a worst case scenario it is assumed that the time for evaporation is about 130 s and that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70 % aqueous dilution (w/w) on rat skin has been estimated as 0.85 $mg/cm^2/h$ (Boatman et al. 1998).		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	log Kow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1/d
	Body weight, adult (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	60 kg
	Weight fraction compound (applicant)	63.1 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	15 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	15 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.5/h
	Applied amount (German TRGS 525, 2014)	21.9 g (25 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mol weight matrix (water)	18 g/mol
	Mass transfer rate (Overarching issues – ConsExpo Web and fact sheets, 2018)	10 m/h = 0.167 m/min
	Inhalation rate, adult (short-term, HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	1.25 m^3/h (0.021 m^3/min)
	Uptake fraction (inhalation absorption)	100 %
	Dermal model	

	Duration (calculated according to TGD on Risk Assessment, App. I, App. IF, 2003)	130 s per application/event (rounded)
	Frequency (CAR, propan-2-ol, 2014)	1/d
	Exposed area (HEEG opinion No.17 Default human factor values for use in exposure assessments for biocidal products, 2013)	410 cm^2 (two hand palms)
	Dermal penetration (CAR, propan-2-ol, 2014)	0.85 $mg/cm^2/h$

Calculations for Scenario [2]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

Inhalation exposure = 3.4 mg/kg bw/d (1 application)

For dermal exposure the evaporation time is calculated according to the following equation:

$t = m \times R \times T / (M \times \beta \times p \times A) \times K$ = 130 s

t: time [s]
m: mass of propan-2-ol on surface: 2277 mg
R: gas constant: 8.314 J/K/mol
T: skin/surface temperature: 303.15 K
M: molar mass: 60.1 g/mol
β: mass transfer coefficient, for calculation see TGD: 8.7 $m\ h^{-1}$
p: vapour pressure of the pure substance: 7600 Pa (30 °C)
A: surface area (hands): 410 cm^2
K: conversion factor: 36000

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

Dermal exposure = dermal flux rate x evaporation time x hand surface / body weight
= 0.85 $mg/cm^2/h$ x 0.0361 h x 410 cm^2 / 60 kg
= 0.21 mg/kg bw/d (1 application)

Table 48

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1	9.39 mg/kg bw/d	1.05 mg/kg bw/d	-	10.44 mg/kg bw/d
Scenario [2]	1	3.40 mg/kg bw/d	0.21 mg/kg bw/d	-	3.61 mg/kg bw/d

- **Combined scenarios**

Based on a decision taken at the BPC-WGVII-2018 exposure from non-professional use in PT2 and PT4 has to be combined.

Table 49

Summary table: systemic exposure of the general public				
Exposure scenario	**Tier / PPE**	**Scenario [1]**	**Scenario [2]**	**Scenario [1] + Scenario [2]**
Scenario [1] + [2]	1	10.44 mg/kg bw/d	3.61 mg/kg bw/d	14.05 mg/kg bw/d

3.6.3.1.4 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 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 non-professional users are amended accordingly.
Exposure and risk assessment is based on the reference product Perform IPA directly applied as a liquid in accordance to the corresponding CARs for propan-2-ol (PT 2 and 4). For the general public only exposure after non-professional use was assessed. It is assumed that this exposure represents also a worst case for secondary exposure after professional use. However, based on the comment of a Member State also an assessment for exposure during professional use in hospital rooms was included.
For the exposure of the general public after non-professionals only the use of wipes is relevant (meta SPC 6). However, it is assumed that direct use of liquids as assessed in the CAR represents a worst case for wipe application. More details are given in the Description of Scenarios in Table 50 and Table 51.
The applications assessed according to the listed scenarios are considered to represent also a realistic worst case for all other potential applications.

- **Scenario [3]**

Table 50

Description of Scenario [3]
PT2: Secondary exposure from disinfection of small surfaces, bathrooms: Secondary acute (daily) non-professional exposure may occur if persons (adults, children, toddlers) enter rooms after use of the biocidal product. As a worst case, inhalation exposure as presented for primary non-professional exposure assessment is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation should be in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons may stay in the same room as the person applying the biocidal product. It is expected that secondary exposure resulting from professional use is also covered by this scenario. It is assumed that a person stay in the room for 5 min. For exposure of children a body weight of 23.9 kg has been selected.

Note that this exposure assessment for bystanders (scenario 3, adults) is essentially identical to the inhalation exposure assessment for non-professional users (scenario 1). Hence, this assessment covers both, exposure of bystanders after use but also exposure during use.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	pKow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1/d
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	63.1 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	5 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	10 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.0/h
	Applied amount (German TRGS 525, 2014)	21.9 g (25 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mass transfer rate (Overarching issues – ConsExpo Web and fact sheets, 2018)	10 m/h = 0.167 m/min
	Mol weight matrix (water)	18 g/mol
	Inhalation rate, adult (short- term, HEAdhoc recommendation No.14 Default human factor	1.25 m^3/h

	values for use in exposure assessments for biocidal products, 2017)	
	Inhalation rate, child (short- term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.32 m³/h
	Inhalation rate, toddler (short- term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [3]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to the corresponding Annex in section 4.

3a. Adults

Inhalation exposure = 1.88 mg/kg bw/d (1 application)

3b. Children

Inhalation exposure = 4.98 mg/kg bw/d (1 application)

3c. Toddlers

Inhalation exposure = 11.40 mg/kg bw/d (1 application)

- **Scenario [4]**

Table 51

Description of Scenario [4]
PT4: Secondary exposure from disinfection of small surfaces, kitchens: Secondary acute (daily) non-professional exposure may occur if persons (adults, children, toddlers) enter rooms after use of the biocidal product. Inhalation exposure is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation are in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons stay in the same room as the person that has applied the biocidal product. As for primary exposure this persons will be exposed acutely. It is expected that exposure from professional use is also covered by this scenario. It is assumed that a person stays in the room for 15 min.

Note that this exposure assessment for bystanders (scenario 4, adults) is essentially identical to the inhalation exposure assessment for non-professional users (scenario 2). Hence, this assessment covers both, exposure of bystanders after use but also exposure during use.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol
	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	pKow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (CAR, propan-2-ol, 2014)	1/d
	Body weight, adult (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	60 kg
	Body weight, child (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	23.9 kg
	Body weight, toddler (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	63.1 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (CAR, propan-2-ol, 2014)	15 min
	Room volume (CAR, propan-2-ol, 2014, Consexpo General Fact Sheet, 2014)	15 m^3
	Ventilation rate (Consexpo General Fact Sheet, 2014)	2.5/h
	Applied amount (German TRGS 525, 2014)	21.9 g (25 mL)
	Release area (CAR, propan-2-ol, 2014)	10000 cm^2
	Application duration (CAR, propan-2-ol, 2014)	5 min
	Mass transfer rate (Overarching issues – ConsExpo Web and fact sheets, 2018)	10 m/h = 0.167 m/min
	Mol weight matrix (water)	18 g/mol
	Inhalation rate, adult (short- term, HEAdhoc recommendation No.14 Default human factor	1.25 m^3/h

	values for use in exposure assessments for biocidal products, 2017)	
	Inhalation rate, child (short- term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.32 m³/h
	Inhalation rate, toddler (short- term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m³/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [4]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to corresponding Annex in section 4.

4a. Adults

Inhalation exposure = 3.40 mg/kg bw/d (1 application)

4b. Children

Inhalation exposure = 9.02 mg/kg bw/d (1 application)

4c. Toddlers

Inhalation exposure = 20.60 mg/kg bw/d (1 application)

- **Scenario [5]**

Table 52

Description of Scenario [5]		
PT2: Secondary exposure from disinfection of small surfaces, professional user, hospital rooms: An additional secondary exposure assessment has been performed for toddlers (worst-case scenario) staying in a hospital room the whole day. Parameters from professional application (scenario 1: A nurse in a hospital performs in-between disinfections of small surfaces in patient rooms) were applied for the toddler's scenario, i.e. room volume, ventilation rate, applied amount, application duration, release area. The exposure duration (stay in the room) was set to 24 h as a worst-case and inhalation rate has been adjusted to 8m³/24 h acc. to HEAdhoc Rec. No 14.		
	Parameters	Value
Tier 1	General Data	
	Molecular weight (CAR, propan-2-ol, 2014)	60.1 g/mol

	Vapour pressure (25°C, CAR, propan-2-ol, 2014)	5780 Pa
	pKow (CAR, propan-2-ol, 2014)	0.05
	Exposure frequency (expert judgement based on scenario 1, professional use)	2/d
	Body weight, toddler (HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	10 kg
	Weight fraction compound (applicant)	63.1 % (w/w)
	Inhalation model: Exposure to vapour – exposure to vapour by evaporation	
	Exposure duration (worst case)	24 h
	Room volume (scenario 1, professional use)	80 m^3
	Ventilation rate (scenario 1, professional use)	1.5/h
	Applied amount (scenario 1, professional use)	10.9 g
	Release area (scenario 1, professional use)	0.5 m^2
	Application duration (scenario 1, professional use)	1 min
	Mass transfer rate (Overarching issues – ConsExpo Web and fact sheets, 2018)	10 m/h = 0.167 m/min
	Mol. weight matrix (water)	18 g/mol
	Inhalation rate, toddler (short- term, HEAdhoc recommendation No.14 Default human factor values for use in exposure assessments for biocidal products, 2017)	1.26 m^3/h
	Uptake fraction (inhalation absorption)	100 %

Calculations for Scenario [5]

Inhalation exposure is calculated according to Consexpo 4.1. For the corresponding Consexpo report refer to corresponding Annex in section 4.

5. Toddlers

Inhalation exposure = 3.84 mg/kg bw/d (2 applications)

Table 53

Summary table: systemic exposure of the general public

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3a]	1	1.88 mg/kg bw/d	-	-	1.88 mg/kg bw/d
Scenario [3b]	1	4.98 mg/kg bw/d	-	-	4.98 mg/kg bw/d
Scenario [3c]	1	11.40 mg/kg bw/d	-	-	11.40 mg/kg bw/d
Scenario [4a]	1	3.40 mg/kg bw/d	-	-	3.40 mg/kg bw/d
Scenario [4b]	1	9.02 mg/kg bw/d	-	-	9.02 mg/kg bw/d
Scenario [4c]	1	20.60 mg/kg bw/d	-	-	20.60 mg/kg bw/d
Scenario [5]	1	3.84 mg/kg bw/d	-	-	3.84 mg/kg bw/d

- **Combined scenarios**

Not relevant.

3.6.3.2 Dietary exposure

The intended use descriptions of the propan-2-ol-containing biocidal products of meta SPC 1 - 8 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 surface disinfectants that do not come into direct contact with food, feedstuff or livestock animals. Even so, use 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 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 PT 2 or PT4 can be excluded.

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

Exposure during production, formulation and disposal of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

The biocidal product is used in different product types. Thus, aggregated exposure resulting from the use in these product types cannot be excluded. This exposure has already been assessed during evaluation of the active substance. Default parameters and models used for this assessment have only changed marginally and in direction to lower exposure. Thus, this assessment can be adopted. For details refer to Doc. IIB 8.2.5 and Doc. IIB 12.4 of the corresponding CARs of PT2 and 4.

3.6.3.5 Summary of exposure assessment

Meta SPC 1 – professional/industrial user

Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6 and 8 (wipes). The exposure assessment for professional/industrial users for biocidal products of meta SPC 2, 5, 6, 7 and 8 is covered by the exposure assessment for biocidal products of meta SPC 1. The results of the estimated total uptake is presented in Table 56.

Meta SPC 3 – professional/industrial user

Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). The exposure assessment for professional users for biocidal products of meta SPC 4 is covered by the exposure assessment for biocidal products of meta SPC 3. The results of the estimated total uptake is represented in Table 57.. results of the estimated total uptake is presented in Table 56.

Non-professional user

Table 54

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1	application, non-professionals, PT2: Disinfection of small surfaces, bath rooms	1	10.44 mg/kg bw/d
2	application, non-professionals, PT4: Disinfection of small surfaces, kitchens	1	3.61 mg/kg bw/d
3a.	post-application, general public, bystanders, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult	1	1.88 mg/kg bw/d
3b.	post-application, general public, bystanders, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, child	1	4.98 mg/kg bw/d

3c.	post-application, general public, bystanders, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler	1	11.40 mg/kg bw/d
4a	post-application, general public, bystanders, PT4: Secondary exposure from disinfection of small surfaces, kitchens, adult	1	3.40 mg/kg bw/d
4b	post-application, general public, bystanders, PT4: Secondary exposure from disinfection of small surfaces, kitchens, child	1	9.02 mg/kg bw/d
4c	post-application, general public, bystanders, PT4: Secondary exposure from disinfection of small surfaces, kitchens, toddler	1	20.60 mg/kg bw/d
5	post-application, general public, bystanders, PT5: Secondary exposure from disinfection of small surfaces, professional user, hospital rooms, toddler	1	3.84 mg/kg bw/d

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)

Table 55

	Value	Source
AEL acute/medium/long-term General population	10.7 mg/kg bw/d	Assessment-Report (RMS DE (2014))
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d	Assessment-Report (RMS DE (2014))

3.6.4.2 Maximum residue limits or equivalent

No MRLs are required

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Endocrine disrupting properties

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance.
No co-formulant of the BPF “perform-IPA” was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision.
There are no further indications that co-formulants of the BPF “perform-IPA” may have endocrine disrupting properties based on the existing knowledge and the available scientific information. Therefore, the co-formulants of the BPF “perform-IPA” are not considered to have endocrine disrupting properties. For further information see chapter 4 of the confidential annex.

3.6.4.5 Risk for industrial users

The risk assessment for industrial users for biocidal products of meta SPC 1, 2, 5, 6, 7 and 8 is covered by the risk assessment for professional users as presented in section 3.6.4.6 for biocidal products of meta SPC 1. Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 4, 5, 6 and 8 (wipes). For details refer to this section.

The risk assessment for industrial users for biocidal products of meta SPC 3 and 4 is covered by the risk assessment for professional users as presented in section 3.6.4.7 for biocidal products of meta SPC 3. Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). For details refer to this section.

3.6.4.6 Risk for professional users – meta SPC 1

General considerations

The BPF comprises eight meta SPCs. The products of meta SPCs 1, 3 and 7 are ready to use solutions. The products of meta SPCs 2, 4, 5, 6 and 8 are ready to use wipes which are impregnated with the disinfectant solution. An overview of the applications applied for the eight meta SPCs is given in Table 36 in chapter 3.6.3. All members of the BPF contain propan-2-ol (CAS No.: 67-63-0) as active substance.

The risk assessment for biocidal products of meta SPC 2, 5, 6, 7 and 8 is covered by the risk assessment as presented in this section 3.6.4.6 for biocidal products of meta SPC 1. Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6 and 8 (wipes).

The risk assessment for biocidal products of meta SPC 4 is covered by the risk assessment as presented in section 3.6.4.7 for biocidal products of meta SPC 3. Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). For details refer to this section.

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

- **Systemic effects**

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

Details of risk characterisation

Reference value
As systemic reference value the AELacute/medium-/long-term of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and exposure-to-AEL ratio (%)
The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Due to the rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm2/h) instead of data on the percentage of dermal absorption is used for the calculation of the dermal uptake. For inhalation route 100% is assumed as default absorption for propan-2-ol. The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal products covered by meta SPC 1 are determined according to the following equations:

Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m3) x 10 m3 / 60 kg x %-inhalation absorption / 100 %.

Dermal uptake (mg/kg bw/d) = dermal flux of propan-2-ol (mg/cm2/h) x exposed skin area (cm2) 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 the biocidal products covered by meta SPC 1 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100%. Table 56 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 56. However, the underlying calculations are based on unrounded exposure values. As shown in Table 56, the scenarios ’Small surface disinfection – in between disinfection (PT02)’, ’Small surface disinfection in laboratory (PT02), ’Small surface disinfection in kitchens and canteens (PT04)’, ‘Disinfection of food processing machinery (PT04)’ and ‘Refilling (PT02 and 04)’ yield an exposure-to-AEL ratio of less than 100 % already in TIER 1.

Table 56: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1

PT	Scenario		AELacute/medium/long-term	Estimated inhalation uptake	Estimated dermal uptake	Estimated total uptake	Estimated total uptake/AEL	Acceptable
			mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%	(yes/no)
2	Small surface disinfection – in between disinfection	Tier 1	17.9	3.47	0.39	3.85	21.5	**yes**
2	Small surface disinfection in laboratory	Tier 1	17.9	7.11	0.48	7.59	42.4	**yes**
4	Small surface disinfection in kitchens and canteens	Tier 1	17.9	3.05	0.39	3.44	19.2	**yes**
4	Disinfection of food processing machinery	Tier 1	17.9	0.87	1.94	2.81	15.7	**yes**
2, 4	Refilling	Tier 1	17.9	0.16	0.02	0.18	1.0	**yes**

Tier 1: no PPE

Conclusion

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from the intended uses ’Small surface disinfection – in between disinfection (PT02)’, ’Small surface disinfection in laboratory (PT02), ’Small surface disinfection in kitchens and canteens (PT04)’, ‘Disinfection of food processing machinery (PT04)’ and ‘Refilling (PT02 and 04)’ with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.
A risk for professional users referring to the active substance propan-2-ol resulting from the combined uses of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields an exposure-to-AEL ration of less than 100 %. Table 58 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 58. However, the underlying calculations are based on unrounded exposure values.
As shown in Table 58, all combined scenarios considered (‘Refilling + Small surface disinfection – in between disinfection (PT02)’, ‘Refilling + Small surface disinfection in laboratory (PT02)’, ‘Refilling + Small surface disinfection in kitchens and canteens (PT04)’ and ‘Refilling + Disinfection of food processing machinery (PT04)’) yield exposure-to-AEL ratio of less than 100 % already in TIER 1. This means that after TIER 1 consideration no risk for professional users is identified.

Table 57: 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 1

PT	combined scenario		$AEL_{acute/medium/long-term}$	Estimated inhalation uptake	Estimated dermal uptake	Estimated total uptake	Estimated total uptake / AEL	Acceptable
			mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%	(yes/no)
02	Refilling + Small surface disinfection - in between disinfection	Tier 1	17.9	3.63	0.41	4.04	22.6	**yes**
02	Refilling + Small surface disinfection in laboratory	Tier 1	17.9	7.27	0.51	7.78	43.4	**yes**
04	Refilling + Small surface disinfection in kitchens and canteens	Tier 1	17.9	3.21	0.41	3.62	20.2	**yes**
04	Refilling + Disinfection of food processing machinery	Tier 1	17.9	1.03	1.96	2.99	16.7	**yes**

Tier 1: no PPE

- **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 has 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 (2015) is “low”.

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015) Table 59 is prepared to carry out the qualitative risk assessment for local effects regarding skin and eye contact of biocidal products covered by meta SPC 1 for the intended uses ’Small surface disinfection – in between disinfection (PT02)’, ’Small surface disinfection in laboratory (PT02), ’Small surface disinfection in kitchens and canteens (PT04)’, ‘Disinfection of food processing machinery (PT04)’ and ‘Refilling (PT02 and 04)’. With the proposed protection measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses.

Table 58: Summary of qualitative conclusions for local risk assessment for the biocidal products covered by meta SPC 1

PT	Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
02	Small surface disinfection - in-between disinfection	RTU (63.1 % a.s.)	Eye Irrit. 2, H319 EUH066	Low	8 tasks per day; duration of dermal exposure 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**
02	Small surface disinfection in laboratory and biotechnology	RTU (63.1 % 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 personal hygiene.	**Yes**
04	Small surface disinfection in kitchens and canteens	RTU (63.1 % 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 personal hygiene.	**Yes**
04	Disinfection of food processing machinery	RTU (63.1 % 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 recommended. Regular cleaning of equipment and work area. Good standard of personal hygiene.	**Yes**
02, 04	Refilling	RTU (63.1 % a.s.)	Eye Irrit. 2, H319 EUH066	Low	1 task per day; duration of dermal exposure 0.5 min per task	incidental eye contact expected, dermal exposure expected	Eye protection recommended. 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 1, the intended uses 'Small surface disinfection – in between disinfection (PT02)', 'Small surface disinfection in laboratory (PT02), 'Small surface disinfection in kitchens and canteens (PT04)', 'Disinfection of food processing machinery (PT04)' and 'Refilling (PT02 and 04)' do not lead to concern for professional users.

Overall Conclusion

In summary, a risk for professional users resulting from the intended use of the biocidal products covered by meta SPC 1 is unlikely. Risk reduction measures described in chapter 2.3 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.

3.6.4.7 Risk for professional users – meta SPC 3

For general considerations regarding risk assessment see section 3.6.4.6 of this PAR.

- **Systemic effects**

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 products covered by meta SPC 3 with H336 (May cause drowsiness or dizziness). The risk characterisation for systemic effects of propan-2-ol is performed with the AEL approach. In this approach total internal body burden (total uptake) is compared to the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the biocidal products covered by meta SPC 3.

Details of risk characterisation

Reference value
As systemic reference value the AELacute/medium-/long-term of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and exposure-to-AEL ratio (%)
The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Due to the rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm2/h) instead of data on the percentage of dermal absorption should be used for the calculation of the dermal uptake. However, some biocidal products covered by meta SPC 3 may contain a surfactant [9]. Surfactants are known to increase dermal absorption. Valid data are not available for such biocidal products. Therefore, the default value of 25 % for active substance concentration above 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment. For inhalation route 100% is assumed as default absorption for the active substance propan-2-ol. The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal products covered by meta SPC 3 are determined according to the following equations:

Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m3) x 10 m3 / 60 kg x %-inhalation absorption / 100 %.

Dermal uptake (mg/kg bw/d) = dermal exposure to propan-2-ol (mg/kg bw/d) x %-dermal absorption / 100 %.

Dermal exposure to propan-2-ol given in mg/kg bw/d is calculated from dermal exposure to propan-2-ol given in mg/person through division by 60 kg/person. 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 the biocidal products covered by meta SPC 3 is acceptable if the exposure-to-AEL ratio (%) for each scenario is below the value of 100%. Table 59 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 3. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 59. However, the underlying calculations are based on unrounded exposure values. As shown in Table 59, the scenarios ’Small surface disinfection – in between disinfection (PT02)’, ’Small surface disinfection in laboratory (PT02), ’Small surface disinfection in kitchens and canteens (PT04)’, ‘Disinfection of food processing machinery (PT04)’ and ‘Refilling (PT02 and 04)’ yield an exposure-to-AEL ratio (%) of less than 100 % already in TIER 1.

Table 59: Overview of detailed systemic risk assessment results referring to the active substance propan-2-ol for the biocidal products covered by meta SPC 3

PT	Scenario		$AEL_{acute/medium/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
02	Small surface disinfection - in between disinfection	Tier 1	17.9	3.47	3.94	7.41	41.4	**yes**
02	Small surface disinfection in laboratory	Tier 1	17.9	7.11	4.93	12.04	67.3	**yes**
04	Small surface disinfection in kitchens and canteens	Tier 1	17.9	3.05	3.94	6.99	39.1	**yes**
04	Disinfection of food processing machinery	Tier 1	17.9	0.87	9.86	10.73	59.9	**yes**
02, 04	Refilling	Tier 1	17.9	0.16	1.15	1.31	7.3	**yes**

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 'Small surface disinfection – in between disinfection (PT02)', 'Small surface disinfection in laboratory (PT02), 'Small surface disinfection in kitchens and canteens (PT04)', 'Disinfection of food processing machinery (PT04)' and 'Refilling (PT02 and 04)' with the biocidal products covered by meta SPC 3 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100 % after TIER 1 consideration.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.
A risk for professional users referring to the active substance propan-2-ol resulting from the combined uses of the biocidal products covered by meta SPC 3 is unlikely if the risk characterisation for each scenario yields an exposure-to-AEL ratio of less than 100 %. Table 60 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 3. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 60. However, the underlying calculations are based on unrounded exposure values.
As shown in Table 60 all combined scenarios considered ('Refilling + Small surface disinfection – in between disinfection (PT02)', 'Refilling + Small surface disinfection in laboratory (PT02)', 'Refilling + Small surface disinfection in kitchens and canteens (PT04)' and 'Refilling + Disinfection of food processing machinery (PT04)') yield exposure-to-AEL ratio of less than 100 % already in TIER 1. This means that after TIER 1 consideration no risk for professional users is identified

Table 60: 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 3

PT	combined scenario		$AEL_{acute/medium/long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
02	Refilling + Small surface disinfection - in between disinfection	Tier 1	17.9	3.63	5.09	8.72	48.7	**yes**
02	Refilling + Small surface disinfection in laboratory	Tier 1	17.9	7.27	6.08	13.35	74.6	**yes**
04	Refilling + Small surface disinfection in kitchens and canteens	Tier 1	17.9	3.21	5.09	8.30	46.4	**yes**
04	Refillin + Disinfection of food processing machinery	Tier 1	17.9	1.03	11.01	12.04	67.3	**yes**

Tier 1: no PPE

- **Local effects**

The local risk assessment for professional users for biocidal products of meta SPC 3 is covered by the local risk assessment as presented in section 3.6.4.5 for biocidal products of meta SPC 1. For details refer to this section.

Overall Conclusion

In summary, a risk for professional users resulting from the intended use of the biocidal products covered by meta SPC 3 is unlikely. Risk reduction measures described in chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 3.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.8 Risk for non-professional users

Table 61: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1	1	68.5	10.7	10.44	98	Yes
2	1	68.5	10.7	3.61	34	Yes

The exposure estimate after 5-fold daily application of the biocidal product in PT 2 (scenario 1) and after single application PT 4 is below the systemic AEL.

- **Combined scenarios**

Based on a decision at the BPC-WGVII-2018 exposure from non-professional use in PT2 and PT4 has to be combined.

Table 62: Systemic effects

Task/ Scenario	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Scenario [1] PT2 + Scenario [2] PT4, Tier 1	68.5	10.7	14.05	131	no
Scenario [1] PT2 + Scenario [2] PT4, Tier 2	68.5	17.9	14.05	78	yes

The Tier 1 combined exposure estimate is above the systemic AEL for the general population (131 % of AEL). All AEL for the general population and for workers have been derived using a chemical-specific adjustment factor for human variability in toxicokinetics according to a physiological based pharmacokinetic modelling for propan-2-ol (Clewell et al., 2001 and 2004). Using this model chemical-specific assessment factors has been derived for different life stages. The highest assessment factor (2.0)

calculated for the age from birth to six month has been used for derivation of the AEL for the general population. For workers the factor for the life stages '5 to 25 years' (1.2) was selected, which was higher than the second relevant factor for the life stage '25 to 75 years' (0.83). For non-professional user it can be generally assumed that they are adults or at least adolescents. Thus, the AEL for workers/professionals is also applicable for this sub-population and for risk characterisation of non-professional primary exposure in this tiered approach. This is in accordance with the CAR for PT2.
The combined exposure estimate is below the AEL for workers.

- **Local effects**

Local reference values for non-professional users are not available. However, the biocidal products of this family relevant for non-professional use are classified as Eye Irrit. 2, H319 and STOT SE 3, H336. A human health risk from these hazards is not expected if the precautionary statements as given in section 2.3.6.3 are followed. For eye-irritating formulations eye protection (P280) is normally required to avoid eye damage by splashes. Since the biocidal products for non-professional use are wipes only, and not the pure liquid, splashes are not expected. Hence, eye contact will not occur unless the non-professional user intentionally rubs his eyes with a wipe. Thus, an appropriate labelling (e.g. Avoid contact with eyes) is sufficient to protect non-professional users.
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 (CLP VO) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation of the biocidal product this precautionary statement is considered not relevant for the non-professional user.

Conclusion

No human health risk from use of biocidal products for meta SPC 6 by non-professional users was identified if the biocidal products are used as intended. To avoid excessive use the typical application rate in a simple form easily understandable for the non-professional user has to appear on the label (e.g. Use one wipe per m^2 surface). In addition, the biocidal product has to be stored out of the reach of children since the unattended use/misuse of the biocidal product by smaller children may result in human health hazards.
Human health hazard based on the classification of the biocidal product as Eye Irrit. 2, H319 and STOT SE 3, H336 can be sufficiently controlled by the corresponding precautionary statements. In addition, a labelling advice to avoid contact to eyes is required.

3.6.4.9 Risk for the general public

Table 63: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3a, adults	1	68.5	10.7	1.88	18	Yes
3b, children	1	68.5	10.7	4.98	47	Yes
3c, toddlers	1	68.5	10.7	11.40	107	No
4a, adults	1	68.5	10.7	3.40	32	Yes
4b, children	1	68.5	10.7	9.02	84	Yes
4c, toddlers	1	68.5	10.7	20.60	193	No
5, toddlers	1	68.5	10.7	3.84	36	Yes

- **Local effects**

Local reference values for the general public are not available.

Conclusion

No human health risk for adults and older children was identified for secondary exposure of the general public resulting from professional and non-professional use of the biocidal product family. For professional use in hospitals no risk was identified for the general public (including toddlers) present during this application. However, for toddlers a risk is identified for single and combined exposure of PT2 and PT4 (scenarioss 3 and 4). Hence, presence during application and re-entry of non-involved third parties, particularly toddlers to rooms, where treatment took place, has to be avoided before adequate ventilation have reduced the active substance concentration to acceptable levels. (based on the calculated models the acceptable aerial concentration for toddlers is about 300 mg/m^3 if exposed for 15 min. Assuming a ventilation rate of 6 h^{-1} this level is reached approximately after 20 min for scenario 4b.) Hence, a corresponding advice is required on the label.

3.6.4.10 Risk for consumers via residues in food

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

3.6.4.11 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 is not required as the product contains only the active substance propan-2-ol and no substances of concern.

3.6.4.12 Summary of risk characterisation

3.6.4.12.1 Summary of risk characterisation for industrial user

The risk assessment for industrial users for biocidal products of meta SPC 1, 2, 5, 6, 7 and 8 is covered by the risk assessment for professional users for biocidal products of meta SPC 1. Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6 and 8 (wipes). For summary of risk characterisation for industrial users refer to section 3.6.4.12.2.

The risk assessment for industrial users for biocidal products of meta SPC 3 and 4 is covered by the risk assessment for professional users for biocidal products of meta SPC 3. Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). For summary of risk characterisation for industrial users refer to section 3.6.4.12.2.

3.6.4.12.2 Summary of risk characterisation for professional user

Meta SPC 1 – professional user

Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6, 7 and 8 (wipes). The risk assessment for professional users for biocidal products of meta SPC 2, 5, 6, 7 and 8 is covered by the risk assessment for biocidal products of meta SPC 1. For summary of systemic risk characterisation for professional/industrial users refer to Table 56 and for summary of local risk assessment for professional users refer to Table 58 in section 3.6.4.6.

Meta SPC 3 – professional user

Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). The risk assessment for professional users for biocidal products of meta SPC 4 is covered by the risk assessment for biocidal products of meta SPC 3. For summary of systemic risk characterisation for professional users refer to Table 59 and to Table 60 in section 3.6.4.7. The local risk assessment for professional users for biocidal products of meta SPC 3 is covered by the local risk assessment as presented in section 3.6.4.6 for biocidal products of meta SPC 1. For summary of local risk assessment for professional users refer to Table 58 in section 3.6.4.6.

3.6.4.12.3 Summary of risk characterisation for non-professional user

Table 64

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
1, Tier 1	10.7	10.44	98	Yes
2, Tier 1	10.7	3.61	34	Yes
1 + 2, Tier 1	10.7	14.05	131	No
1 + 2, Tier 2	17.9	14.05	78	Yes

3.6.4.12.4 Summary of risk characterisation for indirect exposure

Table 65

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
3a, Tier 1	10.7	1.88	18	Yes
3b, Tier 1	10.7	4.98	47	Yes
3c, Tier 1	10.7	11.40	107	No, appropriate labelling required
4a, Tier 1	10.7	3.40	32	Yes
4b, Tier 1	10.7	9.02	84	Yes
4c, Tier 1	10.7	20.60	193	No, appropriate labelling required
5, Tier 1	10.7	3.84	36	Yes

The biocidal product is used in different product types. Thus, aggregated exposure resulting from the use in these product types cannot be excluded. This exposure has already been assessed during evaluation of the active substance. Default parameters and models used for this assessment have only changed marginally and in direction to lower exposure. Thus, this assessment can be adopted. For details refer to Doc. IIB 8.2.5 and Doc. IIB 12.4 of the corresponding CARs of PT 2 and 4.
No additional risk for human health has been identified from aggregate exposure. Additional risk mitigation measures are not required.

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 animal-specific risk is identified and no specific risk mitigation measures are required.
However, a risk for toddlers was identified and corresponding RMMs are provided. These RMMs are also required for pets and have to be adapted accordingly. The presence of pets in rooms during treatment and re-entry of pets to rooms, where treatment took place, have to be avoided before adequate ventilation has reduced the active substance concentration to acceptable levels.

3.8 Risk assessment for the environment

3.8.1 General information

The products of the biocidal products family (BPF) “Perform-IPA” are intended to be used in product type 2 and 4 for disinfection and cleaning of working areas, desks and shelves, in hospitals and public facilities such as nursing homes, or for machinery and devices in canteens, kitchens or any other surface in the food processing and production industry (for a detailed description of the single uses see section 3.8.4).

3.8.2 Effects assessment

The products of the BPF contain no substances of concern for the environment and no additional studies on the ecotoxicity of the active substance propan-2-ol or the products of the BPF were provided. Hence, the environmental effects assessment is based on the information that is available from the CAR for the active substance propan-2-ol (2014, eCA DE).

3.8.2.1 Mixture toxicity

The products of the biocidal product family “Perform-IPA” contain no substances of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance propan-2-ol.As a result of the screening of the C&L inventory by ECHA, it was found that the co-formulants do not fulfil the criteria according to Article 3 (1) f) BPR. The products of the BPF contain no component which has to be defined as substances of concern for the environmental according to CLP Regulation (EC) No 1272/2008. Based on the SDS and the information available from the ECHA dissemination site, the classification and labelling of the product is not indicated due to the co-formulants from an environmental point of view. For further detailed information, please refer to chapter 3 in Confidential Annex.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

According to the CAR, acute and chronic data on effects of propan-2ol on aquatic organisms are available.
For fish a 96 h LC_{50} of 8.692 mg a.s./L (*Pimephales promelas*) and for invertebrates an 48 h EC_{50} of 2.285 mg a.s./L (*Daphnia magna*) was determined. For algae, an E_rC_{50} of 10.500 mg a.s./L from a study with *Pseudokirchneriella subspicata* is described.
The information on long-term effects is limited to studies on invertebrates (*Daphnia magna*) and algae. 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.
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 **$PNEC_{sediment}$ of 2.41 mg a.s./kg ww** (Eq. 70; Guidance on the BPR: Volume IV Part B Risk Assessment, 2015).

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

The effect of propan-2-ol on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 3 hours contact. The EC_{50} was calculated to be >1000 mg a.s./L nominal. For the risk assessment an EC_{50} value of 1000 mg/ L is used as a worst case. Applying an assessment factor of 100 to the EC_{50} of the respiration inhibition test a **$PNEC_{STP}$ of 10 mg a.s./L** was derived.

3.8.2.3 Terrestrial compartment (including groundwater)

Since direct exposure of the products of the BPF to the terrestrial compartment and adsorption of the a.s. to soil must not be expected, the provision of experimentally derived data on the toxicity of the propan-2-ol to terrestrial organisms is not required. Thus, the PNECsoil was determined by applying EPM as described in equation 72 of the Guidance on the BPR: Volume IV Part B Risk Assessment (EU, 2015). Thus, a **$PNEC_{soil}$ of 0.496 mg a.s./kg ww** was determined.

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 0.05, 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 66 Summary of the PNEC-values for the environmental risk assessment

Summary table on calculated PNEC values	
Compartment	**PNEC**
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 290nm and 750nm takes place. Therefore, propan-2-ol is not accessible for direct photodegradation in sunlight. Propan-2-ol is classified as readily biodegradable. Propan-2-ol has a relatively high vapour pressure at 5780 Pa at 25°C, therefore, direct evaporation is expected. The Henry's Law constant for propan-2-ol is 0.82 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 K_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} was estimated as 3.3 L/kg. Therefore, propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-2-ol in soil and a very low geoaccumulation potential.

For a more detailed assessment of the environmental fate and behaviour of the active substance propan-2-ol please refer to the Assessment Report of propan-2-ol of the BPD or chapter 3.8.4.4.

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

In the CAR for propan-2-ol, bioconcentration factors (BCFs) were estimated according to the procedures described in Eq. 74 and 75 of the Guidance on the BPR: Volume IV Part B Risk Assessment (2015). By applying the experimentally derived log K_{OW} of 0.05 a BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww were determined. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-2-ol can be considered negligible.

3.8.4 Exposure assessment

3.8.4.1 General information

The products in the BPF “Perform-IPA” are used in product type 2 and 4 for disinfection and cleaning of working areas, desks and shelves, in hospitals and public facilities such as nursing homes, or for machinery and devices in canteens, kitchens or any other surface in the food processing and production industry. These ready-to-use products may be applied by spraying or pouring techniques and wiping or by wipes pre-soaked with the disinfectant.

Table 67: Intended use of PT2

Assessed PT	PT 2
Assessed scenarios	Use 1: Surface disinfection in institutional areas – professional (all meta SPCs) Use 2: Surface disinfection used for sanitary purposes – non-professional (meta SPC 6) Use 3: Surface disinfection in industrial areas (all meta SPCs)
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	Use 1: average consumption/tonnage Use 2: average consumption/tonnage Use 3: average consumption
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier modelling was performed
Confidential Annexes	YES: In the confidential PAR the tonnage based local emissions for use 1 and 2 are provided.
Life cycle steps assessed	All intended uses: Production: No Formulation No Use: Yes Service life: No
Remarks	

Table 68: Intended uses in PT 4

Assessed PT	PT 4
Assessed intended uses	Use 4: Surface disinfection with ready-to-use solution by spraying – industrial/professional (meta SPC 1, 3, 7) Use 5: Surface disinfection with ready-to-use wipes – industrial/professional (meta SPC 2, 4, 5, 6, 8) and non-professional (meta SPC 6)
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (JRC, 2011)
Approach	Use 4: Average consumption Use 5: Average consumption
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier modelling was performed
Confidential Annexes	NO
Life cycle steps assessed	All intended uses: Production: No Formulation No Use: Yes Service life: No
Remarks	

3.8.4.2 Local emission estimation for relevant environmental compartments

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the 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 part of the BPF “Perform-IPA” containing 70% v/v propan-2-ol, the disinfection is finished when the treated surface completely dried, aka 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 “Perform-IPA” 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 “Perform-IPA” 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. 25 mL/m^2. Using pre-soaked wipes the application rate is slightly lower. From the different pre-soaked wipes available within the BPF (refer to the pdf Spezifikationen Tücher from 29.03.2017 provided by the applicant), the BiCO wipe was selected to represent the worst-case. Wipes of the “BiCO” type contain the highest amount of a.s per wipe, furthermore, they are enclosed in all meta-SPCs. Specifications for the “BiCO” wipe (form, size, produt content, a.s. content) are given in the confidential PAR.

Based on studies provided by the applicant conducted with a standard wipe (see pdf Reichweite_Tücher and 4-Field-Test), it can be assumed that max. 23.6 ml product/m^2 is realised from BiCO wipes to the treated surface. For further information, see confidential PAR.
The application of the b.p. “Perform-IPA” as spray or pour application describes an application rate of 25 mL per m^2. Since the application by spraying or pouring is higher than the application of pre-soaked wipes, the amount applied by spraying and pouring also covers the application rate of “Perform-IPA” pre-soaked wipes. The application as spray or pour application is therefore the worst-case application.

3.8.4.2.1 **PT 2: Intended use 1** [Surface disinfection in institutional areas – professional user] (all meta SPCs)

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 “Perform-IPA” based on tonnage is given in the confidential PAR.

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. Due to the use of a default consumption per capita pre-soaked wipes and ready-to-use liquids are treated similar. The product contains 63.1 g propan-2-ol, taking the density of the product (0.876 g/mL) into account the working solution contains 0.553 kg/L propan-2-ol. The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF "Perform-IPA" is given in Table 69.

Table 69: 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 forms the consumption-based approach should be used for further environmental exposure and risk assessment.

In case of the BPF "Perform-IPA" the break-even point lies at 1510 t/a, since this is more than the regional tonnage the consumption approach represents the most worst-case situation. Therefore, for the environmental exposure and risk assessment the emission based on consumption is used.

3.8.4.2.2 PT 2: Intended use 2 [Surface disinfection used for sanitary purposes – non-professional user] (metaSPC 6)

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 (non-professional) based on tonnage is described in Chapter 2 of the ESD for PT2 (van der Poel, 2001). The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF “Perform-IPA” based on tonnage is given in the confidential PAR.

Consumption based approach

The emission scenario for disinfectants used for sanitary purposes in (non-professional) is described in Chapter 2 of the ESD for PT2 (van der Poel, 2001). The default consumption per capita of the b.p for general purpose and lavatory is 7 mL/d. Due to the use of a default consumption per capita pre-soaked wipes and ready-to-use liquids are treated similar. The product contains 63.1 g propan-2-ol, taking the density of the product (0.876 g/mL) into account the working solution contains 0.553 kg/L propan-2-ol. The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF “Perform-IPA” is given in Table 70.

Table 70: Emission scenario for surface disinfection used for sanitary purpose (non-professional users) based on consumption

Determinants of the local emission according to Chapter 2, Table 2.2; Environmental Emission Scenarios for PT 2 (van der Poel, 2001)	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, van der Poel, 2001)

(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 forms the consumption-based approach should be used for further environmental exposure and risk assessment.

In case of the BPF ”Perform-IPA” the break-even point lies at 2119 t/a, since this is more than the regional tonnage the consumption approach represents the most worst-case situation. Therefore, for the environmental exposure and risk assessment the emission based on consumption is used.

3.8.4.2.3 PT 2: Intended use 3 [Surface disinfection in industrial areas – professional user] (metaSPC 1 - 8)

Consumption based approach

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. 25 mL/m^2 covers both RTU solutions as well as pre-soaked wipes. 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. The resulting local emission of propan-2-ol to the waste water and air from the application of a product in the BPF "Perform-IPA" is given in Table 71.

Table 71: Emission scenario for surface disinfection in industrial areas (professional users) based on consumption

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)	25 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 (D)	1
Fraction of a.s. disintegration (D)	0
Fraction released to wastewater (CAR)	0.1
Fraction released to air (CAR)	0.9
Calculation Results	**Value**
Local release to waste water	0.04 kg/d
Local release to air	0.31 kg/d

(S) – Provided by applicant

(D) – Default (ESD PT2, JRC, 2010)

(CAR) – CAR Propan-2-ol (2014)

3.8.4.2.4 PT 4: Intended use 4 [Surface disinfection with ready-to-use solution – industrial/professional user], (MetaSPC 1,3,7)

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

The surface area to be disinfected by RTU products are defined at the WG ENV I 2017. Whereas large scale catering kitchens with a surface area of 50m^2 covers the realistic worst case. Consequently, an environmental risk assessment for slaughterhouses was not conducted.
It can be assumed that in food and feed producing/processing areas disinfection takes place only during the working week (260 days per year).

Table 72: Emission scenario for calculating the releases of disinfectants used in small scale catering kitchens, canteens, 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)	25 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	13.83 g/m^2
Surface area to be disinfected (WG ENV I 2017) Slaughterhouses Large scale catering kitchens	 10 m^2 50 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	0.069 kg/d
Local release to air	0.622 kg/d

(S) – Provided by applicant

(D) – Default (JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

3.8.4.2.5 PT 4: Intended use 5 [Surface disinfection with ready-to-use wipes – industrial/professional user and non-professional user], (MetaSPC 2, 4, 5, 6, 8)

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

All metaSPCs mention industrial or professional use, besides meta SPC 6, which is envisaged for non-professional users. In the ESD for PT 4, no emission scenario is included for non-professional users and

it is most likely that local emissions from professional and industrial users cover non-professional applications. Professional and industrial users represent the realistic worst case, they are, therefore, calculated only.

The surface area to be disinfected by RTU products are defined at the WG ENV I 2017. Whereas large scale catering kitchens with a surface area of 50 m^2 covers the realistic worst case. Consequently, an environmental risk assessment for slaughterhouses was not conducted.

It can be assumed that in food and feed producing/processing areas disinfection takes place only during the working week (260 days per year).

Table 73: Emission scenario for calculating the releases of disinfectants used in small scale catering kitchens, canteens, 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)	23.6 mL/m^2
Concentration of a.s in b.p (S)	553 g/L
Application rate of the a.s. (S)	13.1 g/m^2
Surface area to be disinfected (WG ENV I 2017) Slaughterhouses Large scale catering kitchens	 10 m^2 50 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	0.066 kg/d
Local release to air	0.59 kg/d

(S) – Provided by applicant

(D) – Default (JRC, 2011)

(CAR) – CAR Propan-2-ol (2014)

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

The application of products part of the BPF “Perform-IPA” used for disinfection result in indirect exposure of the environment via the air (wet deposition) and to a lesser extent via STP.

Table 74: Identification of relevant receiving compartments based on the exposure pathway

	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air
Use 1	Yes	Yes (indirect)	Yes (indirect)	Yes
Use 2	Yes	Yes (indirect)	Yes (indirect)	Yes
Use 3	Yes	yes (indirect)	yes (indirect)	Yes
Use 4	Yes	yes (indirect)	yes (indirect)	Yes
Use 5	Yes	yes (indirect)	yes (indirect)	Yes

3.8.4.4 Fate and distribution in exposed environmental compartments

According, to the CAR of propan-2-ol, experimentally derived data on hydrolysis in water are not available. Propan-2-ol, as an alcohol, possesses no hydrolysable functional groups and therefore, is resistant to hydrolysis. For this reason, hydrolysis under environmental conditions is not expected.

Experimentally derived data on photolysis in water are not available. The molecular structure of propan-2-ol has no chromophore. In addition, for propan-2-ol a cut-off point of 210 nm is given in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 cannot undergo direct photolysis in sunlight. Therefore, the substance is inaccessible for direct photodegradation in sunlight.

The vapour pressure of propan-2-ol at 25°C is 57.8 hPa, consequently, direct evaporation is expected. The Henry’s law constant (0.82 $Pa*m^3$ mol^{-1} at 25°C) indicates moderate volatility from water. Propan-2-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. The half-life of propan-2-ol in the troposphere was estimated to be 3.1 days considering a global 24-hours mean OH-radical concentration of $5x10^5$ OH radicals cm^{-3}.

Experimentally derived soil sorption coefficients are not available. A K_{OC} of 1.1 L/kg can be estimated based on the generally accepted model PCKOCWIN v1.66. In addition, the K_{OC} was estimated according to a QSAR model described in EU TGD on Risk Assessment, Part III, chapter 4.3 (2003). Based on a log K_{OW} of 0.05 and the QSAR for alcohols, the K_{OC} was calculated to 3.3 L/kg. This K_{OC} is used for the environmental exposure assessment. 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 geoaccumulation potential. Adsorption of relevant amounts of propan-2-ol on soils and sediments is not expected.

Table 75: Input parameters (only set values) 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 (Koc)	3.3	L/kg	
Henry's Law Constant	0.82	Pa/m^3/mol	Measured data
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 are calculated using SimpleTreat v.3.1. This resulted in release fractions to air of 0.3 %, water 12.5 %, sludge < 0.1 % and degraded fraction 87.1 %. For further exposure calculations the fraction released to the environment via sludge is considered as negligible.

3.8.4.5 Calculated PEC values

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 b.p. the interval between two releases 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 estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 66, chapter 2.3.8.5, Guidance BPR IV ENV B (2015);
- $PEC_{local\_groundwater}$ according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015) as a first worst-case estimation.

The local PEC values from all intended uses are presented in Table 76 and are used for the environmental risk assessment.

Table 76: Summary table on calculated PEClocal values from intended uses of the biocidal product "perform-IPA"

Use	PT	PEC_{STP} [µg/L]	$PEC_{surface\_water}$ [µg/L]	PEC_{sed} [µg/kg_{wwt}]	PEC_{soil} [µg/kg]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]	$DEPtotal_{ann}$ [mg/(m^2 d)]
1	2	73.0	7.26	6.19	0.25	1.44	2.07 x 10^{-3}	2.98 x 10^{-3}
2	2	73.0	7.26	6.19	0.35	2.03	2.91 x 10^{-3}	4.18 x 10^{-3}
3	2	2.19	0.22	0.19	7.55 x 10^{-3}	0.04	6.16 x 10^{-5}	8.86 x 10^{-5}
4	4	4.3	0.43	0.36	0.02	0.09	1.23 x 10^{-4}	1.77 x 10^{-4}
5	4	4.13	0.41	0.35	0.01	0.08	1.17 x 10^{-4}	1.68 x 10^{-4}

Based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in a zero 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 deposition ($DEPTtotal_{ann}$), which is calculated according to the OPS model in the Guidance BPR IV ENV B (2015). Although the local emissions of use 1 and use 2 are similar,

the difference in PEC_{soil} between use 1 and use 2 is due to the different emission days between professional (260 days) and non-professional use (365 days). The groundwater exposure occurs after wet and dry aerial deposition on soil. The estimated concentration in the groundwater is defined by the concentration of propan-2-ol in pore water of agricultural soils (Guidance BPR IV ENV B (2015)). This is a conservative approach, since degradation in soil, transformation and dilution in deeper soil layers are not taken into account. The calculated results of PEC_{GW} for PT 2 use 3 and PT 4 (use 4 and 5) are below the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83/EC).

For PT2 use 1 and 2 the calculated tier 1 PEC_{GW} (porewater concentration) exceeds the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directive 98/83/EC). However, during the WG ENV VII 2018 it was agreed that for volatile alcohols used in PT2 with a primary release path to air, in general no assessment of the groundwater is needed. Therefore, although in the current assessment concentrations in groundwater are above the groundwater trigger value of 0.1 µg/L, based on expert judgement no exceedance of the groundwater trigger value is expected.

3.8.4.6 Non-compartment specific effects

- **Secondary poisoning**

According to the CAR of propan-2-ol (2014), the relevance of a risk characterisation for secondary poisoning is not applicable for propan-2-ol. Due to its physical properties propan-2-ol has a low potential for bioaccumulation in the terrestrial and in the aquatic food chain (see chapter 3.8.2.5).

3.8.4.7 Aggregated exposure (combined for relevant emission sources)

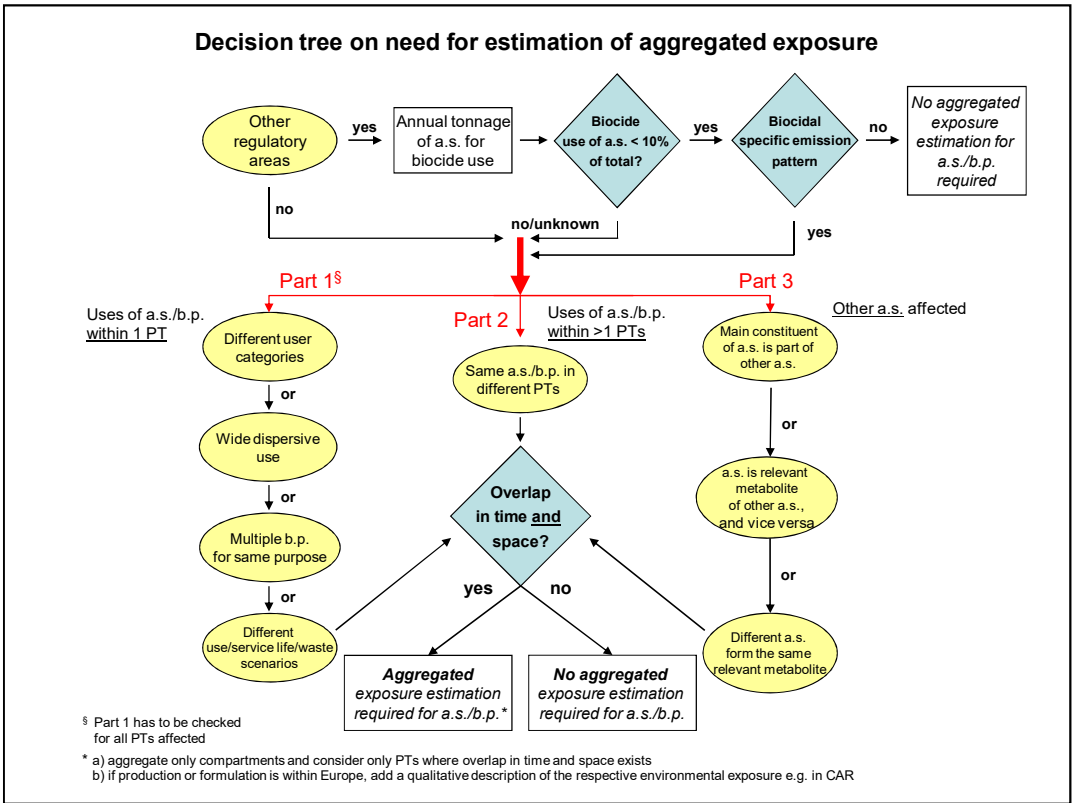

Figure 1: Decision tree on the need for estimation of aggregated exposure

According to the "Decision tree on need for estimation of aggregated exposure" the requirement for aggregated exposure estimations was checked for the products in the BPF "Perform-IPA" containing propan-2-ol as active substance.

The active substance 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. Propan-2-ol's major solvents uses include inks, coatings, cosmetics and pharmaceuticals. 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. Therefore, no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced.

But according to the decision tree (Figure 1) it must be also examined whether specific biocidal emission patterns are available. The main emission pathway for propan-2-ol is through wet and dry deposition; but

this emission route is not limited to biocidal products. Specific biocidal emission patterns are not identified. Therefore, according to the decision tree it is not required to perform aggregated exposure estimation.

3.8.5 Risk characterisation

The BPF Perform-IPA consists of 8 meta-SPCs covering five uses in two PTs (PT 2 and PT 4). Due to the similarity of the intended uses across the 8 meta-SPCs, the environmental risk assessment is performed for the specific uses rather than for each single meta-SPC.
Consequently, the following uses need to be considered in the risk characterisation:

PT 2:
Use 1: Surface disinfection in institutional areas – professional (all metaSPCs)
Use 2: Surface disinfection used for sanitary purposes – non-professional (metaSPC 6)
Use 3: Surface disinfection in industrial areas (all metaSPCs)

PT 4:
Use 4: Surface disinfection with ready-to-use solution – industrial/professional (metaSPC 1, 3, 7)
Use 5: Surface disinfection with ready-to-use wipes – industrial/professional (metaSPC 2, 4, 5, 6, 8) and non-professional (metaSPC 6)

3.8.5.1 Aquatic compartment (sediment and STP)

Table 77 PEC/PNEC ratios for surface water and sediment related to the intended uses

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$
Use 1	2.57×10^{-3}	2.57×10^{-3}
Use 2	2.57×10^{-3}	2.57×10^{-3}
Use 3	7.8×10^{-5}	7.88×10^{-5}
Use 4	1.52×10^{-4}	1.49×10^{-4}
Use 5	1.45×10^{-4}	1.45×10^{-4}

The PEC/PNEC-ratios for surface water and sediment related to all the intended uses of the BPF Perform-IPA are well below 1. Hence, no unacceptable risk for both compartments must be assumed due to the intended uses of the products of the BPF.

- **STP**

Table 78 PEC/PNEC ratios for the STP related to the intended uses

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Use 1	7.3×10^{-3}
Use 2	7.3×10^{-3}
Use 3	2.19×10^{-4}
Use 4	4.3×10^{-4}
Use 5	4.13×10^{-4}

The PEC/PNEC-ratios for the STP related to all the intended uses of the BPF Perform-IPA are well below 1. Hence, no unacceptable risk for the STP must be assumed due to the intended uses of the products of the BPF

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

Table 79 PEC/PNEC ratios for the soil compartment related to the intended uses

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Use 1	5.12×10^{-4}
Use 2	7.18×10^{-4}
Use 3	1.52×10^{-5}
Use 4	4.03×10^{-5}
Use 5	2.14×10^{-5}

The PEC/PNEC-ratios for the soil compartment related to all the intended uses of the BPF Perform-IPA are below 1. Hence, no unacceptable risk for the soil compartment must be assumed due to the intended uses of the products of the BPF.

- **Groundwater**

As described in section 3.8.4.5, the estimated propan-2-ol concentrations related to the intended uses 3, 4 and 5 are within a range from 0.04 to 0.09 µg/L in the pore water of agricultural soils. Hence, no risk for the groundwater compartment needs to be assumed.
However, the environmental exposure assessment for the intended uses 1 and 2 resulted in pore water concentrations of 1.44 µg/L and 2.03 µg/L for propan-2-ol, respectively. The exceedance of the trigger value of 0.1 µg/L for pesticides (as laid down in Council directive 98/83/EC) in the groundwater has to be assumed in the first instance, according to the Guidance on the BPR IV ENV B, 2015, since the estimated concentrations in pore water are supposed to be the equivalent of the concentration in the groundwater compartment. However, during the WG ENV VII 2018 it was agreed that for volatile alcohols used in PT2 with a primary release path to air, in general no assessment of the groundwater is needed. Therefore,

although in the current assessment concentrations in groundwater are above the groundwater trigger value of 0.1 µg/L, based on expert judgement no exceedance of the groundwater trigger value is expected.

3.8.5.3 Atmosphere

As stated in section 3.8.2.4, ecotoxicological data for the air compartment are not available. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

3.8.5.4 Non-compartment specific

As stated in section 3.8.2.5, 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 fulfill 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.
For the active substance Propan-2-ol in the BPF “perform-IPA”, no ED assessment is required during product authorization, because the results of the ED assessment are presented in the EU a.s. dossier and therefore should be followed. As far as the co-formulants present in the BPF “perform-IPA” are concerned, none is identified as an endocrine disruptor for non-target organisms in the environment. Beyond that, none of the co-formulants is contained in the candidate list for substances of very high concern for authorization (SVHC), the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to REACH Regulation 1907/2600 for potential environmental ED-properties.
Nevertheless, regarding one co-formulant there are indications from the peer-reviewed open literature that this co-formulant might have an adverse effect with an endocrine mode of action in non-target organisms in the environment. The potential ED effects on environmental non-target organisms of this co-formulant are currently further assessed under REACH Regulation 1907/2600. As long as the ED assessment at EU level for this co-formulant has not been finalised, it has not to be regarded as an identified endocrine disruptor. For further details please refer to chapter 4 in the Confidential PAR.

3.8.5.7 Summary of risk characterisation

Table 80 Summary of the PEC/PNEC ratios for the concerned environmental compartments

Summary table on calculated PEC/PNEC values				
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**
Use 1	7.3×10^{-3}	2.57×10^{-3}	2.57×10^{-3}	5.12×10^{-4}
Use 2	7.3×10^{-3}	2.57×10^{-3}	2.57×10^{-3}	7.18×10^{-4}

Use 3	2.19×10^{-4}	7.8×10^{-5}	7.88×10^{-5}	1.52×10^{-5}
Use 4	4.3×10^{-4}	1.52×10^{-4}	1.49×10^{-4}	3.04×10^{-5}
Use 5	4.13×10^{-4}	1.45×10^{-4}	1.45×10^{-4}	2.14×10^{-5}

No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal products in the meta-SPCs of the BPF “Perform-IPA”.

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, hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

Table 81

Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
3.1. Appearance (at 20 °C and 101,3 kPa)	Appearance of perform sterile alcohol IPA	Heidel, Judith	2014
3.1. Appearance (at 20 °C and 101,3 kPa)	Appearance of perform sterile wipes IPA	Heidel, Judith	2014
3.1. Appearance (at 20 °C and 101,3 kPa)	Superficid - Specification and measured values	Cielusek, Guy	2016
3.1. Appearance (at 20 °C and 101,3 kPa)	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.1.1. Physical state (at 20 °C and 101,3 kPa)	Appearance of perform sterile alcohol IPA	Heidel, Judith	2014
3.1.1. Physical state (at 20 °C and 101,3 kPa)	Appearance of perform sterile wipes IPA	Heidel, Judith	2014
3.1.1. Physical state (at 20 °C and 101,3 kPa)	Superficid - Specification and measured values	Cielusek, Guy	2016
3.1.1. Physical state (at 20 °C and 101,3 kPa)	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.1.2. Colour (at 20 °C and 101,3 kPa)	Appearance of perform sterile alcohol IPA	Heidel, Judith	2014
3.1.2. Colour (at 20 °C and 101,3 kPa)	Appearance of perform sterile wipes IPA	Heidel, Judith	2014
3.1.2. Colour (at 20 °C and 101,3 kPa)	Superficid - Specification and measured values	Cielusek, Guy	2016
3.1.2. Colour (at 20 °C and 101,3 kPa)	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.1.3. Odour (at 20 °C and 101,3 kPa)	Appearance of perform sterile alcohol IPA	Heidel, Judith	2014
3.1.3. Odour (at 20 °C and 101,3 kPa)	Appearance of perform sterile wipes IPA	Heidel, Judith	2014
3.1.3. Odour (at 20 °C and 101,3 kPa)	Superficid - Specification and measured values	Cielusek, Guy	2016
3.1.3. Odour (at 20 °C and 101,3 kPa)	Superficid pure - Specification and measured values	Cielusek, Guy	2016

3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	pH value of Perform sterile alcohol IPA	Heidel, Judith	2014
3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	Superficid - Specification and measured values	Cielusek, Guy	2016
3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.3. Relative density (liquids) and bulk, tap density (solids)	Density of perform sterile alcohol IPA	Heidel, Judith	2016
3.3. Relative density (liquids) and bulk, tap density (solids)	Density of mikrozid IPA liquid	Heidel, Judith	2015
3.3. Relative density (liquids) and bulk, tap density (solids)	Superficid - Specification and measured values	Cielusek, Guy	2016
3.3. Relative density (liquids) and bulk, tap density (solids)	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.4.1. Storage stability tests	Stability of perform sterile alcohol IPA	Heidel, Judith	2016
3.4.1. Storage stability tests	Stability of perform sterile wipes IPA	Heidel, Judith	2014
3.4.1. Storage stability tests	Study on low-temperature stability of alcoholic disinfectants	Cielusek, Guy	2016
3.4.1. Storage stability tests	Maintenance of sterility in the sterile spray system	Steinhauer, Katrin	2010
3.4.1.2. Long term storage test at ambient temperature	Stability of perform sterile alcohol IPA	Heidel, Judith	2016
3.4.1.2. Long term storage test at ambient temperature	Stability of perform sterile wipes IPA	Heidel, Judith	2014

3.4.1.3. Low temperature stability test (liquids)	Study on low-temperature stability of alcoholic disinfectants	Cielusek, Guy	2016
3.5.7. Persistent foaming	Persistent Foaming of mikrozid IPA liquid	Heidel, Judith	2015
3.8. Surface tension	Surface Tension of perform sterile alcohol IPA	Heidel, Judith	2015
3.8. Surface tension	Surface Tension of mikrozid IPA liquid	Heidel, Judith	2015
3.8. Surface tension	Superficid - Specification and measured values	Cielusek, Guy	2016
3.8. Surface tension	Superficid pure - Specification and measured values	Cielusek, Guy	2016
3.8. Surface tension	Surface Tension of Alcohol Water + Water from 20 to 50 .degree.C	Vazquez, G.; Alvarez, E.; Navaza, J. M.	1995
3.9. Viscosity	Viscosity of perform sterile alcohol IPA	Heidel, Judith	2014
3.9. Viscosity	Superficid - Specification and measured values	Cielusek, Guy	2016
3.9. Viscosity	Superficid pure - Specification and measured values	Cielusek, Guy	2016
4.2. Flammability	The prediction of the flash point for binary aqueous-organic solutions.	Liaw, H.J.; Chiu, Y.Y.	2003
4.2. Flammability	Determination of physico-chemical properties Flammability of solids	Smeykal, Henry	2016
4.2. Flammability	Superficid - Specification and measured values	Cielusek, Guy	2016
4.2. Flammability	Superficid pure - Specification and measured values	Cielusek, Guy	2016
4.17. Additional physical indications of hazard	Material Compatibility with metals of perform sterile alcohol IPA	Heidel, Judith	2014
4.17. Additional physical indications of hazard	Material Compatibility with plastics of perform sterile alcohol IPA	Heidel, Judith	2014

5. METHODS OF DETECTION AND IDENTIFICATION	Analytical method for the determination of 2-Propanol - Isopropylalkohol 70%- - Alternative method - Method development and validation	Ringhand, Martin	2015
5. METHODS OF DETECTION AND IDENTIFICATION	Analytical method for the determination of 2-propanol - „Isopropylalkohol 70o/o" - Method development and validation	Bosnak, Michael	2016
5. METHODS OF DETECTION AND IDENTIFICATION	Analytical method for the determination of 2-Propanol - Perform sterile alcohol IPA WFI- - Alternative method - Method development and validation	Ringhand, Martin	2015
5. METHODS OF DETECTION AND IDENTIFICATION	Analytical method for the determination of 2-propanol - „Perform sterile alcohol IPA WFI" - Method development and validation	Bosnak, Michael	2016
5. METHODS OF DETECTION AND IDENTIFICATION	Determination of active substances and purity (Alcoholic disinfectants)	Lysoform	2008
5. METHODS OF DETECTION AND IDENTIFICATION	Analytical Report - Antiseptica/120/31/2006 Stability Tests 36 Months Poly-Alcohol Hand Antiseptic	Denzel, Klaus	2006
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Expert's report based up the test report Kodan wipes pure active substances solution - 2015 and 2017 Test of the Kodan wipes pure active substances solution from Schülke & Mayr in accordance with the standard methods of the DIN EN 13727:2014 and DIN EN 13624:2013	Sammann, A.	2017

6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 1276 (2009:AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1)	Steinhauer, K.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 1276 (2009:AC:2010) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1)	Steinhauer, K.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Statement on the comparability of the products mikrozid® IPA liquid and pluradent Händedesinfektion concerning their bactericidal effect	Paßvogel, L.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 1650 (1998) Quantitative suspension test for the determination of fungicidal efficacy of chemical disinfectants and antiseptics for the area of food, industry, household and public domain.	Steinhauer, K.	2009
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	PERFORM CLASSIC ALCOHOL IPA YEASTICIDAL EFFICACY (EN 1650)	Koburger-Janssen, T.	2009

6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 14348 (2005) Chemical disinfectants and antiseptic – Quantitative suspension test fort he evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2/ step 2); German version EN 14348:2005	Radischat, N.	2015
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Mykobakterien - Oberflächendesinfektion und Händedesinfektion im häuslichen, industriellen und medizinischen Bereich Begründung für die Prüfung bei kurzen Einwirkzeiten	Goroncy-Bermes, P.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 13697:2015 Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2)	Steinhauer, K.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	PERFORM CLASSIC ALCOHOL IPA BACTERICIDAL AND YEASTICIDAL ACTIVITY (EN 13697)	Koburger-Janssen, T.	2015

6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	EN 13697 (2001) Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical desinfectants used in food, industrial, domestic and institutional areas	Steinhauer, K.	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	PERFORM CLASSIC ALCOHOL IPA BACTERICIDAL AND YEASTICIDAL ACTIVITY (EN 13697)	Koburger-Janssen, T.	2015
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIN EN 16615:2015 Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test). (phase 2, step 2)	Steinhauer, K.	2016
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	The efficacy of perform sterile alcohol IPA against vaccinia virus in the virucidal quantitative suspension test for chemical disinfectants and antiseptics	Enders, Gisela	2009
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	The efficacy of perforrn sterile alcohol IPA against BVDV in the virucidal quantitative suspension test for chernical disinfectants and antiseptics	Enders, Gisela	2009

6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Activity of Kodan wipes pure (active solution) against adenovirus type 5 in a quantitative suspension test according to EN 14476:2013	Steinmann, Jochen	2015
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Efficacy of Kodan Wipes Pure Active Solution Against Murine Norovirus Strain S99	Enders, Gisela	2016
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Activity of Kodan wipes pure (active solution) against human rotavirus in a quantitative suspension test following EN 14476:2013	Steinmann, Jochen	2015
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Efficacy of perform® classic alcohol IPA against Murine norovirus in the quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area	Enders, Gisela	2017
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	The efficacy of perform® classic alcohol IPA against Adenovirus in the quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area (phase2/step2).	Enders, Gisela	2017

6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Bactericidal efficacy of Superficid Proof of non-activity of [redacted] (used as perfume)	Rödger, Hans	2016
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Comment on non-activity of the ingredient [redacted] in the frame of the Biocidal Products Regulation (BPR)	Rödger, Hans	2017
8.8. Food and feedingstuffs studies	Dietary risk from transfer of [redacted] into foods	May, Martin	2015

4.2 List of studies for the active substance(s)

4.2.1 Propan-2-ol

The applicant provided a letter of access to the dossier assessed for the approval and has access to the data from the active substance approval. No new data was submitted. Please, refer to the corresponding Assessment Report for a reference list.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

pdF-File	Content of pdF-File
Scenario1.pdf	Scenario 1 – Small surface disinfection in-between disinfection
Scenario1_Results.pdf Scenario1_CEReport.pdf	Scenario 1 – Results and ConsExpo report
Scenario2.pdf	Scenario 2 - Small surface disinfection in laboratory
Scenario2_CEReport.pdf	Consexpo report Scenario 2
Scenario3.pdf	Scenario 3 - Small surface disinfection in kitchens and canteens
Scenario3_CEreport.pdf	Consexpo report Scenario 3
Scenario4.pdf	Scenario 4 - Disinfection of food processing machinery

Scenario4_CEreport.pdf	Consexpo report Scenario 4
Scenario5_ARTreport.pdf	Scenario 5 - Refilling
Scenario5_ARTreport.pdf	Scenario 5 – ART Report
Additional scenarios	
Small_surface_disinfection_in_patient_roc	Small surface disinfection in patient rooms
Small_surface_disinfection_in_patient_roc	Small surface disinfection in patient rooms – ConsExpo Report
Small_surface_disinfection_in_cleanroom.	Small surface disinfection in clean rooms
Small_surface_disinfection_in_cleanroom_	Small surface disinfection in clean rooms – ConsExpo Report

4.3.2 Safety for non-professional users and the general public

ConsExpo 4.1 report

Scenario 1, PT2: Primary exposure, disinfection of small surfaces, bath rooms

Product

Perform IPA

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/d
body weight	60	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	5	min
room volume	10	m^3
ventilation rate	2	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	1.08E3	mg/m^3
inhalation mean concentration on day of exposure:	18.8	mg/m^3
inhalation air concentration year average :	18.8	$mg/m^3/d$
inhalation acute (internal) dose :	1.88	mg/kg
inhalation chronic (internal) dose :	9.39	mg/kg/d

Integrated (point estimates)

total external dose:	1.88	mg/kg
total acute dose (internal):	1.88	mg/kg
total chronic dose (internal):	9.39	mg/kg/d

ConsExpo 4.1 report

Scenario 2, PT4: Primary exposure. disinfection of small surfaces, kitchens

Product

Perform IPA

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/d
body weight	60	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	15	min
room volume	15	m^3
ventilation rate	2.5	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	653	mg/m^3
inhalation mean concentration on day of exposure:	6.8	mg/m^3
inhalation air concentration year average :	6.8	$mg/m^3/d$
inhalation acute (internal) dose :	3.4	mg/kg
inhalation chronic (internal) dose :	3.4	mg/kg/d

Integrated (point estimates)

total external dose:	3.4	mg/kg
total acute dose (internal):	3.4	mg/kg
total chronic dose (internal):	3.4	mg/kg/d

ConsExpo 4.1 report

Scenario 3a, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, adult

Product

Perform IPA

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/d
body weight	60	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	5	min
room volume	10	m^3
ventilation rate	2	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	1.08E3	mg/m^3
inhalation mean concentration on day of exposure:	3.76	mg/m^3
inhalation air concentration year average :	3.76	$mg/m^3/d$
inhalation acute (internal) dose :	1.88	mg/kg
inhalation chronic (internal) dose :	1.88	mg/kg/d

Integrated (point estimates)

total external dose:	1.88	mg/kg
total acute dose (internal):	1.88	mg/kg
total chronic dose (internal):	1.88	mg/kg/d

ConsExpo 4.1 report

Scenario 3b, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, child

Product

Perform IPA

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/d
body weight	23.9	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	5	min
room volume	10	m^3
ventilation rate	2	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.32	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	1.08E3	mg/m^3
inhalation mean concentration on day of exposure:	3.76	mg/m^3
inhalation air concentration year average :	3.76	$mg/m^3/d$
inhalation acute (internal) dose :	4.98	mg/kg
inhalation chronic (internal) dose :	4.98	mg/kg/d

Integrated (point estimates)

total external dose:	4.98	mg/kg
total acute dose (internal):	4.98	mg/kg
total chronic dose (internal):	4.98	mg/kg/d

ConsExpo 4.1 report

Scenario 3c, PT2: Secondary exposure from disinfection of small surfaces, bathrooms, toddler

Product

Perform IPA

Compound

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

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63,1	%
exposure duration	5	minute
room volume	10	m3
ventilation rate	2	1/hr
applied amount	21,9	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	1,08E3	mg/m3
inhalation mean concentration on day of exposure:	3,76	mg/m3
inhalation air concentration year average :	3,76	mg/m3/day
inhalation acute (internal) dose :	11,4	mg/kg
inhalation chronic (internal) dose :	11,4	mg/kg/day

Integrated (point estimates)

total external dose:	11,4	mg/kg
total acute dose (internal):	11,4	mg/kg
total chronic dose (internal):	11,4	mg/kg/day

ConsExpo 4.1 report

Scenario 4a, PT4: Secondary exposure from disinfection of small surfaces, kitchens, adult

Product

Perform IPA

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/d
body weight	60	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	15	min
room volume	15	m^3
ventilation rate	2.5	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.25	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	653	mg/m^3
inhalation mean concentration on day of exposure:	6.8	mg/m^3
inhalation air concentration year average :	6.8	$mg/m^3/d$
inhalation acute (internal) dose :	3.4	mg/kg
inhalation chronic (internal) dose :	3.4	mg/kg/d

Integrated (point estimates)

total external dose:	3.4	mg/kg
total acute dose (internal):	3.4	mg/kg
total chronic dose (internal):	3.4	mg/kg/d

ConsExpo 4.1 report

Scenario 4b, PT4: Secondary exposure from disinfection of small surfaces, kitchens, child

Product

Perform IPA

Compound

Compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	1	1/day
body weight	23.9	kg

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63.1	%
exposure duration	15	min
room volume	15	m^3
ventilation rate	2.5	1/h
applied amount	21.9	g
release area	1E4	cm^2
application duration	5	min
mol weight matrix	18	g/mol
mass transfer rate	0.167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1.32	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	653	mg/m^3
inhalation mean concentration on day of exposure:	6.8	mg/m^3
inhalation air concentration year average :	6.8	$mg/m^3/d$
inhalation acute (internal) dose :	9.02	mg/kg
inhalation chronic (internal) dose :	9.02	mg/kg/d

Integrated (point estimates)

total external dose:	9.02	mg/kg
total acute dose (internal):	9.02	mg/kg
total chronic dose (internal):	9.02	mg/kg/d

ConsExpo 4.1 report

Scenario 4c, PT4: Secondary exposure from disinfection of small surfaces, kitchens, toddler

Product

Perform IPA

Compound

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

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63,1	%
exposure duration	15	minute
room volume	15	m3
ventilation rate	2,5	1/hr
applied amount	21,9	gram
release area	1E4	cm2
application duration	5	minute
mol weight matrix	18	g/mol
mass transfer rate	0,167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	653	mg/m3
inhalation mean concentration on day of exposure:	6,8	mg/m3
inhalation air concentration year average :	6,8	mg/m3/day
inhalation acute (internal) dose :	20,6	mg/kg
inhalation chronic (internal) dose :	20,6	mg/kg/day

Integrated (point estimates)

total external dose:	20,6	mg/kg
total acute dose (internal):	20,6	mg/kg
total chronic dose (internal):	20,6	mg/kg/day

ConsExpo 4.1 report

Scenario 5, PT2: Secondary exposure from disinfection of small surfaces by professional users, hospital, toddler

Product

Perform IPA

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	2	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	63,1	%
exposure duration	24	hour
room volume	80	m3
ventilation rate	1,5	1/hr
applied amount	10,9	gram
release area	0,5	m2
application duration	1	minute
mol weight matrix	18	g/mol
mass transfer rate	0,167	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	8	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	2,4	mg/m3
inhalation mean concentration on day of exposure:	2,4	mg/m3
inhalation air concentration year average :	4,8	mg/m3/day
inhalation acute (internal) dose :	1,92	mg/kg
inhalation chronic (internal) dose :	3,84	mg/kg/day

Integrated (point estimates)

total external dose:	1,92	mg/kg
total acute dose (internal):	1,92	mg/kg
total chronic dose (internal):	3,84	mg/kg/day