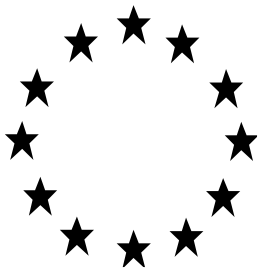
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS



ClearKlens product based on IPA

Product type 2

Active substance: Propan-2-ol (as included in the Union list of approved active substances)

Case Number in R4BP: BC-HD024462-61

Evaluating Competent Authority: The Netherlands

Date: December 2019

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1 CONCLUSION

The outcome of the assessment for the biocidal product ‘Clearklens product based on IPA ’ is specified in the draft BPC opinion.

Assessment report

Summary of product assessment

1: Administrative information

Table 1:Identifier of the product

Identifier	Country
ClearKlens product based on IPA	All countries

Table 2:Trade names of the product

Trade name	Country
ClearKlens IPA	All countries
ClearKlens IPA 70%	All countries
ClearKlens IPA 70% v/v	All countries
ClearKlens IPA VH1	All countries
VH01 ClearKlens IPA	All countries
ClearKlens IPA Airless	All countries
ClearKlens IPA Pouch	All countries
ClearKlens IPA Non Sterile	All countries
ClearKlens IPA Non Sterile VH1	All countries
ClearKlens IPA SS	All countries
ClearKlens IPA SS VH1	All countries
ClearKlens IPA RTU	All countries
ClearKlens IPA RTU VH1	All countries
Texwipe® Sterile 70% Isopropanol	All countries

* Texwipes is a registered name of the ITW Company

Table 3:Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands
Pre-submission phase started on	15 December 2015	
Pre-submission phase concluded on	16 February 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

Table 4:Manufacturers of the product

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands
Location of manufacturing sites:	Diversey España Production S.L.U. Avenida Conde Duque 5, 7 y 9 Poligono Industrial La Postura 28343 Valdemoro (Madrid) ES

	Diversey Italy Production Srl Strada Statale 235 I - 26010 Bagnolo Cremasco (CR) IT
	Diversey UK Production Limited Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton UK
	Flexible Medical Packaging Ltd* Unit 8, Hightown White Cross Industrial Estate Lancanter, Lancashire LA1 4XS UK
	Ardepharm Les Iles Ferays 07300 Tournon-sur-Rhône FR
	Entegris Cleaning Process (ECP) S.A.S 395 rue Louis Lépine 34000 Montpellier FR
	Multifill BV Constructieweg 25a 3640 AJ Mijdrecht NL
	Diversey Netherlands Production BV Rembrandtlaan 414 7545 ZW Enschede NL
	Diversey Germany Production OHG Morschheimer Strasse 12 D-67292 Kirchheimbolanden DE

Table 5:Manufacturers of the active substance

Active substance	Propan-2-ol (IPA)
NAME OF MANUFACTURER	INEOS Solvents GmbH
Address of manufacturer	Anckelmannsplatz D-20537 Hamburg
Location of manufacturing sites	**Plant 1:** Shamrockstrasse 88 D-44623 Herne **Plant 2:** Römerstr. 733 D-47443 Moers
NAME OF MANUFACTURER	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334

	3000 CH Rotterdam
Location of manufacturing sites	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V. Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherland
NAME OF MANUFACTURER	Exxon Mobil Chemicals
Address of manufacturer	Hermeslaan 2 1831 Machelen Belgium
Location of manufacturing sites	**Plant 1:** ExxonMobil's Baton Rouge Refinery and Chemical Plant 4045 Scenic Hwy Baton Rouge LA 70805 United States **Plant 2:** Esso Refinery Fawley Southampton Hampshire SO45 1TX

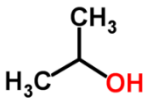
2: Product composition and formulation

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1: Identity of the active substance

Table 6:Identity of the active substance

Main constituent:	
ISO name	Isopropanol Isopropyl alcohol (IPA)
IUPAC or EC name	Propan-2-ol
EC number	200-661-7
CAS number	67-63-0
Index number in Annex VI of CLP	603-117-00-0
Minimum purity / content	99%w/w (Regulation 2015/407/EU)
Structural formula	

2.2: Candidate(s) for substitution

Propan-2-ol is not a candidate for substitution.

2.3: Qualitative and quantitative information on the composition of the biocidal product

Table 7:Composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w %)
Isopropyl alcohol (IPA)	Propan-2-ol	Active substance	67-63-0	200-661-7	63.1 (technical and pure)

The active substance content was originally specified at 64%, using an inappropriate calculation method. Throughout the PAR, where 64% or 64.04% is mentioned, this is based on the calculation method using the densities of water and propan-2-ol. For the risk assessment, the higher value may be considered worst-case and therefore, the PAR was not fully rewritten based on the active substance content of 63.1%, calculated based on the measured density of the formulation.

Considering the high purity of propan-2-ol, the eCA has not included the purity of the active substance. 63.1%w/w therefore refers to both the pure and technical active substance content.

The FAO/WHO tolerance for this product is 25 g/kg (+/-2.5% w/w).

See the confidential annex for more information on the product's composition.

2.4: Information on technical equivalence

The applicant, Diversey Europe Operations B.V., is a review program participant and a member of the "Alcohol Task Force" that submitted an active substance dossier for propan-2-ol as part of the review program. The manufacturers of the active substance used in the biocidal product are from the same sources as the active substance evaluated as part of the review program and as included on the Union List of approved active substances. Therefore, the biocidal product formulation contains propan-2-ol (IPA) that has already been reviewed and approved.

2.5: Information on the substance(s) of concern

The biocidal product does not contain any non-active substances of concern or endocrine disruptors.

2.6: Type of formulation

AL - Any other liquid

The product is applied undiluted.

3: Hazard and precautionary statements

The classification and labelling for the biocidal product formulation is as follows:

Table 8: Classification and labelling according to the Regulation (EC) 1272/2008 for ClearKlens product based on IPA

Classification

Hazard category	Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336	
Hazard statement	H225 H319 H336 EUH066	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking
Labelling		
Signal words	Danger	
GHS pictogram		
Hazard statements	H225 H319 H336 EUH066	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking
Precautionary statements	P210 P303+P361+P353 P403 + P235 P370+P378 P261 P264 P501	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Store in a well-ventilated place. Keep cool. In case of fire: Use … to extinguish. Avoid breathing spray Wash hands thoroughly after handling. Dispose of contents/container in accordance with local regulations.
Note	Propan-2-ol should be on the label according to Art 18(3) of the CLP.	

4: Authorised use(s)

4.1: Use description: Use 1.

Table 9: Use 1.– PT02: Non-porous hard surface disinfectant - professionals - mopping

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor Ready to use product for the disinfection of non-porous hard surfaces in pharmaceutical and cosmetics manufacturing facilities and clean rooms with respectively air change of 60 or 150 per hour or higher.
Application method(s)	Disinfection using a mop Ready to use disinfectant for mopping on cleaned non-porous hard surfaces
Application rate(s) and frequency	Ready to use product (no dilution required) Apply 18.4 ml product / m^2 surface.

Category of users	Professional
Pack sizes and packaging material	Containers (HDPE, PP, PE): 1 – 20 L

4.1.1: Use-specific instructions for use 1

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the mop with the disinfectant and mop the surface. Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. Used mops must be stored in a closed container

4.1.2: Use-specific risk mitigation measures

The product may be applied only in a sufficiently ventilated room. The minimum air change rates required are

- 60/h in pharmaceutical and cosmetics manufacturing facilities

- 150/h in cleanrooms

Do not use more than 18.4 ml product/m^2.

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

See general directions for use.

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

See general directions for use.

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.

4.2: Use description: Use 2.

Table 10: Use 2. – PT02: Non-porous hard surface disinfectant - professionals – cloth

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts

Field of use	Indoor Ready to use product for the disinfection of non-porous hard surfaces in laboratories, pharmaceutical and cosmetics manufacturing facilities and clean rooms with respectively air change of 8, 60 or 150 per hour or higher.
Application method(s)	Disinfection using a cloth: Ready to use disinfectant for wiping with cloth on cleaned non-porous hard surfaces.
Application rate(s) and frequency	Ready to use (no dilution required) Apply 18.4 mL product / m^2 surface.
Category of users	Professional
Pack sizes and packaging material	-Containers (HDPE, PP, PE): 1 - 20 L -Containers (HDPE, PP, PE) with a pump: 200 L (cleanroom only) -IBCs with a pump (HDPE, PP, PE): 950 and 1000 L (cleanroom only)

4.2.1: Use-specific instructions for use 2

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the cloth with the disinfectant and wipe the surface. Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. In cleanrooms, the exact amount of required product can also be dispensed either using a low flow-rate spray lance or into a bucket via a system of pipes. Used cloths must be disposed in a closed container.

4.2.2: Use-specific risk mitigation measures

The product may be applied only in a sufficiently ventilated room. The minimum air change rates required are

- 8/h in laboratories

- 60/h in pharmaceutical and cosmetics manufacturing facilities

- 150/h in cleanrooms

Do not use more than 18.4 ml product/m^2.

The following personal risk mitigation measure can be considered for wiping disinfection unless it can be replaced by technical and/or organisational measures : The use of eye protection during handling of the product is recommended.

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.

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

See general directions for use.

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.

4.3: Use description: Use 3.

Table 11:Use 3. – PT02: Non-porous hard surface disinfectant - professionals – spraying

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor Ready to use product for the disinfection of non-porous hard surfaces in laboratories, pharmaceutical and cosmetics manufacturing facilities and clean rooms with respectively air change of 8, 60 or 150 per hour or higher.
Application method(s)	Disinfection using a trigger spray: Ready to use disinfectant for spraying on cleaned non-porous hard surfaces, wiping optional to spread the product.
Application rate(s) and frequency	Ready to use (no dilution required) Apply 18.4 mL product / m^2 surface.
Category of users	Professional
Pack sizes and packaging material	-Trigger spray pouch (PE) : 0.9 – 20 L -Bag in bottle (multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag in a HDPE, PP or PE bottle: 0.9 – 2 L -Trigger Spray bottle (HDPE, PP, PE: 0.5 – 1.5 L -Airless trigger spray bottle (LDPE): 0.25 – 1 L

4.3.1: Use-specific instructions for use 3

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Spray the surface, wipe if necessary to spread the product. Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. Used clothes must be disposed in a closed container.

Number of applications per type of packaging, necessary to obtain an application rate of about 18.4mL product / m^2 surface:
- Trigger spray pouch: apply 19 sprays / m^2 surface,
- Sterile trigger (bag in bottle): apply 16 sprays / m^2 surface,
- Trigger spray bottle: apply 14 sprays / m^2 surface,
- Airless trigger spray bottle: apply 21 sprays / m^2 surface.

4.3.2: Use-specific risk mitigation measures

The product may be applied only in a sufficiently ventilated room. The minimum air change rates required are

- 8/h in laboratories

- 60/h in pharmaceutical and cosmetics manufacturing facilities

- 150/h in cleanrooms

Do not use more than 18.4 ml product/m^2.

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.

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

See general directions for use.

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.

4.4: Use description: Use 4.

Table 12:Use 4. – PT02: Non-porous glove disinfectant - professionals – non-porous glove disinfection

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor Ready to use product for the disinfection of non-porous gloves in laboratories, pharmaceutical and cosmetics manufacturing facilities and clean rooms with respectively air change of 8, 60 or 150 per hour or higher.
Application method(s)	Disinfection of non-porous gloves: Ready to use disinfectant for disinfection of clean non-porous gloves.
Application rate(s) and frequency	Ready to use (no dilution required) Apply 3 mL product to gloved hands
Category of users	Professional
Pack sizes and packaging material	Automatic dosing: -Containers (HDPE, PP, PE: 1 – 20 L -Containers (HDPE, PP, PE) with a pump: 200 L (cleanrooms only)

	-IBCs with a pump (HDPE, PP, PE): 950 and 1000 L (cleanrooms only) Manual dosing: -Trigger spray pouch (PE): 0.9 – 20 L -Bag in bottle (multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag in a HDPE, PP or PE bottle 0.9 – 2 L -Trigger Spray bottle (HDPE, PP, PE): 0.5 - 1.5 L -Airless trigger spray bottle (LDPE): 0.25 – 1 L

4.4.1: Use-specific instructions for use 4

Ready to use product for the disinfection of non-porous gloves.

Automatic dosing:

Apply 3 ml of the product directly onto clean gloved hands, distribute evenly and make sure to wet the surface completely. Allow to take effect for at least 30 seconds.

Manual dosing:

Spray 3 ml of the product directly onto clean gloved hands, distribute evenly and make sure to wet the surface completely. Allow to take effect for at least 30 seconds.

Number of applications per type of packaging, necessary to apply 3 mL product onto clean gloved hands:
- Trigger spray pouch: apply 3 sprays of the product to two hands,
- Sterile trigger (bag in bottle): apply 3 sprays of the product to two hands,
- Trigger spray bottle: apply 3 sprays of the product to two hands,
- Airless trigger spray bottle: apply 4 sprays of the product to two hands.

4.4.2: Use-specific risk mitigation measures

The product may be applied only in a sufficiently ventilated room. The minimum air change rates required are

- 8/h in laboratories

- 60/h in pharmaceutical and cosmetics manufacturing facilities

- 150/h in cleanrooms

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.

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

See general directions for use.

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.

5: General directions for use

5.1: Instructions for use

See use specific instructions described in section 4 (4.1.1-4.2.1-4.3.1-4.4.1)

5.2: Risk mitigation measures

Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Avoid contact with eyes.

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

Inhalation: May cause drowsiness or dizziness.
Eye contact: Causes severe irritation.

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTRE, doctor or physician if you feel unwell.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation occurs and persists, get medical attention.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical attention or advice if you feel unwell.

Environmental precautions:
Should not reach sewage water or drainage ditch undiluted or unneutralised.
Do not allow to enter drainage system, surface or ground water. Dilute with plenty of water.

5.4: Methods and material for containment and cleaning up. Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).Instructions for safe disposal of the product and its packaging

5.5: The product and its container must be disposed of in a safe way, in compliance with any relevant legislation on the disposal of hazardous waste. Perform disposal or incineration in accordance with the local registrations..Conditions of storage and shelf-life of the product under normal conditions of storage

2 years shelf life

Store away from direct sunlight and below 30°C.

Keep only in original packaging.

Store in a closed container.

5.6 : Other information

Please be aware of the European reference value of 129.26 mg/m3 for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

6: Packaging of the biocidal product

Table 13:Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Container	1 – 20 L	HDPE, PP, PE	Cap (HDPE, PP, PE)	Professional	Yes
Container with a pump	200 L IBC: 950 and 1000 L	HDPE, PP, PE	Cap (PE)	Professional	Yes
Trigger spray pouch	0.9 – 20 L	PE	Trigger device (PE, S/S, PP, Viton)	Professional	Yes
Bag in bottle	0.9 – 2 L	Multilayer coextruded five-layer EVA/EVA/PVDC/EVA/ EVA bag in a HDPE, PP or PE bottle	Trigger device (PE, S/S, PP, Viton)	Professional	Yes
Trigger spray bottle	0.5 – 1.5 L	HDPE, PP, PE	Trigger device (PP/PE)	Professional	Yes
Airless trigger spray bottle	0.25 – 1 L	LDPE	Trigger device (PP, IIR, PBT)	Professional	Yes

7: Documentation

7.1: Data submitted in relation to product application

Please refer to the reference list in Annex 1 for a list of studies for the biocidal product.

7.2: Access to documentation

The applicant is a member of the “Alcohol Task Force” that submitted an active substance dossier for propan-2-ol as part of the review program. A letter detailing the “declaration of ownership” to the propan-2-ol active substance dossier is submitted as part of the biocidal product dossier.

7.3: Similar conditions of use

As stated in the letter from ECHA dated 16 February 2016, the biocidal product *ClearKlens product based on IPA* is deemed to be eligible for Union authorisation. This correspondence is submitted as part of the biocidal product dossier.

Assessment of the biocidal product

1: Intended uses as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See section 4 of the summary for the authorised uses, after assessment of the dossier.

Table 14: Intended uses 1-4 – Hard surface disinfection in cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not applicable
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Ready to use product for the disinfection of hard surfaces and gloves in laboratories, clean rooms and pharmaceutical and cosmetics manufacturing facilities.
Application method(s)	1.Disinfection using a mop: Ready to use for mopping on cleaned surfaces. 2.Disinfection using a cloth: Ready to use for wiping with cloth on cleaned surfaces. 3.Disinfection using a trigger spray: Ready to use for spraying on cleaned surfaces, wiping optional. 4.Disinfection of gloves: Ready to use for disinfection of clean gloves.
Application rate(s) and frequency	Apply ca. 18.4 mL product / m^2 surface OR Apply ca. 3 mL product to gloved hands If necessary, apply according to disinfection protocols.
Category of users	Professional
Pack sizes and packaging material	-Containers (HDPE, PP, PE): 1 - 20 L -Containers (HDPE, PP, PE) with a pump: 200 L (cleanrooms only) -IBCs with a pump (HDPE, PP, PE): 950 and 1000 L (cleanrooms only) -Trigger spray pouch (PE): 0.9 – 20 L -Bag in bottle (multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag in a HDPE, PP or PE bottle): 0.9 – 2 L -Trigger Spray bottle (HDPE, PP, PE): 0.5 – 1.5 L -Airless trigger spray bottle (LDPE): 0.25 – 1 L

2: Physical, chemical and technical properties

The physical, chemical and technical properties of the biocidal product, ClearKlens product based on IPA, are detailed in the following table.

The biocidal product is supplied in different types of packaging and materials: containers and trigger sprays (standard trigger, airless, bag in bottle and pouch). The following products have therefore been chosen for long-term stability testing in order to cover all packaging types:

•Pouch (5 L)
•Can (1000 mL)
•Airless spray (250 mL)
•Trigger bottle (900 mL)
•Spray bottle (500 mL)

All packs are made of comparable polymer(s) (combinations): HDPE, PP, PE or LDPE. Please refer to section 6 above for more detailed information on packaging.

Table 15: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 assessment	64.04% propan-2-ol	Liquid	[redacted] (2016), 2015/343AM
Colour at 20 °C and 101.3 kPa	Visual assessment	64.04% propan-2-ol	Transparent	[redacted] (2016), 2015/343AM
Odour at 20 °C and 101.3 kPa	-	64.04% propan-2-ol	Alcoholic	[redacted] (2016), 2015/343AM
Acidity / alkalinity	CIPAC MT 75	64.04% propan-2-ol	pH (1%) = 5.66 (at 20°C) **eCA remark:** Acceptable. Some drops of a concentrated sodium chloride solution were added to stabilize the reading. Although the product contains water, the pH has not been determined on the undiluted product. This is considered acceptable in this case as the product does	[redacted] (2016), 2015/343AM

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>not contain other compounds that may influence the pH. The pH is therefore expected to be in the neutral range.</td><td></td></tr>
<tr><td>Relative density / bulk density</td><td>CIPAC MT 3.2.1
OECD 109</td><td>64.04% propan-2-ol</td><td>0.871 (20°C)</td><td>[redacted] (2016), 2015/343AM</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3</td><td>64.04% propan-2-ol (packaged in a spray bottle)</td><td>The test material was ClearKlens IPA VH1 and consisted of a transparent liquid contained in a 500 mL plastic (HDPE, PP, PE) bottle closed by a white plastic dispenser.

According to ECHA Guidance on the BPR Volume I Part A Section 3.4.1.1, the accelerated storage stability test does not necessarily have to be conducted in the actual sales packaging. Therefore, the results of this study can be considered relevant to all forms of product packaging. Long term storage stability studies for all packaging forms have been performed and the results are summarised within the table.

No changes were observed in the following parameters during storage at 30°C for 18 weeks:

<table>
<tr><th>Test</th><th>T0</th><th>T18 weeks</th></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent liquid</td><td>No variation from T0</td></tr>
<tr><td>Container appearance</td><td>The packaging is a plastic bottle closed by a white plastic dispenser</td><td>No variation from T0</td></tr>
<tr><td>Weight loss</td><td>-</td><td>0.06%</td></tr>
<tr><td>A.I. content</td><td>71.44% v/v
(102.1% of the theoretical value)</td><td>73.73% v/v
(103.2% of the theoretical value)</td></tr>
<tr><td>pH1%</td><td>5.66</td><td>5.60</td></tr>
<tr><td>Relative density (20°C)</td><td>0.871</td><td>0.872</td></tr>
</table>

eCA remark:
Acceptable. The study was not performed in the commercial packaging, but compatibility with packaging is addressed in the real-time shelf-life study (see below).</td><td>[redacted] (2016), 2015/343AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>The analytical method used to determine the a.s. content is S-2015-02695AM-MdP, which is the same method as reported in the analytical method section (Cassese S, 2015).</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td></td><td></td><td>Long term storage stability studies have been performed at ambient temperature for 24 months. The following products were tested:
- Container (Sterile can, 1000 mL)
- Bag in bottle (Sterile trigger bottle, 900 mL)
- Airless spray (250 mL)
- Non sterile trigger (Spray bottle, 500 mL)
- Pouch (5 L)

Each packaging form of the product has been tested for long term storage stability. For all products, with the exception of the pouch, the smallest pack size has been tested. This is considered to represent the potential worst case for stability due to the larger packaging surface area to product volume ratio.

[redacted] Therefore, it can be assumed that there would be no differences in the product stability for smaller or much larger pack sizes compared to those tested.

Although the smallest pouch was not tested, it can therefore be justified to read across the results on the 5 L pouch to smaller pouch sizes.</td><td></td></tr>
<tr><td>Container (Sterile can, 1000 mL)</td><td>-</td><td>64.04% propan-2-ol</td><td>The test material was ClearKlens IPA VH1 (Sterile Can 1000 mL). The packaging is a 1000 mL plastic (HDPE, PP, PE) bottle closed by a screw cap.

The results from this study can be extrapolated to all plastic cans with volumes of 1000 mL or greater.

<table>
<tr><th>Test</th><th>T0</th><th>T12</th><th>T18</th><th>T24</th></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent liquid</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Packaging appearance</td><td>The packaging is a plastic</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
</table>
</td><td>[redacted] (2018), 2016/29 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>bottle (1000 mL), closed by screw cap.</td><td></td><td></td><td></td></tr>
<tr><td>Weight loss</td><td>-</td><td>0.221%</td><td>0.140%</td><td>0.238%</td></tr>
<tr><td>A.I. content</td><td>70.94%v/v (101.3% of the theoretical value)</td><td>70.77%v/v (99.8% of T0)</td><td>70.75%v/v (99.4% of T0)</td><td>71.271%v/v (100.5% of T0)</td></tr>
<tr><td>Relative density (20°C)</td><td>0.873</td><td>0.875</td><td>0.875</td><td>0.876</td></tr>
<tr><td>$pH_{1\%}$</td><td>6.24</td><td>6.54</td><td>5.81</td><td>6.54</td></tr>
<tr><td>Sterility</td><td>Sterile</td><td>-</td><td>-</td><td>Sterile</td></tr>
</table>
.
</td><td></td></tr>
<tr><td>Airless spray (250 mL)</td><td>-</td><td>64.04% propan-2-ol</td><td>
The test material was ClearKlens IPA VH1 (Airless Spray). The packaging is a transparent soft plastic (LDPE) bottle, closed by a white plastic cap with an airless spray dispenser.

The results from this study can be extrapolated to all airless spray bottles with volumes of 250 mL or greater.
<table>
<tr><td>Test</td><td>T0</td><td>T12</td><td>T18</td><td>T24</td></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent liquid</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Packaging appearance</td><td>The packaging is a transparent soft plastic bottle, closed by a white plastic cap with spray</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
</table>
</td><td>[redacted] (2018), 2016/30 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>airless dispenser.</td><td></td><td></td><td></td></tr>
<tr><td>Weight loss</td><td>-</td><td>1.937%</td><td>2.481%</td><td>3.321%</td></tr>
<tr><td>A.I. content</td><td>70.82%v/v (101.2% of the theoretical value)</td><td>71.26%v/v (100.6% of T0)</td><td>70.61%v/v (99.7% of T0)</td><td>70.92%v/v (100.7% of T0)</td></tr>
<tr><td>Relative density (20°C)</td><td>0.871</td><td>0.875</td><td>0.874</td><td>0.874</td></tr>
<tr><td>pH1%</td><td>5.86</td><td>6.18</td><td>5.87</td><td>5.77</td></tr>
<tr><td>Sterility</td><td>Sterile</td><td>-</td><td>-</td><td>Sterile</td></tr>
<tr><td>Spray rate (25°C)</td><td>0.846 g (RSD = 3.4%)</td><td>0.691 g (RSD = 20.8%)</td><td>-</td><td>0.82 g (RSD = 4.9%)</td></tr>
<tr><td>Valve clogging (25°C)</td><td>No clogging</td><td>No clogging</td><td>-</td><td>No clogging</td></tr>
<tr><td>Particle size distribution</td><td>Dv(50) = 136.27 µm</td><td>Dv(50) = 91.0 µm</td><td>-</td><td>Dv(50) = 92.21 µm</td></tr>
<tr><td>Spray and stream character</td><td>Cone like spray</td><td>Cone like spray</td><td>-</td><td>Cone like spray</td></tr>
</table>
</td><td></td></tr>
<tr><td>Bag in bottle (Sterile trigger bottle, 900 mL)</td><td>-</td><td>64.04% propan-2-ol</td><td>
The test material was ClearKlens IPA VH1 (Sterile trigger 900 mL). The packaging is a plastic (HDPE, PP, PE) bottle (900 mL), containing a multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag, closed by a white plastic dispenser and characterized by a little hole close to the dispenser.

The results from this study can be extrapolated to all spray bottles with volumes of 900 mL or greater.
<table>
<tr><td>Test</td><td>T0</td><td>T12</td><td>T18</td><td>T24</td></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
</table>
</td><td>[redacted] (2018), 2015/220 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>liquid</td><td></td><td></td><td></td></tr>
<tr><td>Packaging appearance</td><td>The packaging is a plastic bottle (900 mL), closed by a white plastic dispenser and characterized by a little hole close to the dispenser</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Weight loss</td><td>-</td><td>0.87%</td><td>1.46%</td><td>2.04%</td></tr>
<tr><td>A.I. content</td><td>69.53%v/v (99.3% of the theoretical value)</td><td>69.89%v/v (100.5% of T0)</td><td>70.12%v/v (100.8% of T0)</td><td>71.23%v/v (102.4% of T0)</td></tr>
<tr><td>Relative density (20°C)</td><td>0.876</td><td>0.8755</td><td>0.8761</td><td>0.8761</td></tr>
<tr><td>$pH_{1\%}$</td><td>5.70</td><td>5.80</td><td>5.87</td><td>5.79</td></tr>
<tr><td>Sterility</td><td>Sterile</td><td>-</td><td>-</td><td>Sterile</td></tr>
<tr><td>Spray rate (25°C)</td><td>1.02 g (RSD = 1.96%)</td><td>0.47 g (RSD = 4.90%)</td><td>-</td><td>1.08 g (RSD = 2.1%)</td></tr>
<tr><td>Valve clogging (25°C)</td><td>No clogging recorded</td><td>No clogging recorded</td><td>-</td><td>No clogging recorded</td></tr>
<tr><td>Particle size distribution</td><td>Dv(50) = 97.6 µm</td><td>Dv(50) = 81.8 µm</td><td>-</td><td>Dv(50) = 77.2 µm</td></tr>
<tr><td>Spray and stream character</td><td>Like a spray</td><td>Like a spray</td><td>-</td><td>Like a spray</td></tr>
</table>
After 24 months at 25°C no important variations in the appearance, pH and
</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>density were observed; the weight loss was equal to 2.04% and the content of propan-2-ol active ingredient was 102.4% with respect to T0.</td><td></td></tr>
<tr><td>Spray bottle (500 mL)</td><td>-</td><td>64.04% propan-2-ol</td><td>The test material was ClearKlens IPA VH1 (Spray bottle). The packaging is a plastic (HDPE, PP, PE) bottle, closed by a white plastic dispenser.

The results from this study can be extrapolated to all spray bottles with volumes of 500 mL or greater.

<table>
<tr><th>Test</th><th>T0</th><th>T12</th><th>T18</th><th>T24</th></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent liquid</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Packaging appearance</td><td>The packaging is a plastic bottle, closed by a white plastic dispenser.</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Weight loss</td><td>-</td><td>0.17%</td><td>0.27%</td><td>0.35%</td></tr>
<tr><td>A.I. content</td><td>70.707%v/v (101.0% of the theoretical value)</td><td>70.693%v/v (100.0% of T0)</td><td>72.505%v/v (102.5% of T0)</td><td>71.776%v/v (101.5% of T0)</td></tr>
<tr><td>Relative density (20°C)</td><td>0.873</td><td>0.872</td><td>0.873</td><td>0.873</td></tr>
<tr><td>$pH_{1\%}$</td><td>5.70</td><td>5.79</td><td>6.10</td><td>5.72</td></tr>
<tr><td>Spray rate (25°C)</td><td>1.14 g (RSD = 0.72%)</td><td>1.12 g (RSD = 4.69%)</td><td>-</td><td>1.18 g (RSD = 2.89%)</td></tr>
<tr><td>Valve clogging (25°C)</td><td>No clogging recorded</td><td>No clogging recorded</td><td>-</td><td>No clogging recorded</td></tr>
<tr><td>Particle size</td><td>Dv(50) =</td><td>Dv(50) =</td><td>-</td><td>Dv(50) =</td></tr>
</table></td><td>[redacted] (2018), 2015/252 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>distribution</td><td>98.6 µm</td><td>112.9 µm</td><td></td><td>87.6 µm</td></tr>
<tr><td>Spray and stream character</td><td>Like a spray</td><td>Like a spray</td><td>-</td><td>Like a spray</td></tr>
</table>

After 24 months at 25°C, no important variations in the chemical-physical characteristics were observed; the content of propan-2-ol active ingredient was 101.5% with respect to T0.</td><td></td></tr>
<tr><td>5 L pouch</td><td>-</td><td>64.04% propan-2-ol</td><td>The test material was ClearKlens IPA VH1 (5 L Pouch). The packaging is a white plastic (PE) pouch (5 L), closed by a white plastic cap with a plastic tube with a spray trigger.

[redacted] Therefore, it can be assumed that there would be no differences in the product stability for smaller or much larger pack sizes compared to those tested.

Although the smallest pouch was not tested, it can therefore be justified to read across the results on the 5 L pouch to both larger and smaller pouch sizes.

<table>
<tr><td>Test</td><td>T0</td><td>T12</td><td>T18</td><td>T24</td></tr>
<tr><td>Product appearance</td><td>The test item consists of a transparent liquid</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>Packaging appearance</td><td>The packaging is a plastic pouch (5 L), closed by a white plastic cap with a plastic tube with spray trigger.</td><td>No variation from T0</td><td>No variation from T0</td><td>No variation from T0</td></tr>
<tr><td>A.I. content</td><td>68.64%v/v (98.1% of</td><td>69.43%v/v (101.2% of</td><td>69.27%v/v (100.9% of</td><td>66.94%v/v (97.5% of</td></tr>
</table></td><td>[redacted] (2018), 2015/308 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>the theoretical value)</td><td>theoretical value)</td><td>theoretical value)</td><td>T0 value)</td></tr>
<tr><td>Relative density (20°C)</td><td>0.880</td><td>0.880</td><td>0.879</td><td>0.881</td></tr>
<tr><td>$pH_{1\%}$</td><td>5.69</td><td>5.67</td><td>5.48</td><td>5.77</td></tr>
<tr><td>Spray rate (25°C)</td><td>Not applicable</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Valve clogging (25°C)</td><td>No clogging recorded</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Particle size distribution</td><td>Dv(50) = 69.14 µm</td><td>Dv(50) = 75.5 µm</td><td>-</td><td>Dv(50) = 78.0 µm</td></tr>
<tr><td>Spray and stream character</td><td>Cone like spray</td><td>Cone like spray</td><td>-</td><td>Cone like spray</td></tr>
</table>

After 24 months at 25°C, no important variations in the appearance, weight, pH and density were observed; the content of propan-2-ol active ingredient was 97.5% with respect to T0.
</td><td></td></tr>
<tr><td></td><td></td><td></td><td>eCA remark on product stability
Stability was addressed in the following packaging types: LDPE, PE, HDPE (HDPE, PP, PE) and container with a EVA/EVA/PVDC/EVA/EVA internal pouch. LDPE is considered a worst-case packaging type, representative for all materials applied for. Two packaging types included a trigger spray / dispenser which showed acceptable spray characteristics before and after storage.

The analytical method (GC-FID) used for determination of the active substance content is method S-2015-02695AM-MdP, validated and reported in section 2.2.4 (analytical methods).

Sterility was tested according to method S-2015-02698AM, which involved an incubation at 28-32°C for 14 days, after which microbial growth was investigated using a ‘sterility kit’. Considering sterility is not a formal requirement for a BPR authorization, no additional information on the test method was requested by the eCA.</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
The particle size (CIPAC MT187, by lazer diffraction) of droplets was reported in more detail (sterile trigger, 900 mL):

T = 0
<table>
<tr><td>Parameter</td><td colspan="3">Sample</td></tr>
<tr><td></td><td>A</td><td>B</td><td>C</td></tr>
<tr><td>Dv(10), µm</td><td>53.1</td><td>43.8</td><td>44.1</td></tr>
<tr><td>Dv(50), µm</td><td>114.3</td><td>97.6</td><td>102.3</td></tr>
<tr><td>Dv(90), µm</td><td>243.8</td><td>221.9</td><td>231.3</td></tr>
<tr><td>D[4,3], µm</td><td>132.9</td><td>114.8</td><td>121.7</td></tr>
<tr><td>D[3,2], µm</td><td>85.5</td><td>76.9</td><td>78.5</td></tr>
<tr><td>V<10µm, %</td><td>0.2</td><td>0.2</td><td>0.5</td></tr>
<tr><td>V<5µm, %</td><td>0.1</td><td>0.0</td><td>0.0</td></tr>
<tr><td colspan="4">Single actuation weight: 1014 mg (average)</td></tr>
</table>
T = 24 months
<table>
<tr><td>Parameter</td><td colspan="3">Sample</td></tr>
<tr><td></td><td>A</td><td>B</td><td>C</td></tr>
<tr><td>Dv(10), µm</td><td>32.2</td><td>51.6</td><td>50.1</td></tr>
<tr><td>Dv(50), µm</td><td>77.2</td><td>107.3</td><td>99.1</td></tr>
<tr><td>Dv(90), µm</td><td>206.0</td><td>227.3</td><td>216.7</td></tr>
<tr><td>D[4,3], µm</td><td>100.6</td><td>125.2</td><td>118.3</td></tr>
<tr><td>D[3,2], µm</td><td>60.6</td><td>89.5</td><td>86.4</td></tr>
<tr><td>V<10µm, %</td><td>0.38</td><td>0.19</td><td>0.1</td></tr>
<tr><td>V<5µm, %</td><td>0.11</td><td>0.01</td><td>0.0</td></tr>
<tr><td colspan="4">Single actuation weight: 957 mg (average)</td></tr>
</table>
For the spray bottle:

T = 0
<table>
<tr><td>Parameter</td><td colspan="3">Sample</td></tr>
<tr><td></td><td>A</td><td>B</td><td>C</td></tr>
<tr><td>Dv(10), µm</td><td>48.4</td><td>44.4</td><td>50.0</td></tr>
<tr><td>Dv(50), µm</td><td>104.8</td><td>98.6</td><td>108.2</td></tr>
<tr><td>Dv(90), µm</td><td>232.1</td><td>224.8</td><td>236.4</td></tr>
<tr><td>D[4,3], µm</td><td>124.2</td><td>118.4</td><td>127.3</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>D[3,2], µm</td><td>84.4</td><td>77.9</td><td>85.3</td></tr>
<tr><td>V<10µm, %</td><td>0.3</td><td>0.5</td><td>0.2</td></tr>
<tr><td>V<5µm, %</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
<tr><td colspan="4">Single actuation weight: 1109 mg (average)</td></tr>
</table>
T = 24 months
<table>
<tr><td rowspan="2">Parameter</td><td colspan="3">Sample</td></tr>
<tr><td>A</td><td>B</td><td>C</td></tr>
<tr><td>Dv(10), µm</td><td>38.5</td><td>40.8</td><td>42.0</td></tr>
<tr><td>Dv(50), µm</td><td>87.6</td><td>90.3</td><td>90.7</td></tr>
<tr><td>Dv(90), µm</td><td>201.0</td><td>208.5</td><td>206.9</td></tr>
<tr><td>D[4,3], µm</td><td>106.5</td><td>109.4</td><td>109.5</td></tr>
<tr><td>D[3,2], µm</td><td>68.2</td><td>71.2</td><td>72.7</td></tr>
<tr><td>V<10µm, %</td><td>0.45</td><td>0.50</td><td>0.4</td></tr>
<tr><td>V<5µm, %</td><td>0.09</td><td>0.06</td><td>0.1</td></tr>
<tr><td colspan="4">Single actuation weight: 1109 mg (average)</td></tr>
</table>
For the airless spray:
T = 0
<table>
<tr><td rowspan="2">Parameter</td><td colspan="3">Sample</td></tr>
<tr><td>A</td><td>B</td><td>C</td></tr>
<tr><td>Dv(10), µm</td><td>67.69</td><td>69.38</td><td>67.77</td></tr>
<tr><td>Dv(50), µm</td><td>136.27</td><td>140.34</td><td>137.42</td></tr>
<tr><td>Dv(90), µm</td><td>263.14</td><td>266.64</td><td>264.54</td></tr>
<tr><td>D[4,3], µm</td><td>152.13</td><td>155.37</td><td>153.02</td></tr>
<tr><td>D[3,2], µm</td><td>112.82</td><td>116.14</td><td>112.89</td></tr>
<tr><td>V<10µm, %</td><td>0.08</td><td>0.07</td><td>0.12</td></tr>
<tr><td>V<5µm, %</td><td>0.03</td><td>0.03</td><td>0.03</td></tr>
<tr><td colspan="4">Single actuation weight: 756 mg (average)</td></tr>
</table>
T = 24 months
<table>
<tr><td rowspan="2">Parameter</td><td colspan="4">Sample</td></tr>
<tr><td>A</td><td>B</td><td>C</td><td>D</td></tr>
<tr><td>Dv(10), µm</td><td>59.97</td><td>55.81</td><td>45.88</td><td>46.36</td></tr>
<tr><td>Dv(50), µm</td><td>122.01</td><td>122.21</td><td>92.21</td><td>96.34</td></tr>
<tr><td>Dv(90), µm</td><td>239.93</td><td>246.07</td><td>220.09</td><td>208.66</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>D[4,3], µm</td><td>138.24</td><td>137.92</td><td>118.23</td><td>113.88</td></tr>
<tr><td>D[3,2], µm</td><td>102.78</td><td>96.00</td><td>79.52</td><td>79.08</td></tr>
<tr><td>V<10µm, %</td><td>0.09</td><td>0.19</td><td>0.33</td><td>0.32</td></tr>
<tr><td>V<5µm, %</td><td>0.02</td><td>0.02</td><td>0.03</td><td>0.04</td></tr>
<tr><td colspan="5">Single actuation weight: 672 mg (average)</td></tr>
</table>

The guidance requires the amount of particles < 50µm to be reported. Judging the data above, approximately 10% of the particles has a particle size of 50µm. 90% of the particles has a size of >200µm. This applies to all three spraying systems.

Lastly, the pump attachment was not tested in stability studies. This pump is intended to transfer product from the large bulk containers to smaller containers. Therefore, the spray characteristics are not important for this pump. Blocking of the nozzle is not possible based on the composition of the product. In addition, the applicant has indicated there are no known issues with the packaging based on experience in use.</td><td></td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 39.3</td><td>64.04% propan-2-ol (packaged in a sterile can 1000 mL)</td><td>The treatment of the test item ClearKlens IPA VH1 (Sterile Can 1000 ml) at 0°C for 7 days did not produce any modification of the test item appearance. The biocidal product is therefore considered stable when stored at low temperatures.</td><td>[redacted] (2016), S-2016-00251 AM</td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 39.3</td><td>64.04% propan-2-ol (packaged in a spray bottle)</td><td>The treatment of the test item ClearKlens IPA VH1 (Sterile Can 1000ml) at 0°C for 7 days did not produce any modification of the test item appearance. The biocidal product is therefore considered stable when stored at low temperatures.</td><td>[redacted] (2016), 2015/343AM</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product -</td><td></td><td></td><td></td><td></td></tr>
<tr><td>light</td><td>Waiver</td><td>-</td><td>The MSDS for the biocidal product recommends that the product is stored in a cool place away from heat and direct sunlight. If stored as recommended, the long term storage stability studies show that there is no effect of light on the</td><td>NA</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			stability of the biocidal product. Furthermore, propan-2-ol is not expected to undergo photolysis. **eCA remark** Acceptable. Considering the product is classified as flammable, storing away from directly sunlight is advisable.	
temperature and humidity	Waiver	-	The MSDS for the biocidal product recommends that the product is stored in a cool place away from heat and direct sunlight. The effect of storage at 30°C for 18 weeks has been covered by an accelerated study and in a long term study the effect of ambient temperature (25°C) is assessed. Humidity is assessed at 65%RH in the accelerated stability test. **eCA remark** Acceptable. The product is flammable. Therefore, generally it is advisable to store under cool conditions. The accelerated study was performed at 30°C. Therefore, the storage conditions should be limited to this temperature.	NA
reactivity towards container material	CIPAC MT 46.3	64.04% propan-2-ol	An accelerated storage stability study was performed at 30°C for 18 weeks on ClearKlens IPA VH1 contained in a plastic (HDPE, PP, PE) bottle closed by a white plastic dispenser. No variation was observed in the container material or product characteristics during accelerated storage. Furthermore, long-term storage stability studies have been performed for all packaging forms at ambient and have shown no variations in either the container material or the product characteristics. These results demonstrate that there is no reactivity of the product towards the container material.	
Technical characteristics of the biocidal product	Waiver	-	Technical characteristics of the biocidal product have been assessed as part of the long term storage stability studies. Therefore, please refer to the results given above for the spray rates, particle size distribution, spray and stream character and valve clogging for the various packaging forms.	NA
Evaporation study	-	64.04% propan-2-ol	ClearKlens IPA was added to a Petri dish and placed under a laminar flow (flow rate: 1.03 m s^{-1}) When ClearKlens IPA was applied to a surface at a rate equivalent to 32 g/m^2, it remained on the surface for at least 5 minutes. When applied at a concentration equivalent to 16 g/m^2, ClearKlens IPA remained on the surface for at least 2 minutes but after 5 minutes only residual droplets were visible.	[redacted] (2016)
Wettability	Waiver	-	Not considered relevant for this biocidal product	NA
Suspensibility,	Waiver	-	Not considered relevant for this biocidal product	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test	Waiver	-	Not considered relevant for this biocidal product	NA
Emulsifiability, re-emulsifiability and emulsion stability	Waiver	-	Not considered relevant for this biocidal product	NA
Disintegration time	Waiver	-	Not considered relevant for this biocidal product	NA
Particle size distribution, content of dust/fines, attrition, friability	Waiver	-	Not considered relevant for this biocidal product Please refer to the shelf-life data for the particle size information on droplets.	NA
Persistent foaming	Waiver	-	Not considered relevant for this biocidal product	NA
Flowability/Pourability/Dustability	Waiver	-	Not considered relevant for this biocidal product	NA
Burning rate — smoke generators	Waiver	-	Not considered relevant for this biocidal product	NA
Composition of smoke — smoke generators	Waiver	-	Not considered relevant for this biocidal product	NA
Spray pattern	-	ClearKlens IPA VH01-02 FM003771: 0.5L Trigger can 0.9L Trigger can 5.0L Trigger pouch 0.250L Airless spray	The spray pattern from one trigger hub was measured at a distance of 30 cm for different triggers. The spray pattern of the trigger devices covers a surface area from 0.013 to 0.036 m^2 (Δ = 0.023 m^2) and the results of the spray volume analysis ranged from 0.99 to 1.28 mL (0.87 g to 1.12 g) (Δ = 0.29 mL). From the results of this study, it can be concluded that no significant variations between the different trigger heads, which are used for this formulation, are present. Data on the particle size and possibility of nozzle blockage is reported within the scope of the shelf-life data.	[redacted] (2017)
Physical compatibility	Waiver	-	The biocidal product is not applied with other substances, mixtures or biocidal or non-biocidal products. Therefore, a study is not required.	NA
Chemical compatibility	Waiver	-	The biocidal product is not applied with other substances, mixtures or biocidal or non-biocidal products. Therefore, a study is not required.	NA
Surface tension	EU Method A5	64.04% propan-2-ol (packaged in a sterile	26.7 mN/m at 20°C for the undiluted product.	[redacted] (2016),

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		can 1000 mL)		201600613
Viscosity	OECD 114	64.04% propan-2-ol (packaged in a sterile can 1000 mL)	The kinematic and dynamic viscosity determinations at 20°C were 4.525 mm²/s and 3.938 mPa*s, respectively and at 40°C were 2.350 mm²/s and 2.011 mPa*s, respectively.	[redacted] (2016), S-2016-00251 AM

Conclusion: The biocidal product is a transparent liquid, with a pH (1%) of 5.66, a relative density of 0.871, a surface tension of 26.7 mN/m, a kinematic viscosity of 4.525 mm²/s and a dynamic viscosity of 3.938 mPa*s at 20°C.

An accelerated storage stability study has shown that the product is stable at 30°C for 18 weeks. Long term storage stability studies were performed for 24 months at 25°C on the 1 L container, airless spray (250 mL), bag in bottle (900 mL), spray bottle (500 mL) and 5 L pouch products and showed no important variations in the chemical-physical characteristics. The propan-2-ol content was between 97.5% and 102.4% of the initial value after 24 months of storage.

The particle size of the droplets produced are not within the range relevant for inhalation and after 2 years storage no significant change in particle size was observed.

An evaporation study performed with the biocidal product has shown that when it was applied to a surface at a rate equivalent to 32 g/m^2, it remained on the surface for at least 5 minutes. When applied at a concentration equivalent to 16 g/m^2, the product remained on the surface for at least 2 minutes but after 5 minutes only residual droplets were visible. The results of the spray pattern study concluded that there are no significant variations between the different trigger heads which are used for ClearKlens formulation.

3: Physical hazards and respective characteristics

The physical hazards and respective characteristics of the biocidal product, ClearKlens product based on IPA, are detailed in the following table.

Table 16:Physical hazards and respective characteristics of the biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waiver	-	According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is not classified as explosive. The biocidal product contains 64% propan-2-ol and 36% inert material and is therefore not considered explosive (please refer to the confidential annex for full details on the product's composition).	NA
Flammable gases	Waiver	-	The biocidal product is not a gas.	NA
Flammable aerosols	Waiver		The biocidal product is not an aerosol.	NA
Oxidising gases	Waiver		The biocidal product is not a gas.	NA
Gases under pressure	Waiver		The biocidal product is not a gas.	NA
Flammable liquids	Waiver	-	According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is classified as a flammable liquid. The biocidal product contains 64% propan-2-ol and 36% inert material (please refer to the confidential annex for full details on the product's composition).. It is therefore considered that the biocidal product is also flammable and is classified accordingly as flammable liquid category 2. **eCA remark** Acceptable. The harmonized classification for pure propan-2-ol is flammable liquid catergory 2. For this product, the flash point is expected to be <23°C, based on publically available information (IChemE, 2004, G.R. Astbury , J. Bugand-Bugandet , E. Grollet and K.M. Stell). Therefore it is classified as flammable liquid category 2 (H225, highly flammable liquid and vapour).	NA
Flammable solids	Waiver	-	The biocidal product is not a solid.	NA
Self-reactive substances and mixtures	Waiver	-	Propan-2-ol and other component(s) in the formulation are not considered self-reactive compound(s), not thermally unstable and do not possess explosive properties. Therefore, the biocidal product is not considered a self-reactive mixture. Please refer to the confidential annex for full details on the product's composition.	NA
Pyrophoric liquids	Waiver	-	None of the components in the formulation are pyrophoric.	NA

Pyrophoric solids	Waiver	-	The biocidal product is not a solid.	NA
Self-heating substances and mixtures	Waiver	-	None of the components in the formulation are self-heating.	NA
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	Since water is present in the product and the product is stable, no reaction can take place between the propan-2-ol and water and hence no flammable gases are emitted.	NA
Oxidising liquids	Waiver	-	According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is not classified as oxidising. The biocidal product contains 64% propan-2-ol and 36% inert co-formulants and is therefore also not considered oxidising (please refer to the confidential annex for full details on the product's composition).	NA
Oxidising solids	Waiver	-	The biocidal product is not a solid.	NA
Organic peroxides	Waiver	-	The biocidal product does not contain any organic peroxides.	NA
Corrosive to metals	Waiver	-	Experience in use shows that the biocidal product is not corrosive to metals. **eCA remark** The product has a pH in the neutral range and it contains no acids or bases. Therefore, the eCA considers testing not required to support the claim that the product does not need to be classified as metal corrosive. According to the latest agreement included in the TAB (technical agreements biocides) a test should not be necessary (please refer to the confidential annex for full details on the product's composition).	NA
Auto-ignition temperatures of products (liquids and gases)	Waiver	-	According to handbook data, the auto-ignition temperature of propan-2-ol is 455°C. **eCA remark** This line of reasoning is acceptable given the simple composition of the product. No auto-flammable components are present in this product.	NA
Relative self-ignition temperature for solids	Waiver	-	The biocidal product is not a solid.	NA
Dust explosion hazard	Waiver	-	The biocidal product is not a dust and does not produce a dust. Therefore, no dust explosion hazard is possible.	NA

Conclusion: With regard to physical and chemical hazards, the biocidal product is classified as a highly flammable liquid and vapour category 2 (H225).

4: Methods for detection and identification

The analytical method to determine the concentration of the active (propan-2-ol) in the product is summarised below:

Table 17:Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Propan-2-ol (IPA)	GC-FID with internal standard (1-propanol) HP mod. 7890 split/splitless injection Column: 6% cyano/94% polydimethylsiloxane, 30 m x 0.32mm x 1.8µm, Agilent Injection temp.: 160 °C Carrier gas: He Flow:1.8 mL/min Injection vol.: 1µl, Split Ratio: 1:20 Temperature:20 °C for 5 min; rate 40 °C/min to 120 °C for 1 min Detector temp.:.200 °C Retention time: Isopropanol ~3.6 min 1-Propanol (IS) ~5.2 min An aliquot of the product (1mL) is dissolved in methanol (approx. 0.2%v/v or 2mL/L,	3 different concentrations, corresponding to 50%, 100% and 150% of the theoretical concentration, analysed in duplicate	Range: 50-150% of the nominal concentration (0.56-1.7mg/mL, n=5 in duplicate) r^2 = 1.000, y = 0.7551x – 0.0035	Method proved to be specific, no peak interference. Identity confirmed by GC-MS.	@50% 101.1, 102.3 @100% 101.1, 100.6 @150%. 100.5, 100.3	@50%: 101.7 @100% 100.9 @150% 100.4 (acceptable range: 98 – 102%)	Precision: 0.37% (n=6) Horwitz criterion: 1.41%	Not determined	[redacted] (2015), S-2015-02695 AM

	corresponding to approx. 1.4mL/L IPA).								
Methods for relevant impurities and/or substances of concern are not relevant. The product does not contains SoCs or relevant impurities which may be formed during storage.									

Conclusion: The analytical method was validated and proved to be specific, linear, precise and accurate.

An analytical method for the detection of propan-2-ol in air is available in the active substance dossier. Therefore, further testing with the biocidal product is not required.

Analytical methods for the determination of propan-2-ol in soil, water and food/feed of plant and animal origin are not required as no residues are expected in these compartments. Analytical methods for the determination of propan-2-ol in body fluids and tissues are also not required as the product is not classified as toxic or very toxic.

5: Efficacy against target organisms

5.1: Function and field of use

The function of the biocidal product is a bactericide and yeasticide. The biocidal product is a ready to use product for the disinfection of non-porous hard surfaces and non-porous gloves in cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories for professional use only.

5.2: Organisms to be controlled and products, organisms or object to be protected

Organisms to be controlled are bacteria and yeasts.

The goal is to prevent spread of micro-organisms via surface contact and through that, protect humans, cosmetics and pharmaceutical products and any product susceptible to microbial deterioration.

5.3: Effects on target organisms, including unacceptable suffering

Cell death

5.4: Mode of action, including time delay

According to the Assessment Report for propan-2-ol:

Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm’s proteins. This process (referred to as denaturation) and the enzymes’ coagulation leads to a loss of cellular activity resulting in the cell’s death.

5.5: Efficacy data

The efficacy data on the biocidal product is summarised in the following table:

Table 18:Experimental data on the efficacy of the biocidal product

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Bacteria: *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	EN 1276	End concentrations: 80%, 50% and 30% (v/v) Contact times: 30 and 60 seconds Clean conditions: 0.3 g/L bovine albumin	Bactericidal (log reduction ≥ 5) at 20°C under clean conditions (0.3 g/L bovine albumin) in 30 seconds at a test concentration of 80% (v/v) against the test strains.	[redacted] (2017), L17/0015.1
Bactericide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Bacteria: *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	EN 1276	End concentrations: 97%, 80%, 50% and 5% (v/v) Contact time: 5 minutes Clean conditions: 0.3 g/L bovine albumin	Bactericidal (log reduction ≥ 5) at 20°C under clean conditions (0.3 g/L bovine albumin) in 5 minutes when diluted at 97%, 80% and 50% (v/v) against the test strains.	[redacted] (2016), SN 19836 EN 1276
Yeasticide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Yeast: *Candida albicans*	EN 1650	End concentrations: 80%, 50% and 30% (v/v) Contact times: 30 and 60 seconds Clean conditions: 0.3 g/L bovine albumin	Yeasticidal (log reduction ≥ 4) at 20°C under clean conditions (0.3 g/L bovine albumin) in 30 seconds at a test concentration of 80% (v/v) against the test strain.	[redacted] (2017), L17/0015.2
Yeasticide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Yeast: *Candida albicans*	EN 1650	End concentrations: 97%, 80%, 50% and 5% (v/v) Contact time: 15 minutes Clean conditions: 0.3 g/L bovine albumin	Yeasticidal (log reduction ≥ 4) at 20°C under clean conditions (0.3 g/L bovine albumin) in 15 minutes when diluted at 97%, 80% and 50% (v/v) against the test strain.	[redacted] (2016), SN 19836 EN 1650
Bactericide Yeasticide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Bacteria: *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa* Yeast:	EN 13697	End concentrations: 100%, 80%, 50% and 5% (v/v) Contact times: Bacteria: 0.5, 1 and 5 minutes; Yeast: 1 and 15 minutes Clean conditions: 0.3 g/L bovine albumin	The product possesses at 20°C - 22°C under clean conditions undiluted in ½ minute a bactericidal activity (≥4 log reduction) for the test strains. Undiluted it also possesses in 1 minute, a yeasticidal activity (≥3 log reduction) for the referenced test strain *Candida albicans*.	[redacted] (2016), SN 19836 EN 13697

			Candida albicans				
Yeasticide	Hard surface disinfectant for professional use only	VH01 ClearKlens IPA (70% v/v IPA)	Yeast: *Candida albicans*	EN 13697	End concentrations: 100%, 80%, 50% and 5% (v/v) Contact time: 30 seconds Clean conditions: 0.3 g/L bovine albumin	The undiluted product is yeasticidal (log reduction ≥ 3) at 20°C under clean conditions (0.3 g/L bovine albumin) in 30 seconds against the test strain.	[redacted] (2017), L17/0015.3

Conclusion on the efficacy of the product:

The biocidal product was demonstrated to be efficacious against bacteria and yeasts in phase 2 step 1 and phase 2 step 2 tests under clean conditions. These tests demonstrate efficacy for the claimed disinfection of non-porous hard surfaces and non-porous gloves in laboratories, clean rooms and pharmaceutical and cosmetics manufacturing facilities. The products are applied as Ready To Use products at room temperature with a contact time of 30 seconds.

5.6: Occurrence of resistance and resistance management

According to the Assessment Report for propan-2-ol:

Due to the unspecific mode of action of 2-propanol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where 2-propanol is ineffective at any concentration.

5.7: Known limitations

None

5.8: Evaluation of the label claims

The claim on the label states that the biocidal product is effective against bacteria and yeasts when used according to the use instructions on non-porous hard surfaces and non-porous gloves in laboratories, clean rooms and pharmaceutical and cosmetics manufacturing facilities. This claim is supported by the efficacy studies performed with the biocidal product and summarised above.

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

The product is not intended to be authorised for use with another biocidal product.

6: Risk assessment for human health

6.1: Assessment of effects on human health

There are no toxicological data available on the biocidal product itself. The biocidal product contains [redacted]. Therefore, information on propan-2-ol can be used to predict the toxicological effects of the biocidal product.

The human health effects assessment of propan-2-ol is summarised in the Assessment Report (13 January 2015).

The Acceptable Exposure Levels (AELs) derived from the toxicological data evaluated are detailed in Section 6.3.

6.1.1: Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Skin corrosion and irritation

Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient propan-2-ol as detailed in the assessment report. Propan-2-ol is not considered to be irritating to skin. [redacted] and hence synergistic effects will not occur. Testing is therefore scientifically unjustified.

6.1.2: Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritant
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Eye Irrit. Cat. 2

Data waiving	
Information requirement	Eye irritation
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Propan-2-ol is classified as Eye Irrit. Cat. 2 in accordance with Regulation (EC) No. 1272/2008. As the concentration of propan-2-ol in the biocidal product is 70% (v/v), the product is also classified as Eye Irrit. Cat. 2. Therefore, a study is scientifically unjustified.

6.1.3: Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitiser
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Skin sensitisation
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected; - that available information indicates that the product should be classified for skin sensitisation or corrosivity; or - the substance is a strong acid (pH <2.0) or base

	(pH > 11.5) Data is available for the active ingredient propan-2-ol as detailed in the assessment report. Propan-2-ol is not considered to be a skin sensitiser. [redacted] and hence synergistic effects will not occur. Testing is therefore scientifically unjustified.

6.1.4: Respiratory sensitization *(ADS)*

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser
Justification for the value/conclusion	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitisation
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP); and synergistic effects between any of the components are not expected. Data is available for the active ingredient propan-2-ol as detailed in the assessment report. Propan-2-ol is not considered to be a respiratory sensitiser. [redacted] and hence synergistic effects will not occur. Testing is therefore scientifically unjustified.

6.1.5: Acute toxicity

6.1.5.1: Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic via the oral route (LD_{50} of propan-2-ol = 4400 mg/kg bw)
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP); and synergistic effects between any of the components are not expected. Data is available for the active ingredient propan-2-ol as detailed in the assessment report (LD_{50} = 4400 mg/kg bw). [redacted] Based on the available information, the biocidal product does not need to be classified for acute oral toxicity and a study would be considered scientifically unjustified.

6.1.5.2: Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic via inhalation (LC_{50} of propan-2-ol = 17100 mg/kg bw (47.5 mg/L air for 8 h; whole body vapour))
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP); and synergistic effects between any of the components are not expected. Data is available for the active ingredient propan-2-ol as detailed in the assessment report (LC_{50} = 17100 mg/kg bw (47.5 mg/L air for 8 h; whole body vapour)). [redacted]. Based on the available information the biocidal product does not need to be classified for acute inhalation toxicity and a study would be considered scientifically unjustified.

6.1.5.3: Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic via the dermal route (Rabbit: LD_{50} of propan-2-ol = 12900 mg/kg bw)
Justification for the selected value	See waiver justification
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute dermal toxicity
Justification	According to the guidance on information requirements (Volume III Part A, November 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP); and synergistic effects between any of the components are not expected. Data is available for the active ingredient propan-2-ol as detailed in the assessment report (rabbit: 12900 mg/kg bw). [redacted] Based on the available information the biocidal product does not need to be classified for acute dermal toxicity and a study would be considered scientifically unjustified.

6.1.6: Dermal absorption

Table 19:Values used in the risk assessment – Dermal absorption

Substance	Propan-2-ol (IPA)
Values	Default dermal absorption as stated in CA-July13-Doc.6.2.b – Final: **25%** (used in a first Tier assessment only) Transdermal flux rate as cited in the Assessment Report: **0.85 mg/cm^2/h**
Justification for the selected value	Point 8.6 of Annex III to the BPR states that information on dermal absorption is required when exposure occurs to the biocidal product and the assessment of this endpoint should proceed using a tiered approach. The guidance on the approach to dermal absorption assessment for biocidal products authorisation (CA-July13-Doc.6.2.b – Final) specifies the following: Step 1) If available, use of data on the specific formulation is recommended. Step 2) If data on the specific formulation is not available, the applicant in consultation with the evaluating CA, could use either: 2.a) A default value for a first worst-case exposure estimate from the EFSA Guidance on Dermal Absorption. Or 2.b) Data from the Assessment Report for Annex I inclusion or for product authorisation provided that conditions 1 and 2 are met: 1. It is justified that the formulations presented in dermal absorption studies submitted for Annex I inclusion or for product authorisation have a similar composition as compared to the BP to be authorised. 2. The applicant holds a letter of access (LoA) from the data owner of the dermal absorption study which is relevant for the BP to be authorised. According to the Assessment Report for propan-2-ol and the disseminated active substance dossier, the dermal absorption and transdermal flux rate were derived from an in vivo study in rats investigated under occlusive conditions using a 70% (w/w) aqueous solution of propan-2-ol. The ClearKlens IPA biocidal product is a 70% (v/v) aqueous solution of propan-2-ol. Therefore, the only difference between the two formulations is a slight variation in the content of propan-2-ol. However, it is considered that this would have a negligible effect on the dermal absorption of the propan-2-ol. [redacted] the dermal absorption of the formulations and the active itself will essentially be the same. Furthermore, the applicant holds a letter of ownership to the data submitted as part of the active substance review program and therefore can legally refer to the information submitted on propan-2-ol. For the reasons stated above, the performance of an in vitro or in vivo dermal absorption test on the biocidal product is considered scientifically unjustified and dermal absorption data available in the Assessment Report for propan-2-ol is considered applicable to the ClearKlens biocidal product. The transdermal flux rate of 0.85 mg/cm^2/h will therefore be used in the risk assessment to determine dermal exposure to propan-2-ol following use of the biocidal product.

6.1.7: Others

6.1.7.1 : Endocrine disruptor Assessment

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance. The biocidal product contains only water as co-formulant.

6.1.8: Available toxicological data on non-active substance(s) (i.e. substance(s) of concern)

There are no substances of concern in the biocidal product. [redacted]

6.1.9: Available toxicological data relating to a mixture

There are no toxicological data available on the biocidal product itself. [redacted] information on propan-2-ol can be used to predict the toxicological effects of the biocidal product.

6.2: Exposure assessment

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

Table 20: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	Not applicable	Yes	Not applicable	Not applicable	Yes	No	Not applicable
Dermal	Not applicable	Yes	Not applicable	Not applicable	Yes	No	Not applicable
Oral	Not applicable	No	Not applicable	Not applicable	No	No	Not applicable

6.2.2: Summary of exposure scenarios

Table 21:Summary table: description of scenarios

Scenario number	**Disinfection room**	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Cleanrooms	Mopping	Primary exposure: Disinfection using a mop in cleanrooms: The product is poured directly onto the mop and the surface is then mopped and left wet for 30 seconds.	Professionals
2.	Cleanrooms	Wiping	Primary exposure: Disinfection using a cloth in cleanrooms: The product is poured directly onto the cloth and the surface is then wiped and left wet for 30 seconds.	Professionals
3.	Cleanrooms	Spraying and wiping	Primary exposure: Disinfection using a trigger spray in cleanrooms: The product is sprayed onto the surface or equipment, wiped if necessary and left wet for 30 seconds.	Professionals
4.	Cleanrooms	Glove disinfection	Primary exposure: Disinfection of gloves in cleanrooms: Apply the product directly onto clean gloved hands, distribute evenly and leave wet for 30 seconds.	Professionals
5.	Pharmaceutical and cosmetic manufacturing facilities	Mopping	Primary exposure: Disinfection using a mop in pharmaceutical and cosmetic manufacturing facilities: The product is poured directly onto the mop and the surface is then mopped and left wet for 30 seconds.	Professionals

6.	Pharmaceutical and cosmetic manufacturing facilities	Wiping	Primary exposure: Disinfection using a cloth in pharmaceutical and cosmetic manufacturing facilities: The product is poured directly onto the cloth and the surface is then wiped and left wet for 30 seconds.	Professionals
7	Pharmaceutical and cosmetic manufacturing facilities	Spraying and wiping	Primary exposure: Disinfection using a trigger spray in pharmaceutical and cosmetic manufacturing facilities: The product is sprayed onto the surface or equipment, wiped if necessary and left wet for 30 seconds.	Professionals
8	Pharmaceutical and cosmetic manufacturing facilities	Glove disinfection	Primary exposure: Disinfection of gloves in pharmaceutical and cosmetic manufacturing facilities: Apply the product directly onto clean gloved hands, distribute evenly and leave wet for 30 seconds.	Professionals
9.	Laboratories	Mopping	Primary exposure: Disinfection using a mop in laboratories: The product is poured directly onto the mop and the surface is then mopped and left wet for 30 seconds.	Professionals
10.	Laboratories	Wiping	Primary exposure: Disinfection using a cloth in laboratories: The product is poured directly onto the cloth and the surface is then wiped and left wet for 30 seconds.	Professionals
11.	Laboratories	Spraying and wiping (optional)	Primary exposure: Disinfection using a trigger spray in laboratories: The product is sprayed onto the surface or equipment, wiped if necessary and left wet for 30 seconds.	Professionals
12.	Laboratories	Glove disinfection	Primary exposure: Disinfection of gloves in laboratories: Apply the product directly onto clean gloved hands, distribute evenly and leave wet for 30 seconds.	Professionals
13.	All	Secondary exposure	Secondary exposure: Exposure of other professionals who are present in the room while surface, equipment or gloves are being disinfected or who re-enter the room during or after a disinfection episode.	Professionals

The mixing and loading scenario is not required. The product from the smaller containers are not transferred to any other container or bottle and trigger spray bottles are never re-used. The product is applied directly to the surface from the product container. Hence, a loading scenario does not need to be considered. The only instance where a separate container might be used is when the product is dispensed from a system of pipes which feed the product directly into the cleanroom. In this case, the user will only dispense a product amount equivalent to the amount they require to disinfect the surface and no more. In this way their potential exposure will be the same as assessed during the use since they will always be exposed to the same amount of product regardless of the way in which it is dispensed.

6.2.3: Industrial exposure

A consideration of industrial exposure during manufacture of the biocidal products is not required as this is covered by other legislation.

6.2.4: Professional exposure

The biocidal product is used as a disinfectant for professional use only in cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories. Each disinfection location will be considered separately using different parameters appropriate to each location.

6.2.4.1: Derivation of indicative product application rates

Historically, little information is available regarding application rates and use frequencies on product labels for propan-2-ol based products as professional workers would follow disinfection protocols specific to the working location. Therefore, in order to assess the risk to professionals from use of the products, approximate use rates and frequencies need to be derived.

In the Biocides Human Health Exposure Methodology (Version 1, October 2015), an equation is given for the calculation of the evaporation time of volatile substances:

$$t\ (s) = (m\ T\ R / (M\ ß\ p\ A))\ x\ K,$$

where:

t = evaporation time (seconds)

m = mass of compound (mg)

R = gas constant (8.314 J K/mol)

T = temperature in Kelvin (298.15 K, equal to 25 ºC, room temperature)

M = molar mass of compound (60.09 g/mol for propan-2-ol)

ß = coefficient of mass transfer in the vapour phase (8.7 m/h)

p = vapour pressure of compound (5780 Pa for propan-2-ol at 25 °C)

A = applied area (100000 cm^2 i.e. 10 m^2 equal to the floor surface area in a cleanroom)

K = conversion factor (3.6×10^4)

As demonstrated by the efficacy studies, the biocidal product is efficacious after a contact time with the treated surface of 30 seconds. Therefore, using the input parameters specified above and an evaporation time of 30 seconds, a mass of propan-2-ol (i.e. the minimum amount of propan-2-ol that must be applied to a surface in order for it to remain in contact (remain wet and not evaporate) with the surface for at least 30 seconds and thereby be efficacious) can be calculated. The mass calculated will allow a product application rate to be derived which can then be used to calculate the amount of product applied to ALL surfaces.

Therefore, the mass of compound calculated is equal to **101.584 g propan-2-ol**. Since the product contains 64% (w/w) propan-2-ol, this mass is equivalent to **159 g** product.

If 159 g product is applied to an area of 10 m^2, the product application rate is therefore approximately:

Application rate: 16 g product/m^2 treated area

The relative density of the biocidal product is 0.87 (Bugatti S., 2016). Therefore, the application rate calculated above is equivalent to:

Application rate: 18.4 mL product/m^2 treated area

This application rate can then be used to calculate the amount of product applied to all surfaces for the purposes of assessing the dermal and inhalation exposures to professional workers.

6.2.4.2: Key parameters

The biocidal product is used as a disinfectant for professional use only in cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories. Each cleaning location is considered separately using different parameters appropriate to each location. The parameters which differ between the three different locations are primarily the room volumes, ventilation rates and disinfection frequencies and are summarised in the following table.

Table 22:Summary table of key parameters

Parameter	**Cleanrooms**	**Pharmaceutical and cosmetic manufacturing facilities**	**Laboratories**
Room volume	25 m^3	80 m^3	25 m^3
Ventilation rate	150 h^{-1}	60 h^{-1}	8 h^{-1} (referenced in the Assessment Report for propan-2-ol for a lab)
Disinfection frequency	Mopping – 3 times/day Wiping – 20 times/day Spraying- 80 times/day Gloves- 80 times/day	Mopping – 1 time/day Wiping – 5 times/day Spraying- 80 times/day Gloves- 40 times/day	Mopping – 1 time/day Wiping – 10 times/day Spraying- 10 times/day Gloves- 10 times/day

eCA comment: The room volume and ventilation rate in laboratories are derived from the laboratory scenario evaluated in the CAR for propan-2-ol (PT2). These paramters used in ths PAR are consistent with HEAd hoc recommendation no. 13 for laboratories, which was discussed during BPC HHWG VI 2018 (Dec 2018).

Exposure in cleanrooms and pharmaceutical and cosumetic manufactureing facilities were not evaluated in the CAR for propan-2-ol, and the realistic worst case parameters were derived for this PAR by the applicant. The applicant has also provided a statement for an argument. The summary is presented below. For the full statement please see Confidential Annex of the PAR.

High ventilation rate up to 150/h

Cleanrooms are following the ISO standard for cleanroom. The ISO standard sets the maximum allowable number of particles per unit volume and the particle size in relation to the cleanroom classes. To keep the particle levels low there are 4 important elements to control and one of them is heading, ventilation and air conditioning (HVAC) system. The ISO standard, however, does not state absolute values for air changes rate per hour (ACR) as this depends on other elements. Different studies are submitted by the applicant, which refer to ventiration rates in clean rooms. One study[1] stated that the recommended design for ISO Class 5 (Class 100) cleanroom ACRs are 250-700 /h, which could be reduced to 94-276 /h by optimising clean room design. Tow more documents[2, 3] were submitted, which mention typical ventiration rates between 8 and >750/h.

Based on the submitted information by the applicant, eCA considers that the hige ventiration rates up to 150/h are not unrealistically high. Together with the assigned field of use “Ready-to-use product for the disinfection in l aboratories, pharmaceutical and cosmetics manufacturing facilities and clean rooms with respectively air change of 8, 60 or 150 per hour or higher”, eCA consiers it is acceptable to use the proposed ventration rates for exposure assessment.

Disinfection frequency

The applicant has asked to some of its customres to provide input for difinfection frequency. Based on the information collected, the worst case scenario was determined in combination with the ventilation rate of 150 /h. In addition, time used for difinection was considered. Assuming each small surfaces/glove disinfection takes 40 seconds (10 sec application + 30 sec contact time), the total duration required for small disinfection is 40 sec × 180 times (total of wiping, spraying and glove disinfection) = 120 min. This duration is 25% of a normal workday of 8 hours. On top of it, 3 times mopping per day is assumed for the exposure assessment. In total, more than 25% of total working hour is used only for disinfection in one clean room based on the proposed values. Therefore it is unlikely the worker will spend more time on disinfections than proposed in the PAR. For the worst cases assessment, it is assumed that all disinfection is executed by one person, considering the simulation assumes a small room of 10 m^2.

References

1. A. Bhatia, HVAC Design for Cleanroom Facilities, Continuing Education and Development, Inc., Course No: M06-008, Credit: 6 PDH (downloaded March 2019, from https://www.cedengineering.com/userfiles/HVAC%20Design%20for%20Cleanroom%20Facilities.pdf)
2. A. Bhatia, HVAC Design for Cleanroom Facilities, Continuing Education and Development, Inc., Course No: M06-008, Credit: 6 PDH (downloaded March 2019, from https://www.cedengineering.com/userfiles/HVAC%20Design%20for%20Cleanroom%20Facilities.pdf)
3. Rajan Jaisinghani, "Energy Efficient Low Operating Cost Cleanroom Airflow Design" presented at ESTECH 2003 Conference Phoenix

Professional use in cleanrooms

Cleanrooms need to be highly sterile environments due to the nature of the work undertaken. Contamination must be avoided and minimised at all costs. The workers will be highly professional who will have received training in what PPE should be worn and how it should be used. The following pictures show representative PPE that would be worn in cleanrooms.

Gloves MUST be worn at all times in order to protect the room, environment and surfaces/ implements etc from contamination by the worker. The gloves are not reused and would be changed every time the worker enters and exits the cleanroom.

6.2.4.2.1 Scenario 1: Disinfection using a mop in cleanrooms

Table 23:Description of scenario 1

The biocidal product can be used to disinfect floors using a mop. A small amount of the product is poured directly from the container onto the mop head (or floor) and then the surface can be mopped.

Exposure of professional workers in cleanrooms would be via the dermal and inhalation routes. Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practices.

Inhalation and dermal exposures can be calculated as follows.

Inhalation exposure:

The ConsExpo database includes a model for floor mopping systems (cleaning and washing database; floor, carpet and furniture products category; floor mopping systems as the default product). This model seems the most appropriate choice since the product is applied directly to the surface or mop head and does not involve the use of a bucket.

The physico-chemical properties of propan-2-ol predict that it will readily evaporate during application. The concentration in air will depend on a number of factors; the applied dose, the room volume, the room temperature (which will affect the vapour pressure) and the air exchange rate. The concentration of propan-2-ol in the air will therefore quickly reach a maximum and will then decline due to air exchange in the room.

A floor surface area of 22 m^2 is considered to be representative of a cleanroom of room volume 55 m^3. The amount of product applied to the floor is calculated based on the product application rate of 16 g/m^2 derived in Section 6.2.4.1 and equals 352 g product (16 g/m^2 x 22 m^2). The application duration is 5 minutes based on the HEAdhoc Recommendation No. 2 (referenced in Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.2)) which states that the mopping duration in hospitals is set to be 5 minutes followed by 10 min wiping per room for formaldehyde evaluation made by Germany. The product is used in cleanrooms for mopping purposes up to 3 times per day.

A Tier 1 assessment is performed based on the assumption in ConsExpo that the product evaporates from the floor at once (i.e. instantaneous release). The Tier 2 assessment assumes that the product evaporates continuously (i.e. evaporation).

The ConsExpo input parameters for the mopping scenario are detailed in the table below.

Dermal exposure:

Dermal exposure will be minimal during mopping but could occur when the pad is taken off the mop head after disinfection.

BEAT and Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1)) use the same reference source (Schipper et al, 1996). The model is based on the dilution and mixing of disinfectant and cleaning of surfaces with a wrung cloth or mop and wringer bucket. The value for deposition on bare hands is 1030 mg/min. This model will overestimate the potential exposure since the biocidal product is ready to use; therefore, mixing and loading is not required and the product is not emptied into a wringer bucket prior to use. Therefore, use of this model will therefore represent the worst case.

A Tier 1 assessment is performed using a default dermal absorption of 25% as specified in the guidance on the approach to dermal absorption assessment for biocidal product authorisation (CA-July13-Doc.6.2.b – Final). Tier 1 assumes that 25% of the total amount of product applied to the skin is absorbed and that no gloves are worn. This will be the worst case for dermal exposure since the dermal absorption of propan-2-ol is actually lower than the default value and that in reality professionals are expected to wear gloves at all times when working in cleanrooms.

A Tier 2 assessment is performed using the transdermal flux rate of 0.85 $mg/cm^2/h$ as derived in the Assessment Report for propan-2-ol. Again, it is assumed that gloves are not worn.

A Tier 3 refinement can be performed since professional workers will wear gloves whilst performing this task. According to the Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3), a default protection factor of 95% (i.e. 5% penetration/ exposure) can be applied to the Tier 2 systemic exposure for the use of protective gloves when new gloves are used for each working shift.
The calculations for determination of the dermal systemic doses for each Tier are detailed in Annex 2.

Table 24:Input parameters for Scenario 1

Scenario 1. Inhalation exposure during mopping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Exposure to vapour - Instantaneous release**		
	Exposure frequency	once a day	Instantaneous release
	Exposure duration	8 hours	Duration for a working shift
	Product amount	1056 g/application	Product use information – application rate of 16 g/m^2 x 22 m^2 treated area = 352 g per time (Equivalent to 225 g propan-2-ol) x 3 times/day
	Weight fraction compound	0.64	Product information
	Room volume	55 m^3	HEAd hoc recommendation No.15
	Ventilation rate	150 h^{-1}	Considered representative of a cleanroom (an ISO 6 (Class 1,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limited to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Exposure frequency	3 times/day	Product information
	Exposure duration	180 minutes/ application	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection.
	Product amount	352 g/application	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area = 160 g per time (Equivalent to 102.4 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	22 m^2	Considered representative of a cleanroom Assessment Report for propan-2-ol
	Application duration	5 min	HEAdhoc Recommendation No. 2 (referenced in Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.2)) for the mopping time per hospital room
Scenario 1. Dermal exposure during mopping:			
TIER 1	Exposure frequency	3 /day	Product use information
	Indicative hand exposure	1030 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Indicative body exposure	87.6 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Exposure duration	5 minutes/ application	HEAdhoc Recommendation No. 2 (referenced in Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.2)) for the mopping and wiping time per hospital room
	Product amount	16764 mg	(1030+87.6) mg/min x 5 min x 3 applications/

			day = 16764 mg product/ person/ day Equivalent to 10729 mg propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	0.215 hour	Refer to calculation in Annex 2 Section 1.2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of adult hands (palm only), HEEG opinion no. 17[2]
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

[2] According to the surface disinfection model 1 comtamination occurs also on the body. However, the indiacative values (1030 mg/min on hands vs 87.6 mg/min on body) suggest that the main dermal exposure is on hands. Therefore the exposure area of both palms is used.

6.2.4.2.2 Calculations for scenario 1

Please refer to the relevant calculations for Scenario 1 in Annex 2.

Table 25: Summary table: estimated exposure from professional uses in cleanrooms – Scenario 1

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 (mopping)	Tier 1 – No PPE	1.7 mg/kg bw/day	44.7 mg/kg bw/day	-	46.4 mg/kg bw/day
	Tier 2 – No PPE	1.7 mg/kg bw/day	1.25 mg/kg bw/day	-	2.95 mg/kg bw/day
	Tier 3 – PPE (95% gloves)	1.7 mg/kg bw/day	0.062 mg/kg bw/day	-	1.76 mg/kg bw/day

6.2.4.2.3 Scenario 2: Disinfection using a cloth in cleanrooms

Table 26:Description of Scenario 2

The biocidal product can be used to disinfect surfaces, walls and furniture using a cloth. The product is poured directly onto the cloth or surface to be disinfected. In cleanrooms the product can also be dispensed either directly onto the surface using a spray lance (with a low flow rate) or into a bucket via a system of pipes which feed the disinfectant directly into the cleanroom, therefore an area to be disinfected may be large. At any one time the user will only dispense a product amount equivalent to the amount they require to disinfect the surface and no more. In this way their potential exposure will be the same as assessed during the use since they will always be exposed to the same amount of product regardless of the way in which it is dispensed. Exposure of professional workers in cleanrooms and laboratories would be via the dermal and inhalation routes. Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practices.

Inhalation and dermal exposures can be calculated as follows.

Inhalation exposure:

The physico-chemical properties of propan-2-ol predict that it will readily evaporate during application. The concentration in air will depend on a number of factors; the applied dose, the room volume, the room temperature (which will affect the vapour pressure) and the air exchange rate. The concentration of propan-2-ol in the air will therefore quickly reach a maximum and will then decline due to air exchange in the room.

The inhalation assessment uses ConsExpo and is based on the disinfection of a surface area of 10 m^2. The treated surface area of 10 m^2 per application is based on the ConsExpo database, a model for liquid cleaners in the cleaning and washing database and all- purpose cleaners category. The ConsExpo Cleaning Products Fact Sheet (RIVM report 2016-0179, Section 8.1) describes the cleaning of 10 m^2 furniture (such as tables and cupboards) in the living room. The amount of product applied to the surface(s) is calculated based on the product application rate of 16 g/m^2 derived in Section 6.2.4.1 and equals 160 g product (16 g/m^2 x 10 m^2). The application duration for wiping this area 30 minutes was calculated from the duration of 5 min to disinfect 1.71 m^2 kitchen top using wet wipes (RIVM report 2016-0179, Section 8.3.1). Assuming the same speed about 30 min (5 min x (10/1.71) = 29.2 min) is needed to disinfect 10 m^2.. The product is used in cleanrooms for wiping of surfaces up to 20 times per day.

A Tier 1 assessment is performed based on the assumption in ConsExpo that the product evaporates from the surface at once (i.e. instantaneous release). The Tier 2 assessment assumes that the product evaporates continuously (i.e. evaporation).

The ConsExpo input parameters for the wiping scenario are detailed in the table below.

Dermal exposure:

Dermal exposure to the product will occur during wiping of the treated surfaces as a result of hand contact with a cloth that is wet with product.
BEAT includes a model for large scale surface wiping in which the 75th percentile value for hand exposure is quoted as 2950 µL/min. This can be used to calculate the dermal exposure per person per day as shown in Annex 2.

A Tier 1 assessment is performed using a default dermal absorption of 25% as specified in the guidance on the approach to dermal absorption assessment for biocidal products authorisation (CA-July13-Doc.6.2.b – Final). No gloves are assumed for this Tier 1, although in reality, the professionals are obliged to wear gloves at all times in the clean room .

A Tier 2 assessment is performed using the transdermal flux rate of 0.85 $mg/cm^2/h$ as derived in the Assessment Report for propan-2-ol. No gloves are assumed for this Tier, although in reality, the professionals are obliged to wear gloves in the cleanroom.

A Tier 3 refinement can be performed since professional workers will wear gloves whilst performing this task. According to the Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3), a default protection factor of 95% (i.e. 5% penetration/ exposure) can be applied to the indicative exposure for the use of protective gloves when new gloves are used for each working shift.
The calculations for determination of the dermal systemic doses for each Tier are detailed in Annex 2.

Table 27:Input parameters for Scenario 2

Scenario 2. Inhalation exposure during wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration for a working shift
	Product amount	3200 g	Product use information – application rate of

			16 g/m^2 x 10 m^2 treated area per time (Equivalent to 102.4 g propan-2-ol) x 20 times
	Weight fraction compound	0.64	Product information
	Room volume	55 m^3	HEAd hoc recommendation No.15
	Ventilation rate	150 h^{-1}	applicable to an ISO 6 (Class 1,000) cleanroom
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limited to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Frequency	20 times per day	Product information
	Exposure duration	60 minute/ application	Assessment Report for propan-2-ol and HEAd hoc recommendation no.15
	Product amount	160 g/application	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area per time (Equivalent to 102.4 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	10 m^2	ConsExpo Cleaning Products Fact Sheet
	Application duration	30 minute/ application	Based on ConsExpo Cleaning Products Fact Sheet
Scenario 2. Dermal exposure during wiping:			
TIER 1	Exposure frequency	20 times/day	Product use information
	Potential hand exposure	2950 µL/min	BEAT model for large scale surface wiping
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	70991 seconds	Refer to calculation in Annex 2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of two adult hands (palm only) (HEEG opinion No.17)
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

NL CA comment: During commenting phase a Member state showed its concern to use BEAT as this model is no longer maintained and available for downloading. Apart from BEAT the dermal exposure may be estimated by using surface disinfection model 1 (HEAd hoc recommentation 6, no 5). The model provides 1030 mg/min (hands) and 87.6 mg/min (body) as indicative values. The sum 1117.6 mg/min is lower than the value obtained from BEAT i.e. 2950 µl/min = 2566 mg/min. As BEAT covers a worse case than the alternative model Surface disinfection model 1, and the use in manufacturing facilities result in the safe use, the calculation in the PAR based on BEAT was considered acceptable.

6.2.4.2.4 Calculations for Scenario 2

Please refer to the relevant calculations for Scenario 2 in Annex 2.

Table 28: Summary table: estimated exposure from professional uses in cleanrooms – Scenario 2

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2 (wiping)	Tier 1 – No PPE	5.2 mg/kg bw/day	4106 mg/kg bw/day	None	4111 mg/kg bw/day
	Tier 2 – No PPE	5.1 mg/kg bw/day	114.5 mg/kg bw/day	None	119.6 mg/kg bw/day
	Tier 3 – PPE (95% gloves)	5.1 mg/kg bw/day	5.7 mg/kg bw/day	None	10.8 mg/kg bw/day

6.2.4.2.5 Scenario 3: Disinfection using a trigger spray in cleanrooms with wiping

The biocidal product can be packaged in a trigger spray. The product is sprayed onto the surface (e.g. work bench, machines and equipment within the cleanroom) which can then either be wiped with a cloth once a sufficient contact time has elapsed or left to dry.

In order to account for the worst case, dermal and inhalation exposure has been considered from spraying and then wiping the surface after application with a cloth.

Table 29:Description of Scenario 3

During the use of surface sprays, three phases can be distinguished. First, the product is sprayed onto the surface; then, it is left on the surface for an appropriate contact time (surface area must remain wet); finally, the surface may be wiped with a cloth. Exposure of professional workers in cleanrooms and laboratories would be via the dermal and inhalation routes. Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practices. Inhalation and dermal exposures will be calculated using ConsExpo and consumer product spraying and dusting model 2, respectively, during spraying of the product. Inhalation and dermal exposures during wiping of the surface(s) are calculated using ConsExpo and BEAT, respectively. ***Inhalation exposure:*** The physico-chemical properties of propan-2-ol predict that it will readily evaporate during application. The concentration in air will depend on a number of factors; the applied dose, the room volume, the room temperature (which will affect the vapour pressure) and the air exchange rate. The concentration of propan-2-ol

in the air will therefore quickly reach a maximum and will then decline due to air exchange in the room.

The inhalation exposure during spraying of the biocidal product can be calculated using the spray model in ConsExpo. The Tier 1 assessment is performed based on the assumption in ConsExpo that the product is released instantaneously, whereas the Tier 2 assessment takes into account the spray parameters.

The inhalation exposure during wiping of the surface (post-spraying) is based on the disinfection of a surface area of 0.5 m^2. A Tier 1 assessment is performed based on the assumption in ConsExpo that the product evaporates from the surface at once (i.e. instantaneous release). The Tier 2 assessment assumes that the product evaporates continuously (i.e. evaporation).The ConsExpo input parameters for the spraying and wiping scenarios are detailed in the table below.

Dermal exposure:

Dermal exposure to the product will occur during trigger spraying and wiping of the treated surfaces as a result of hand contact with a cloth that is potentially wet with the product.

Dermal exposure could occur to the hand and forearm during product spraying and can be estimated using the Consumer Product Spraying and Dusting Model 2 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.13.2)). According to this model, the 75th% value for hand and forearm exposure from use of a hand-held trigger spray is equal to 36.1 mg/min. It is estimated that spraying occurs for 10 seconds and that the product is applied in cleanrooms up to 80 times/ day. The calculations are detailed in Annex 2.

BEAT includes a model for small scale surface wiping in which the 75th percentile value for hand exposure is quoted as 214 µL/min. This can be used to calculate the dermal exposure per person per day from wiping surfaces as shown in Annex 2.

Tier 1 assessments are performed using a default dermal absorption of 25% as specified in the guidance on the approach to dermal absorption assessment for biocidal products authorisation (CA-July13-Doc.6.2.b – Final). No gloves are assumed for this Tier, although in reality, professionals are obliged to wear gloves at all times in cleanrooms.

Tier 2 assessments are performed using the transdermal flux rate of 0.85 mg/cm^2/h as derived in the Assessment Report for propan-2-ol. Again, no gloves are assumed for this Tier.

Tier 3 refinements can be performed since professional workers will wear gloves whilst performing these tasks. According to the Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3), a default protection factor of 95% (i.e. 5% penetration/ exposure) can be applied to the indicative exposure for the use of protective gloves when new gloves are used for each working shift.

The calculations for determination of the dermal systemic doses for each Tier are detailed in Annex 2.

Table 30:Input parameters for scenario 3

Scenario 3. Inhalation exposure during spraying & wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**SPRAYING + Wiping: Release mode: Instant release**		
	Exposure frequency	Once a day	Instant release
	Exposure duration	8 hours	Duration of a working shift
	Released mass	640 g	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol) x 80 times/day
	Weight fraction compound	0.64	Product information
	Room volume	55 m^3	HEAd hoc recommendation No.15
	Ventilation rate	150 h^{-1}	Considered representative of a cleanroom (an ISO 6 (Class 1,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	

	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limted to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**SPRAYING: Release mode: Spraying & wiping : Exposure to vapour**		
	Frequency	80 times/day	Product use information
	Exposure duration	45 minute/ application	Assessment Report for propan-2-ol and HEAd hoc recommendation no.15
	Product amount	8 g/time	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	0.5 m^2	Assessment Report for propan-2-ol
	Application duration	0.17 minute/ application	Spraying duration of 10 second
Scenario 3. Dermal exposure during spraying & wiping:			
TIER 1	**Exposure during spraying**		
	Exposure frequency	80 times a day	Product use information
	Indicative exposure of hand and forearms	36.1 mg/min	Consumer Product Spraying and Dusting Model 2 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.13.2))
	Spray duration	10 seconds	Product use information
	Product amount deposited on hands	481 mg	36.1 mg/min x 0.167 minutes/application x 80 applications/ day = 481 mg product/ person/day Equivalent to 308 mg propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Exposure during wiping		
	Exposure frequency	80 times/day	Product use information
	Potential hand exposure	214 µL/min	BEAT model for small scale surface wiping
	Exposure duration	1 minute	Assessment Report for propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2	**Exposure during spraying**		
	Evaporation time	9.33 seconds	Refer to calculation in Annex 2 Section 3.2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	974.4 cm^2	Surface area of hand and forearm of one arm HEAdhoc Recommendation No. 14
	Exposure during wiping		
	Evaporation time	1373 seconds	Refer to calculation in Annex 2 Section 3.2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	205 cm^2	Assessment Report for propan-2-ol

			Surface area of one adult hand (one palm only)
TIER 3	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.2.6 Calculations for Scenario 3

Please refer to the relevant calculations for Scenario 3 in Annex 2.

Table 31:Summary table: estimated exposure from professional uses in cleanrooms – Scenario 3

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3 (spraying and wiping)	Tier 1 – No PPE	1.0 mg/kg bw/day	1.28 + 39.72 = 41.0 mg/kg bw/day	None	**42.0 mg/kg bw/day**
	Tier 2 – No PPE	1.0 mg/kg bw/day	0.036 + 1.11 = 1.15 mg/kg bw/day	None	**2.15 mg/kg bw/day**
	Tier 3 – PPE (95% gloves)	1.0 mg/kg bw/day	0.0018 + 0.056 = 0.058 mg/kg bw/day	None	**1.06 mg/kg bw/day**

6.2.4.2.7 Scenario 4: Disinfection of gloves in cleanrooms

Table 32:Description of Scenario 4

For staff undertaking critical activities in cleanrooms where sterility is of prime concern, gloved hands should be sanitized on a frequent basis using an effective hand sanitizer. Disinfected gloved hands can aid staff who need to carry out aseptic practices. The ClearKlens product can be fitted to automatic dispensers (fed via a pipe network or from an isolated unit) and then used to disinfect gloves used by the professional workers or manually sprayed onto the hands.

According to product use information, 3 mL of biocidal product is applied to both gloved hands (1.5 mL product per hand, equivalent to one dose of the product from the dispenser per hand) and is evenly distributed over the gloves by rubbing. The task duration can be assumed to be 2 minutes as this would account for the application duration to the gloves (less than 1 minute) and the time the biocidal product remains on the glove. The evaporation time of propan-2-ol is estimated to be c.a. 1 min based on the following calculation:

Evaporation time: = t (s) = (m T R / (M ß p A)) x K,
where:

t = evaporation time (seconds)
m = mass of compound (1670 mg, see the parameter table below)
R = gas constant (8.314 J K/mol)
T = temperature in Kelvin (298.15 K, equal to 25 ºC, room temperature)
M = molar mass of compound (60.09 g/mol for IPA)
ß = coefficient of mass transfer in the vapour phase (8.7 m/h)
p = vapour pressure of compound (5780 Pa for IPA at 25°C)
A = applied area (820 cm^2 – surface area of two hands)
K = conversion factor (3.6 x 10^4)

Therefore: Evaporation time = 60.1 sec

Exposure to professional workers in cleanrooms and laboratories would be via the dermal and inhalation routes. Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practices.

Inhalation and dermal exposures will be calculated using ConsExpo and manual calculation methods, respectively, using known use parameters.

Inhalation exposure:

The physico-chemical properties of propan-2-ol predict that it will readily evaporate during application. The concentration in air will depend on a number of factors; the applied dose, the room volume, the room temperature (which will affect the vapour pressure) and the air exchange rate. The concentration of propan-2-ol in the air will therefore quickly reach a maximum and will then decline due to air exchange in the room.

The ConsExpo input parameters for the glove disinfection scenario are detailed in the table below.

Dermal exposure:

Dermal exposure to the product could occur during disinfection of gloves. The product is intended for the disinfection of gloves only and not for application to bare hands. Since gloves will always be worn during this task, the potential exposure of hands inside gloves is negligible. No calculation is therefore made.

Table 33:Input parameters for Scenario 4

Scenario 4. Inhalation exposure during the disinfection of gloves:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	209 g	Product use information – application rate 1.5 mL per hand per time Equivalent to 2.61 g product (1.67 g propan-2-ol) x 80 times/day
	Weight fraction compound	0.64	Product information
	Room volume	55 m^3	HEAd hoc recommendation No.15
	Ventilation rate	150 h^{-1}	Considered representative of a cleanroom (an ISO 6 (Class 1,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration limited to saturated air concentration
	Temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Exposure frequency	80 times/day	Product use information
	Exposure duration	45 min/time	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection.
	Product amount	2.61 g per time	Product use information – application rate 1.5 mL per hand per time Equivalent to 2.61 g product (1.67 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default

	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (constant)	820 cm^2	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1) (surface area of hands, palms and backs of both hands)
	Emission duration	2 min	1 min for application + 1 min for evaporation

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.2.8 Calculations for scenario 4

Please refer to the relevant calculations for Scenario 4 in Annex 2.

Table 34: Summary table: estimated exposure from professional uses in cleanrooms – Scenario 4

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4 (glove disinfection)	Tier 1 – gloves	0.34 mg/kg bw/day	negligible	None	**0.34 mg/kg bw/day**
	Tier 2 – gloves	0.16 mg/kg bw/day	negligible	None	**0.16 mg/kg bw/day**

6.2.4.2.9 Combined scenarios

It is possible that one professional worker performs all of the disinfection tasks (worst case) or a selected combination in one 8 hour working day. Therefore, as a worst case, the combined assessment is based on the exposure per professional worker per day. However, the length of time the worker spends disinfecting their work space will only be a small fraction of their total working day. Although the professional worker can perform various combinations of disinfection tasks within one working day, they are not professional cleaners and therefore consideration must be given to the total time spent disinfecting per day versus the time required to perform their actual job.

The combined assessment is therefore based on combining the estimated inhalation and dermal exposures for Scenarios 1 – 4 for cleanrooms as follows:

Table 35:Combined estimated exposure from professional uses in cleanrooms

Exposure scenarios combined	**Tier/PPE**	**Combined estimated inhalation uptake**	**Combined estimated dermal uptake**	**Combined estimated oral uptake**	**Combined estimated total uptake**
Scenarios 1, 2, 3 and 4	Tier 1 – No PPE	1.7 + 5.2 + 1.0 + 0.34 = 8.24 mg/kg bw/day	44.7 + 4106 + 41.0 = 4192 mg/kg bw/day	None	4200 mg/kg bw/day
	Tier 2 – No PPE	1.7 + 5.1 + 1.0 + 0.16 = 7.96 mg/kg bw/day	1.25 + 114.4 + 1.15 =116.8 mg/kg bw/day	None	124.8 mg/kg bw/day
	Tier 3 – PPE (95% gloves)	7.96 mg/kg bw/day	0.062 + 5.72 + 0.058 = 5.84 mg/kg bw/day	None	13.8 mg/kg bw/day

[1] Combining the individual mean air concentrations of propan-2-ol for the 4 different scenarios, accounts for the worst case by assuming that multiple activities are happening simultaneously e,g, by different people in the same room.

6.2.4.3: Professional use in pharmaceutical and cosmetic manufacturing facilities

Pharmaceutical and cosmetic manufacturing facilities have disinfection procedures in place to ensure that the facilities remain very hygienic and that a high standard of housekeeping is maintained. Workers in these facilities will therefore be trained professionals and PPE will be worn. A tiered approach will therefore be used to assess the risk from dermal exposure to propan-2-ol.

6.2.4.3.1 Scenario 5: Disinfection using a mop in pharmaceutical and cosmetic manufacturing facilities

Table 36:Description of Scenario 5

The inhalation and dermal exposures from disinfection tasks using a mop in pharmaceutical and cosmetic manufacturing facilities can be estimated using the same methodology as for Scenario 1 with the following differences:

- Frequency of use: Once per day
- Ventilation rate: 60 h^{-1}
- Room volume: 80 m^3
- Treated surface area: 32 m^2

The ConsExpo input parameters and the calculation values for the mopping scenario are detailed in the table below and in Annex 2.

Table 37:Input parameters for Scenario 5

Scenario 5. Inhalation exposure during mopping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	512 g	Product use information – application rate of 16 g/m^2 x 32 m^2 treated area Equivalent to 327.7 g propan-2-ol
	Weight fraction compound	0.64	Product information
	Room volume	80 m^3	Considered representative of a pharmaceutical /cosmetic manufacturing facility
	Ventilation rate	60 h^{-1}	Considered representative of a pharmaceutical/ cosmetic manufacturing facility and an ISO 7 (Class 10,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Temperature	20 °C	Concentration is limited to saturated air concentration
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	

TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Frequency	Once a day	Product use information
	Exposure duration	180 minute/ application	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection.
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	32 m^2	Considered representative of the mopped floor surface area in a pharmaceutical/ cosmetic manufacturing facility
	Application duration	15 min	HEAdhoc Recommendation No. 6 version 3 for the mopping and wiping[3]
Scenario 5. Dermal exposure during mopping:			
TIER 1	Exposure frequency	Once a day	Product use information
	Indicative hand exposure	1030 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Indicative body exposure	87.6 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Exposure duration	15 minutes/ application	HEAdhoc Recommendation No. 6 version 3 for the mopping and wiping[3]
	Product amount	16764 mg	(1030 + 87.6) mg/min x 15 min x 1 applications/ day = 16764 mg product/ person/ day Equivalent to 10729 mg propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	772.8 second	Refer to calculation in Annex 2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of adult hands (palm only), HEEG opinion no. 17[2]
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

[2] According to the surface disinfection model 1 contamination occurs also on the body. However, the indiacative values (1030 mg/min on hands vs 87.6 mg/min on body) suggest that the main dermal exposure is on hands. Therefore the exposure area of both palms is used.

[3] The HEAdhoc recommendation states that the duration for mopping is 5 minutes. However, since the treated surface is approximately 3 times larger than in Scenario 1, it was considered reasonable that the application duration is 15 min (5 min x 3).

6.2.4.3.2 Calculations for scenario 5

Please refer to the relevant calculations for Scenario 5 in Annex 2.

Table 38:Summary table: estimated exposure from professional uses in pharmaceutical and cosmetic manufacturing facilities – Scenario 5

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 5 (mopping)	Tier 1 – No PPE	1.4 mg/kg bw/day	44.7 mg/kg bw/day	None	46.2 mg/kg bw/day
	Tier 2 – No PPE	1.4 mg/kg bw/day	1.25 mg/kg bw/day	None	2.65 mg/kg bw/day
	Tier 3 – PPE (gloves)	1.4 mg/kg bw/day	0.062 mg/kg bw/day	None	1.46 mg/kg bw/day

6.2.4.3.3 Scenario 6: Disinfection using a cloth in pharmaceutical and cosmetic manufacturing facilities

Table 39:Description of Scenario 6

The inhalation and dermal exposures from disinfection tasks using a cloth in pharmaceutical and cosmetic manufacturing facilities can be estimated using the same methodology as for Scenario 2 with the following differences:

- Frequency of use: 5 times/ day
- Ventilation rate: 60 h^{-1}
- Room volume: 80 m^3
-

The ConsExpo input parameters and the calculation values for the disinfection scenario are detailed in the table below and in Annex 2.

Table 40:Input parameters for Scenario 6

Scenario 6. Inhalation exposure during wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	800 g	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area per time Equivalent to 102.4 g propan-2-ol x 5 times/day
	Weight fraction compound	0.64	Product information
	Room volume	80 m^3	Considered representative of a pharmaceutical/ cosmetic manufacturing facility
	Ventilation rate	60 h^{-1}	Considered representative of a pharmaceutical/ cosmetic manufacturing facility and an ISO 7 (Class 10,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limited to saturated air

	Applciation temperature	20 °C	concentration
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Frequency	5 times per day	Product information
	Exposure duration	1 hour/ application	30 min disinfection + 30 min other tasks in the same room
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	10 m^2	ConsExpo Cleaning Products Fact Sheet
	Application duration	30 minute/ application	Based on ConsExpo Cleaning Products Fact Sheet
Scenario 6. Dermal exposure during wiping:			
TIER 1	Exposure frequency	5 times/day	Product use information
	Potential hand exposure	2950 µL/min	BEAT model for large scale surface wiping
	Application/ exposure duration	30 minutes/ application	Recalculated based on data available in RIVM factsheet 2016-0179
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	11831 seconds	Refer to calculation in Annex 2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of one adult hand (two palms) (HEAd hoc recommendation no. 12)
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

NL CA comment: During commenting phase a Member state showed its concern to use BEAT as this model is no longer maintained and available for downloading. Apart from BEAT the dermal exposure may be estimated by using surface disinfection model 1 (HEAd hoc recommentation 6, no 5). The model provides 1030 mg/min (hands) and 87.6 mg/min (body) as indicative values. The sum 1117.6 mg/min is lower than the value obtained from BEAT i.e. 2950 µl/min = 2566 mg/min. As BEAT covers a worse case than the alternative model Surface disinfection model 1, and the use in manufacturing facilities result in the safe use, the calculation in the PAR based on BEAT was considered acceptable.

6.2.4.3.4 Calculations for Scenario 6

Please refer to the relevant calculations for Scenario 6 in Annex 2.

Table 41:Summary table: estimated exposure from professional uses in pharmaceutical and cosmetic manufacturing facilities – Scenario 6

	Tier/PPE	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6	Tier 1 – No PPE	2.2 mg/kg bw/day	1026.6 mg/kg bw/day	None	1028.8 mg/kg bw/day

	Tier 2 – No PPE	2.2 mg/kg bw/day	28.6 mg/kg bw/day	None	30.8 mg/kg bw/day
	Tier 3 – PPE (gloves)	2.2 mg/kg bw/day	1.43 mg/kg bw/day	None	3.63 mg/kg bw/day

6.2.4.3.5 Scenario 7: Disinfection using a trigger spray in pharmaceutical and cosmetic manufacturing facilities with wiping

The biocidal product can be packaged in a trigger spray. The product is sprayed onto the surface (e.g. work bench, machines and equipment within the pharmaceutical or cosmetic manufacturing facility) which can then either be wiped with a cloth once a sufficient contact time has elapsed or left to dry.

In order to account for the worst case, dermal and inhalation exposure has been considered from spraying and then wiping the surface after application with a cloth.

Table 42:Description of Scenario 7

The inhalation and dermal exposures from disinfection tasks using a trigger spray and cloth in pharmaceutical and cosmetic manufacturing facilities can be estimated using the same methodology as for Scenario 3 with the following differences:

- Ventilation rate: 60 h^{-1}
- Room volume: 80 m^3

The ConsExpo input parameters and the calculation values for the disinfection scenario are detailed in the table below and in Annex 2.

Table 43:Input parameters for Scenario 7

Scenario 7. Inhalation exposure during spraying & wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**SPRAYING + Wiping : Release mode: Instant release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Released mass	640 g	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol) x 80 times/day
	Weight fraction compound	0.64	Product information
	Room volume	80 m^3	Considered representative of a pharmaceutical/ cosmetic manufacturing facility
	Ventilation rate	60 h^{-1}	Considered representative of a pharmaceutical/ cosmetic manufacturing facility and an ISO 7 (Class 10,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October

			2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limted to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**SPRAYING: Release mode: Spraying + wiping :Exposure to vapour**		
	Frequency	80 times/day	Product use information
	Exposure duration	45 minute/ application	Assessment Report for propan-2-ol and HEAd hoc recommendation no.15
	Product amount	8 g/time	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	0.5 m^2	Assessment Report for propan-2-ol
	Application duration	0.17 minute/ application	Spraying duration of 10 second
Scenario 7. Dermal exposure during spraying & wiping:			
TIER 1	**Same as scenario 3 Tier 1**		
TIER 2	**Same as Scenario 3 Tier 2**		
TIER 3	**Same as Scenario 3 Tier 2**		

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.3.6 Calculations for Scenario 7

Please refer to the relevant calculations for Scenario 7 in Annex 2.

Table 44:Summary table: estimated exposure from professional uses in pharmaceutical and cosmetic manufacturing facilities – Scenario 7

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 7 (spraying and wiping)	Tier 1 – No PPE	1.8 mg/kg bw/day	1.28 + 39.72 = 41.0 mg/kg bw/day	None	**42.8 mg/kg bw/day**
	Tier 2 – No PPE	1.8 mg/kg bw/day	0.036 + 1.11 = 1.15 mg/kg bw/day	None	**2.95 mg/kg bw/day**
	Tier 3 – PPE (95% gloves)	1.8 mg/kg bw/day	0.0018 + 0.056 = 0.058 mg/kg bw/day	None	**1.86 mg/kg bw/day**

6.2.4.3.7 Scenario 8: Disinfection of gloves in pharmaceutical and cosmetic manufacturing facilities

Table 45:Description of Scenario 8

The inhalation and dermal exposures from glove disinfection in pharmaceutical and cosmetic manufacturing facilities can be estimated using the same methodology as for Scenario 4 with the following differences: • Frequency of use: 40 times/ day

- Ventilation rate: 60 h^{-1}
- Room volume: 80 m^3

The ConsExpo input parameters and the calculation values for the glove disinfection scenario are detailed in the table below and in Annex 2.

Table 46:Input parameters for Scenario 8

Scenario 8. Inhalation exposure during the disinfection of gloves:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	104 g	Product use information – application rate 1.5 mL per hand Equivalent to 2.61 g product (1.67 g propan-2-ol) x 40 times/day
	Weight fraction compound	0.64	Product information
	Room volume	80 m^3	Considered representative of a pharmaceutical/ cosmetic manufacturing facility
	Ventilation rate	60 h^{-1}	Considered representative of a pharmaceutical/ cosmetic manufacturing facility and an ISO 7 (Class 10,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration limited to saturated air concentration
	Temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Exposure frequency	40 times/day	Product use information
	Exposure duration	45 minutes/time	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection.
	Product amount	2.61 g per time	Product use information – application rate 1.5 mL per hand per time Equivalent to 2.61 g product (1.67 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (constant)	820 cm^2	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1) (surface area of hands, palms and backs of both hands)
	Emission duration	2 min	1 min for application + 1 min for evaporation

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.3.8 Calculations for Scenario 8

Please refer to the relevant calculations for Scenario 8 in Annex 2.

Table 47:Summary table: estimated exposure from professional uses in pharmaceutical and cosmetic manufacturing facilities – Scenario 8

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 8 (glove disinfection)	Tier 1 – gloves	0.29 mg/kg bw/day	negligible	None	**0.29 mg/kg bw/day**
	Tier 2 – gloves	0.14 mg/kg bw/day	negligible	None	**0.14 mg/kg bw/day**

6.2.4.3.9 Combined scenarios

Please refer to Section 6.2.4.3.9 for further details.

The combined assessment is therefore based on combining the estimated inhalation and dermal exposures for Scenarios 5 – 8 for pharmaceutical and cosmetic manufacturing facilities as follows:

Table 48:Combined estimated exposure from professional uses in pharmaceutical and cosmetic manufacturing facilities

Exposure scenarios combined	Tier/PPE	Combined estimated inhalation uptake	Combined estimated dermal uptake	Combined estimated oral uptake	Combined estimated total uptake
Scenarios 5, 6, 7 and 8	Tier 1 – No PPE	1.4 + 2.2 + 1.8 + 0.29 = 5.7 mg/kg bw/day	44.7 + 1026.6 + 41.0 = 1112 mg/kg bw/day	None	1117.7 mg/kg bw/day
	Tier 2 – No PPE	1.4 + 2.2 + 1.8 + 0.14 = 5.5 mg/kg bw/day	1.25 + 28.6 + 1.15 = 31 mg/kg bw/day	None	36.5 mg/kg bw/day
	Tier 3 – PPE (95% gloves)	5.5 mg/kg bw/day	0.062 + 1.43 + 0.058 = 1.55 mg/kg bw/day	None	7.1 mg/kg bw/day

[1] Combining the individual mean air concentrations of propan-2-ol for the 4 different scenarios, accounts for the worst case by assuming that multiple activities are happening simultaneously e,g, by different people in the same room.

6.2.4.4: Professional use in laboratories

The biocidal product will be used in laboratories where a hygienic environment with a high standard of housekeeping is required. Workers in these facilities will therefore be trained professionals and PPE will be worn. A tiered approach will therefore be used to assess the risk from dermal exposure to propan-2-ol.

6.2.4.4.1 Scenario 9: Disinfection using a mop in laboratories

Table 49:Description of Scenario 9

The inhalation and dermal exposures from disinfection tasks using a mop in laboratories can be estimated using the same methodology as for Scenario 1 with the following differences:

- Frequency of use: Once per day
- Ventilation rate: 8 h^{-1}
- Room volume: 25 m^3
- Treated surface area: 10 m^2

The ConsExpo input parameters and the calculation values for the mopping scenario are detailed in the table below and in Annex 2.

Table 50:Input parameters for Scenario 9

Scenario 9. Inhalation exposure during mopping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	160 g	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area Equivalent to 102.4 g propan-2-ol
	Weight fraction compound	0.64	Product information
	Room volume	25 m^3	Considered representative of a laboratory
	Ventilation rate	8 h^{-1}	Considered representative of a laboratory (as referenced in the Assessment Report for propan-2-ol) and an ISO 8 (Class 100,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Temperature	20 °C	Concentration is limited to saturated air concentration
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Frequency	Once a day	Product use information
	Exposure duration	180 minute/ application	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection.
	Product amount	160 g/application	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area = 160 g per time (Equivalent to 102.4 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	10 m^2	Considered representative of a cleanroom Assessment Report for propan-2-ol
	Application duration	5 min	HEAdhoc Recommendation No. 2 (referenced in Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.2)) for the

			mopping time per hospital room
Scenario 9. Dermal exposure during mopping			
TIER 1	Exposure frequency	Once a day	Product use information
	Indicative hand exposure	1030 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Indicative body exposure	87.6 mg/min	Surface Disinfection (manual) Model 1 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.6.1))
	Exposure duration	5 minutes/ application	HEAdhoc Recommendation No. 2 (referenced in Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.2)) for the mopping time per hospital room
	Product amount	5588 mg	(1030 + 87.6) mg/min x 5 min x 1 applications/ day = 5588 mg product/ person/ day Equivalent to 3576 mg propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	258 second	Refer to calculation in Annex 2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of adult hands (palm only), HEEG opinion no. 17[2]
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

2 According to the surface disinfection model 1 contamination occurs also on the body. However, the indiacative values (1030 mg/min on hands vs 87.6 mg/min on body) suggest that the main dermal exposure is on hands. Therefore the exposure area of both palms is used.

6.2.4.4.2 Calculations for Scenario 9

Please refer to the relevant calculations for Scenario 9 in Annex 2.

Table 51:Summary table: estimated exposure from professional uses in laboratories – Scenario 9

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 9 (mopping)	Tier 1 – No PPE	11 mg/kg bw/day	14.9 mg/kg bw/day	None	25.9 mg/kg bw/day
	Tier 2 – No PPE	11 mg/kg bw/day	0.41 mg/kg bw/day	None	11.4 mg/kg bw/day
	Tier 3 – PPE (gloves)	11 mg/kg bw/day	0.02 mg/kg bw/day	None	11.0 mg/kg bw/day

6.2.4.4.3 Scenario 10: Disinfection using a cloth in laboratories

Table 52:Description of Scenario 10

The inhalation and dermal exposures from disinfection tasks using a cloth in laboratories can be estimated using

the same methodology as for Scenario 6 with the following differences:

- Frequency of use: 10 times per day
- Room volume: 25 m^3
- Ventilation rate: 8 h^{-1}

The ConsExpo input parameters and the calculation values for the disinfection scenario are detailed in the table below and in Annex 2.

Table 53:Input parameters for Scenario 10

Scenario 10. Inhalation exposure during wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	once a day	instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	1600 g	Product use information – application rate of 16 g/m^2 x 10 m^2 treated area Equivalent to 1024 g propan-2-ol
	Weight fraction compound	0.64	Product information
	Room volume	25 m^3	Considered representative of a laboratory
	Ventilation rate	8 h^{-1}	Considered representative of a laboratory (as referenced in the Assessment Report for propan-2-ol) and an ISO 8 (Class 100,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limited to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Frequency	10 times per day	Product information
	Exposure duration	60 min/ application	Assessment Report for propan-2-ol
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	10 m^2	ConsExpo Cleaning Products Fact Sheet
	Application duration	30 minute/ application	Based on ConsExpo Cleaning Products Fact Sheet
Scenario 10. Dermal exposure during wiping:			
TIER 1	Exposure frequency	10 time/day	Product use information
	Potential hand exposure	2950 µL/min	BEAT model for large scale surface wiping
	Application/ exposure duration	30 minute/ application	Assessment Report for propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health

			Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2[1]	Evaporation time	35495 seconds	Refer to calculation in Annex 2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	410 cm^2	Surface area of two adult hands (two palms) (HEAd hoc recommendation no. 12)
TIER 3[1]	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

NL CA comment: During commenting phase a Member state showed its concern to use BEAT as this model is no longer maintained and available for downloading. Apart from BEAT the dermal exposure may be estimated by using surface disinfection model 1 (HEAd hoc recommentation 6, no 5). The model provides 1030 mg/min (hands) and 87.6 mg/min (body) as indicative values. The sum 1117.6 mg/min is lower than the value obtained from BEAT i.e. 2950 µl/min = 2566 mg/min. As BEAT covers a worse case than the alternative model Surface disinfection model 1, and the use in manufacturing facilities result in the safe use, the calculation in the PAR based on BEAT was considered acceptable.

6.2.4.4.4 Calculations for Scenario 10

Please refer to the relevant calculations for Scenario 10 in Annex 2.

Table 54:Summary table: estimated exposure from professional uses in laboratories – Scenario 10

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 10	Tier 1 – No PPE	33 mg/kg bw/day	2053 mg/kg bw/day	None	2086 mg/kg bw/day
	Tier 2 – No PPE	10 mg/kg bw/day	57.3 mg/kg bw/day	None	67.3 mg/kg bw/day
	Tier 3 – PPE (gloves)	10 mg/kg bw/day	2.87 mg/kg bw/day	None	12.9 mg/kg bw/day

6.2.4.5: Scenario 11: Disinfection using a trigger spray in laboratories with wiping

The biocidal product can be packaged in a trigger spray. The product is sprayed onto the surface (e.g. work bench, machines and equipment within the laboratory) which can then either be wiped with a cloth once a sufficient contact time has elapsed or left to dry.

In order to account for the worst case, dermal and inhalation exposure has been considered from spraying and then wiping the surface after application with a cloth.

Table 55:Description of Scenario 11

The inhalation and dermal exposures from disinfection tasks using a trigger spray and cloth in laboratories can

be estimated using the same methodology as for Scenario 3 with the following differences:

- Exposure frequency: 10 times/ day
- Ventilation rate: 8 h^{-1}
- Room volume: 25 m^3

The ConsExpo input parameters and the calculation values for the disinfection scenario are detailed in the table below and in Annex 2.

Table 56:Input parameters for Scenario 11

Scenario 11. Inhalation exposure during spraying & wiping:			
	Parameters	**Value**	**Reference source**
TIER 1	**SPRAYING + Wiping: Release mode: Instant release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Released mass	80 g	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol) x 10 times
	Weight fraction compound	0.64	Product information
	Room volume	25 m^3	Considered representative of a laboratory
	Ventilation rate	8 h^{-1}	Considered representative of a laboratory (as referenced in the Assessment Report for propan-2-ol) and an ISO 8 (Class 100,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration is limted to saturated air concentration
	Applciation temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**SPRAYING: Release mode: Spraying & Wiping : Exposure to vapour**		
	Frequency	10 times/day	Product use information
	Exposure duration	45 min	According to the CAR for propan-2-ol
	Product amount	8 g/time	Product use information – application rate of 16 g/m^2 x 0.5 m^2 treated area per time (Equivalent to 5.12 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (increasing)	0.5 m^2	Assessment Report for propan-2-ol
	Application duration (spraying)	0.167 minute/ application	Spraying duration of 10 second
Scenario 11. Dermal exposure during spraying & wiping:			
TIER 1	**Exposure during spraying**		
	Exposure frequency	10 times a day	Product use information
	Indicative exposure of hand and forearms	36.1 mg/min	Consumer Product Spraying and Dusting Model 2 (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 10.13.2))
	Spray duration	0.167 minute/ application	Spraying duration of 10 second

	Product amount deposited on hands	60.3 mg	36.1 mg/min x 0.167 minutes/application x 10 applications/ day = 60.3 mg product/ person/day Equivalent to 38.58 mg propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Exposure during wiping		
	Exposure frequency	10 times/day	Product use information
	Potential hand exposure	214 µL/min	BEAT model for small scale surface wiping
	Exposure duration	1 minute/ application	Assessment Report for propan-2-ol
	Weight fraction compound	0.64	Product information
	Dermal absorption	25%	Default (CA-July13-Doc.6.2.b – Final)
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
TIER 2	**Exposure during spraying**		
	Evaporation time	1.17 seconds	Refer to calculation in Annex 2 Section 7.2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	974.4 cm^2	Surface area of hand and forearm of one arm HEAdhoc Recommendation No. 14 (12 June 2017)
	Exposure during wiping		
	Evaporation time	171.7 seconds	Refer to calculation in Annex 2 Section 7.2
	Dermal flux rate	0.85 mg/cm^2/h	Assessment Report for propan-2-ol
	Total exposed skin surface	205 cm^2	Assessment Report for propan-2-ol
TIER 3	Protection factor for the use of protective gloves when new gloves are used for each work shift	95% (i.e. 5% penetration)	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 3.3)

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.5.1 Calculations for Scenario 11

Please refer to the relevant calculations for Scenario 11 in Annex 2.

Table 57:Summary table: estimated exposure from professional uses in laboratories – Scenario 11

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 11 (spraying and wiping)	Tier 1 – No PPE	5.3 mg/kg bw/day	0.161 + 4.96 = 5.12 mg/kg bw/day	None	**10.4 mg/kg bw/day**
	Tier 2 – No PPE	5.3 mg/kg bw/day	0.0019 + 0.139 = 0.141 mg/kg bw/day	None	**5.44 mg/kg bw/day**
	Tier 3 – PPE (gloves)	5.3 mg/kg bw/day	0.000095 + 0.0070 = 0.0071 mg/kg bw/day	None	**5.31 mg/kg bw/day**

6.2.4.5.2 Scenario 12: Disinfection of gloves

Table 58:Description of Scenario 12

The inhalation and dermal exposures from glove disinfection in laboratories can be estimated using the same methodology as for Scenario 4 with the following differences:

- Frequency of use: 10 times/ day
- Ventilation rate: 8 h^{-1}
- Room volume: 25 m^3

The ConsExpo input parameters and the calculation values for the glove disinfection scenario are detailed in the table below and in Annex 2.

Table 59:Input parameters for Scenario 12

Scenario 12. Inhalation exposure during the disinfection of gloves:			
	Parameters	**Value**	**Reference source**
TIER 1	**Mode of release in ConsExpo: Instantaneous release**		
	Exposure frequency	Once a day	Instantaneous release
	Exposure duration	8 hours	Duration of a working shift
	Product amount	26.1 g	Product use information – application rate 1.5 mL per hand per time (Equivalent to 2.61 g product (1.67 g propan-2-ol)) x 10 times
	Weight fraction compound	0.64	Product information
	Room volume	25 m^3	Considered representative of a laboratory
	Ventilation rate	8 h^{-1}	Considered representative of a laboratory (as referenced in the Assessment Report for propan-2-ol) and an ISO 8 (Class 100,000) cleanroom (http://www.cleanroomswest.com/air-flow-rates/)
	Inhalation absorption	100%	
	Inhalation rate	1.25 m^3/h	Adult inhalation rate (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Bodyweight	60 kg	Adult bodyweight (Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1))
	Vapour pressure	4260 Pa	Concentration limited to saturated air concentration
	Temperature	20 °C	
	Molecular weight	60 g/mol	
TIER 2	**Mode of release in ConsExpo: Evaporation**		
	Exposure frequency	10 times/day	Product information
	Exposure duration	45 minutes/time	No harmonised value available. Based on an assumption that the user will stay in the room after disinfection
	Product amount	2.61 g per time	Product use information – application rate 1.5 mL per hand per time Equivalent to 2.61 g product (1.67 g propan-2-ol)
	Temperature	20 °C	ConsExpo database
	Molecular weight	60 g/mol	
	Vapour pressure	4260 Pa	
	Mass transfer rate	10 m/h	ConsExpo database default
	Mol. weight matrix	18 g/mol	The a.s. is dissolved in water (18 g/mol)
	Release area (constant)	820 cm^2	Biocides Human Health Exposure Methodology (Version 1, October 2015, Section 2.1) (surface area of hands, palms and backs of both hands)
	Emission duration	2 min	1 min for application + 1 min for evaporation

[1] Only the parameters changed with respect to the previous Tier are specified

6.2.4.5.3 Calculations for scenario 12

Please refer to the relevant calculations for Scenario 12 in Annex 2.

Table 60:Summary table: estimated exposure from professional uses in laboratories – Scenario 12

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 12 (glove disinfection)	Tier 1 – gloves	1.7 mg/kg bw/day	negligible	None	**1.7 mg/kg bw/day**
	Tier 2 – gloves	0.75 mg/kg bw/day	negligible	None	**0.75 mg/kg bw/day**

6.2.4.5.4 Combined scenarios

Please refer to Section 6.2.4.3.9 for further details.

The combined assessment is therefore based on combining the estimated inhalation and dermal exposures for Scenarios 9 – 12 for laboratories as follows:

Table 61:Combined estimated exposure from professional uses in laboratories

Exposure scenarios combined	Tier/PPE	Combined estimated inhalation uptake	Combined estimated dermal uptake	Combined estimated oral uptake	Combined estimated total uptake
Scenarios 9, 10, 11 and 12	Tier 1 – No PPE	11+ 33 + 5.3 + 1.7 = 51 mg/kg bw/day	14.9 + 2053.2 + 5.12 = 2073 mg/kg bw/day	None	2124 mg/kg bw/day
	Tier 2 – No PPE	11 + 10 + 5.3 + 0.75 = 27.1 mg/kg bw/day	0.41 + 57.3 + 0.141 = 57.9 mg/kg bw/day	None	85.0 mg/kg bw/day
	Tier 3 – PPE (95% gloves)	27.1 mg/kg bw/day	0.02 + 2.9 + 0.0071 = 2.9 mg/kg bw/day	None	30.0 mg/kg bw/day

[1] Combining the individual mean air concentrations of propan-2-ol for the 4 different scenarios, accounts for the worst case by assuming that multiple activities are happening simultaneously e,g, by different people in the same room.

6.2.4.6: Scenario 13: Secondary exposure of bystander (professionals)

Seondary exposure may occur if other professionals are present in the same room while surface, equipment or gloves are being disinfected or on re-entry into treated rooms or areas. It is possible that other professionals within one room are also disinfecting with the same biocidal product, therefore the scenario combinations should actually be per room. As a worst case, it is assumed that one person performs all tasks. As this has been already evaluated in the combined scenario calculation for each room type, the calculation is not repeated.

6.2.5: Non-professional exposure

The biocidal products are used by professionals only and hence there is no exposure to non-professionals or the general public.

6.2.6: Monitoring data

There are no monitoring data available for the use of propan-2-ol based disinfectants.

6.2.7: Dietary exposure

The biocidal products are used by professionals only in cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories. Hence, there will be no exposure to food, drinking water or livestock.

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

This is covered by other legislation and therefore does not need to be discussed as part of this risk assessment.

6.3: Risk characterisation for human health

The following reference values will be used, where appropriate, in the risk characterisation.

Table 62:Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
For the general public:					
AELshort, medium and long-term	Inhalation – human volunteer study	NOAEC 200 ppm	6.4 (for intraspecies variability)	-	10.7 mg/kg bw/day (31.25 ppm for 8 hours/d)
For professional workers:					
AELshort, medium and long-term	Inhalation – human volunteer study	NOAEC 200 ppm	3.8 (for intraspecies variability)	-	17.9 mg/kg bw/day (52.6 ppm for 8 hours/d)
ARfD	Not necessary, no residues in food are expected				
ADI	Not necessary, no residues in food are expected				

6.3.1: Risk for industrial users

A consideration of industrial exposure during manufacture of the biocidal products is not required as this is covered by other legislation.

6.3.2: Risk for professional users

Professionals will be using the biocidal product on a daily basis and are therefore considered to be chronically exposed. The systemic exposures are therefore compared to the long-term AEL for professional workers of 17.9 mg/kg bw/day as derived in the Assessment Report for propan-2-ol.

The risk characterisations for cleanrooms, pharmaceutical and cosmetic manufacturing facilities and laboratories will be considered separately for each scenario and combination of scenarios.

6.3.2.1: Risk characterisation for professional use in cleanrooms

The risk characterisation for professional workers per scenario (or combination of scenarios relating to one task) in cleanrooms is as follows:

Table 63:Systemic effects for professional exposure in cleanrooms

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 (pouring and mopping)	Tier 1 – No PPE[1]	17.9	46.4	259	**No**
	Tier 2 – No PPE[2]	17.9	2.95	17	**Yes**
	Tier 3 – PPE)[3]	17.9	1.76	10	**Yes**
Scenario 2 (pouring and wiping)	Tier 1 – No PPE[1]	17.9	4111	22967	**No**
	Tier 2 – No PPE[2]	17.9	119.6	668	**No**
	Tier 3 – PPE[3]	17.9	10.8	60	**Yes**
Scenario 3 (trigger spraying and wiping)	Tier 1 – No PPE[1]	17.9	42.0	235	**No**
	Tier 2 – No PPE[2]	17.9	2.2	12	**Yes**
	Tier 3 – PPE[3]	17.9	1.1	6	**Yes**
Scenario 4 (glove disinfection)	Tier 1 – gloves	17.9	0.34	1.9	**Yes**
	Tier 2 – gloves	17.9	0.16	0.9	**Yes**

[1] uses a default dermal absorption of 25% without PPE
[2] assumes that no gloves are worn.
[3] uses a default protection factor of 95% for the use of new gloves each working shift

The risk characterisation for combined exposure for professionals in cleanrooms is summarised below:

Table 64:Combined scenarios for professional exposure in cleanrooms

Task/ scenarios combined	Tier	AEL mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1 – 4 (pouring, mopping, wiping, spraying and glove disinfection)	Tier 1 – No PPE	17.9	4200	23464	**No**
	Tier 2 – No PPE	17.9	124.8	697	**No**
	Tier 3 – PPE (95% gloves)	17.9	13.8	77	**Yes**

Local effects

The biocidal product is labelled with H319 (Eye irrit. 2) and 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 product will be used by highly trained professionals who adhere to strict cleanroom protocols. In addition, there are following risk mitigation measures assigned for this product.

- Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) (all Uses)
- Avoid contact with eyes (all Uses)
- The following personal risk mitigation measure can be considered for wiping disinfection unless it can be replaced by technical and/or organisational measures : The use of eye protection during handling of the product is recommended. (Use #2)

Eye and skin exposure will therefore be minimised and the risk for local effects are considered acceptable.

The Assessment Report concluded that the systemic AEL sufficiently covers local irritant effects in eyes/airways. Therefore, it can be considered that no further assessment of the local effects via inhalation is required.

6.3.2.2: Risk characterisation for professional use in pharmaceutical and cosmetic manufacturing facilities

The risk characterisation for professional workers per scenario (or combination of scenarios relating to one task) in pharmaceutical and cosmetic manufacturing facilities is as follows:

Table 65:Systemic effects for professional exposure in pharmaceutical and cosmetic manufacturing facilities

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 (pouring and mopping)	Tier 1 – No PPE[1]	17.9	46.2	258	**No**
	Tier 2 – No PPE[2]	17.9	2.7	15	**Yes**
	Tier 3 – PPE [3]	17.9	1.5	8	**Yes**
Scenario 6 (pouring and wiping)	Tier 1 – No PPE[1]	17.9	1029	5749	**No**
	Tier 2 – No PPE[2]	17.9	30.8	172	**No**
	Tier 3 – PPE[3]	17.9	3.6	20	**Yes**

Scenario 7 (trigger spraying and wiping)	Tier 1 – No PPE[1]	17.9	42.8	239	**No**
	Tier 2 – No PPE[2]	17.9	3.0	17	**Yes**
	Tier 3 – PPE[3]	17.9	1.9	11	**Yes**
Scenario 8 (glove disinfection)	Tier 1 – gloves	17.9	0.29	2	**Yes**
	Tier 2 – gloves	17.9	0.14	0.78	**Yes**

[1] uses a default dermal absorption of 25% without PPE
[2] assumes that no gloves are worn.
[3] uses a default protection factor of 95% for the use of new gloves each working shift

The risk characterisation for combined exposure for professionals in pharmaceutical and cosmetic manufacturing facilities is summarised below:

Table 66:Combined scenarios for professional exposure in pharmaceutical and cosmetic manufacturing facilities

Task/ scenarios combined	**Tier**	**AEL mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenarios 5 – 8 (pouring, mopping, wiping, spraying and glove disinfection)	Tier 1 – No PPE	17.9	1118	6245	**No**
	Tier 2 – No PPE	17.9	36.5	204	**No**
	Tier 3 – PPE (95% gloves)	17.9	7.1	40	**Yes**

Local effects

The biocidal product is labelled with H319 (Eye irrit. 2) and 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 product will be used by highly trained professionals who adhere to good laboratory practices. In addition, there are following risk mitigation measures assigned for this product.

- Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) (all Uses)
- Avoid contact with eyes (all Uses)
- The following personal risk mitigation measure can be considered for wiping disinfection unless it can be replaced by technical and/or organisational measures : The use of eye protection during handling of the product is recommended. (Use #2)

Eye and skin exposure will therefore be minimised and the risk for local effects are considered acceptable.

The Assessment Report concluded that the systemic AEL sufficiently covers local irritant effects in eyes/airways. Therefore, it can be considered that no further assessment of the local effects via inhalation is required.

6.3.2.3: Risk characterisation for professional use in laboratories

The risk characterisation for professional workers per scenario (or combination of scenarios relating to one task) in laboratories:

Table 67:Systemic effects for professional exposure in laboratories

Task/ Scenario	Tier	Acceptable (yes/no)	AEL mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 9 (pouring and mopping)	Tier 1 – No PPE[1]	**Yes**	17.9	25.9	145	**No**
	Tier 2 – No PPE[2]		17.9	11.4	64	**Yes**
	Tier 3 – PPE[3]		17.9	11.0	61	**Yes**
Scenario 10 (pouring and wiping)	Tier 1 – No PPE[1]	**Yes**	17.9	2086	11654	**No**
	Tier 2 – No PPE[2]		17.9	67.3	356	**No**
	Tier 3 – PPE[3]		17.9	12.9	72	**Yes**
Scenario 11 (trigger spraying and wiping)	Tier 1 – No PPE[1]	**Yes**	17.9	10.4	58	**Yes**
	Tier 2 – No PPE[2]		17.9	5.4	30	**Yes**
	Tier 3 – PPE[3]		17.9	5.3	30	**Yes**
Scenario 12 (glove disinfection)	Tier 1 – gloves	**Yes**	17.9	1.7	10	**Yes**
	Tier 2 – gloves		17.9	0.75	4	**Yes**

[1] uses a default dermal absorption of 25% without PPE
[2] assumes that no gloves are worn.
[3] uses a default protection factor of 95% for the use of new gloves each working shift

The risk characterisation for combined exposure for professionals in laboratories is summarised below:

Table 68:Combined scenarios for professional exposure in laboratories

Task/ scenarios combined	Tier	Acceptable (yes/ no)	AEL mg/kg bw/d	Estimated total uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 9 – 12 (pouring,	Tier 1 – No PPE	**Yes**	17.9	2124	11866	**No**
	Tier 2 –		17.9	85.0	475	No

mopping, wiping, spraying and glove disinfection)	No PPE					
	Tier 3 – PPE (95% gloves)		17.9	30.0	168	**No**

The the combined exposure from the four uses in laboratories exceeds the AEL, therefore adverse effects cannot be excluded for the protected professionals using gloves. To subscribe RPE (respirttory protection equipment) is not realistic considering the users may apply the product for the entire working shift.

eCA comment: Because unacceptable risk was idenfiried from the use in laboratories, the applicant has decided to withdraw the proposed Use 1 (application by mopping) in laboratories after the HHWG (Sep 2019). Use 1 is therefore authorised only for manufacturing facilities and cleanrooms.

Without the application by mopping the combined exposure of a protected professional user in laboratories from 3 uses are reduced to be below the AEL of 17.9 mg/kg bw/d, as presented in the table below.

Exposure scenarios combined	**Tier/PPE**	**Combined estimated inhalation uptake**	**Combined estimated dermal uptake**	**Combined estimated oral uptake**	**Combined estimated total uptake**	**Acceptable (yes/no)**
Scenarios 9, 11 and 12	Tier 1 – No PPE	11+ 5.3 + 1.7 = 18.0 mg/kg bw/day	14.9 + 5.12 = 20.0 mg/kg bw/day	None	38.0 mg/kg bw/day	**No** (212%AEL)
	Tier 2 – No PPE	11 + 5.3 + 0.75 = 17.1 mg/kg bw/day	0.41 + 0.14 = 0.55 mg/kg bw/day	None	17.7 mg/kg bw/day	**Yes** (99%AEL)
	Tier 3	17.1 mg/kg	0.02 + 0.0071	None	17.1 mg/kg	**Yes**

Local effects

The biocidal product is labelled with H319 (Eye irrit. 2) and 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 product will be used by highly trained professionals who adhere to good laboratory practices. In addition, there are following risk mitigation measures assigned for this product.

- Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) (all Uses)
- Avoid contact with eyes (all Uses)
- The following personal risk mitigation measure can be considered for wiping disinfection unless it can be replaced by technical and/or organisational measures : The use of eye protection during handling of the product is recommended. (Use #2)

Eye and skin exposure will therefore be minimised and the risk for local effects are considered acceptable.

The Assessment Report concluded that the systemic AEL sufficiently covers local irritant effects in eyes/airways. Therefore, it can be considered that no further assessment of the local effects via inhalation is required.

6.3.2.4: Risk characterisation for secondary exposure

Secondary exposure does not need to be considered separately as the risk is covered by considering the combined exposure of professional users per room in the primary exposure. As the bystanders will have the same PPE as for the users of the product, no adverse effects are expected for the bystanders.

6.3.2.5: Conclusion for risk characterisation

The risk assessment showed that no systemic or local adverse health effects are expected for the protected (new gloves) professional users due to exposure to propan-2-ol, after using ClearKlens product based on IPA, when used in accordance with the SPC.

The risk assessment furthermore showed that there are no systemic or local adverse health effects expected for bystander professionals due to indirect exposure to propan-2-ol, after using ClearKlens product based on IPA, when used in accordance with the SPC.

6.3.3: Risk for non-professional users

The biocidal products are used by professionals only; hence, there is no exposure for non-professionals.

6.3.4: Risk for the general public

The biocidal products are used by professionals only. There is no exposure for the general public.

6.3.5: Risk for consumers via residues in food

There will be no exposure to food during use of the biocidal products. Therefore, the risk to consumers via residues in food does not need to be assessed.

7: Risk assessment for animal health

There are no risks posed to animals from use of the biocidal products. Therefore, a risk assessment for animal health is not required.

8: Risk assessment for the environment

8.1: Effects assessment on the environment

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

8.1.1.1: Further Ecotoxicological studies

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	Not classified as hazardous to the environment
Justification for the value/conclusion	See waiver justification

Data waiving	
Information requirement	Further ecotoxicological studies
Justification	According to the guidance on information requirements (Volume IV Part A, November 2014) - further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product. Ecotoxicity data is available for the active ingredient propan-2-ol as detailed in the assessment report. [redacted] hence synergistic effects will not occur. Based on the available information, the biocidal product does not need to be classified as hazardous to the environment. Since the available data on the active substance provides sufficient information and there are no indications of risk due to specific properties of the biocidal product, further ecotoxicological studies are therefore considered scientifically unjustified.

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

No data is available.

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

No data is available.

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

No data is available.

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

Not relevant.

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

The biocidal products are used in laboratories, clean rooms and pharmaceutical and cosmetics manufacturing facilities and therefore will not be poured down the drain. The high vapour pressure of propan-2-ol means that it will evaporate within a few minutes after application onto surfaces and therefore the primary emission route to the environment will be to air not to the STP (via drain). An environmental risk assessment has been performed using the assumption given in the Assessment Report for propan-2-ol that 10% is emitted to waste water and therefore 90% of the applied propan-2-ol is emitted to air.

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

Further studies on the fate and behaviour of the biocidal product are not required. Data and information on the fate and behaviour of the active ingredient propan-2-ol are available in the Assessment Report and are sufficient to cover the risk from the biocidal product in the event that emission to the environment was to occur. The biocidal product is used indoors only and hence there are no direct emissions to soil, water or surfaces and there is no direct release to drain. [redacted] the product does not contain any substances of concern. There is therefore no justification to perform fate and behaviour studies on the components in the biocidal product.

8.1.1.8: Leaching behaviour (ADS)

Studies to determine the leaching behaviour of the active substance, propan-2-ol, are not required. Sufficient data are available in the Assessment Report in order to predict the potential leaching behaviour of propan-2-ol and hence studies are considered scientifically unjustified.

8.1.1.9: Testing for distribution and dissipation in soil, water and sediment and air (ADS)

Further distribution and dissipation studies with the product are not required. Data and information on the active ingredient propan-2-ol are available in the Assessment Report and are sufficient to cover the risk from the biocidal product in the event that emission to the environment was to occur. The biocidal product is used indoors only and hence there are no direct emissions to soil, water or surfaces and there is no direct release to drain. [redacted] the product does not contain any substances of concern.

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

Not relevant.

8.1.1.11: If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS).

Not relevant.

8.1.1.12: Summary of PNEC values for propan-2-ol

Based on the Assessment Report for propan-2-ol, the following PNEC values were derived:

Table 69:PNEC values for propan-2-ol

Compartment	PNEC	Assessment factor	Derivation
Water	2.82 mg/L	50	16 d NOEC of 141 mg/L for *Daphnia magna*
STP	10 mg/L	100	EC_{50} of 1000 mg/L from a respiration inhibition test
Sediment	2.41 mg/kg_{wwt}	-	Derived using the equilibrium partitioning method
Soil	0.496 mg/kg_{wwt}	-	Derived using the equilibrium partitioning method
Air	No quantitative estimation of PNECair for the active substance is possible		

PBT Assessment:

The active substance propan-2-ol is neither a PBT - nor vP/vB- candidate.

According to ready biodegradability tests, propan-2-ol is considered to be readily biodegradable and is therefore expected to rapidly biodegrade in the environment. On the basis of this assumption, the P criterion as well as the vP criterion is not fulfilled.

For propan-2-ol with a log K_{ow} less than three, the calculated bioconcentration factor for fish is 0.22 L/kg_{wwt} and for earthworm 0.85 L/kg_{wwt}. Therefore, the B criterion as well as the vB criterion is not fulfilled.

The lowest long-term NOEC is 141 mg/L for *Daphnia magna*, and thus is clearly above the trigger value (long term NOEC for freshwater organism < 0.01 mg/L). Therefore, the T criterion is not fulfilled.

Endocrine disruption potential assessment:

[redacted]. For propan-2-ol no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Report (July 2014) states that propan-2-ol would not be considered as having endocrine disrupting properties. For the co-formulant there is no indication of ED.

8.2: Exposure assessment

Information used for the environmental exposure assessment is outlined in the table below:

Table 70:General information

Assessed PT	**PT 2**
Assessed scenarios	Scenario 1: Mopping in cleanrooms, pharmaceutical/ cosmetic manufacturing facilities and laboratories Scenario 2: Glove disinfection
ESD(s) used	PT 2, 1000 m^2 default for large-scale application (Supplement to the ESD for PT 2, JRC Scientific and Technical Reports, 2011)
Approach	Scenario 1: Average consumption Scenario 2: Covered by scenario 1
Distribution in the environment	Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017. Technical Agreements for Biocides Environment (ENV). Version 2.0, 29 August 2018. European Chemicals Agency, Helsinki, Finland.
Groundwater simulation	No, see chapter 8.3
Confidential Annexes	No
Life cycle steps assessed	Both scenarios: Application; direct emission to air and distribution via STP
Remarks	-

The biocidal products are used in a manner which will not result in them being poured down the drain. The high vapour pressure of propan-2-ol indicates that it will evaporate within a few minutes after application onto surfaces and therefore the primary emission route to the environment will be via air, not via waste water to the STP.

Emission estimation

Application

Although the BPR guidance allows a qualitative approach for volatile actives applied to surfaces, the eCA has requested that the methodology followed in the Assessment Report should be followed. Therefore, a quantitative assessment has been performed. The starting point in the Assessment Report methodology is the assumption that 10% of the evaporated propan-2-ol goes to waste water. Therefore, 90% of the applied amount is released to air.

Scenario 1

The default area for surface disinfection is 1000 m^2 based on Table 2 of the "Supplement to the ESD for PT 2: Emission scenarios for private and public health area disinfectants and other biocidal products" (JRC, 2011). In that table, the default number of applications per day = 1.

The application rate is 16 g product/m^2(equivalent to 18.4 ml/m^2)

Therefore, mass of product applied = 16 g/m^2 x 1000 m^2 = 16000 g.

%propan-2-ol = 64.04% w/w.

Therefore, mass of propan-2-ol applied = 16000 g x 64.04% = 10246.4 g.

- **10% = 1024.6 g,** which is assumed to go to the STP.
- 90% = **9221.8 g/day**, which is assumed to go to air.

Table 71:Input values for propan-2-ol used in SimpleTreat 4.0 with 3.1 settings (TAB 2018, ENV 9)

Parameter	Value	Comment
Vapour pressure	5780 Pa	25 °C, LoEP
Water solubility	100000 mg/L	LoEP:miscible with water.
Readily biodegradable	Yes	
K_{oc}	3.3 L/kg	LoEP
Log K_{ow}	0.05	LoEP

Melting point	-89.5 °C	LoEP
Boiling point	82.5 °C	LoEP
Molecular mass	60.09 g/mol	LoEP
Local emission to wastewater during episode		
Scenario 1	**1.0246 kg/d**	Value directly input to Simple Treat 4.0
Local emission to air during episode		
Scenario 1	**9.2218 kg/d**	Value directly input to Simple Treat 4.0

PECs

Local PECs were calculated by SimpleTreat 4.0and are shown in the tables below.

Aquatic compartment:

Table 72:Local PECs in aquatic compartments

	Local PEC
Scenario 1	
Local PEC in surface water during emission episode	6.37E-03 mg/L
Local PEC in freshwater sediment during emission episode	5.44E-03 mg/kgwwt
PEC for micro-organisms in the STP	0.0637 mg/L

Terrestrial compartment:

Table 73:Local PECs in terrestrial compartments

	Local PEC
Scenario 1	
Local PEC in agricultural soil(total) averaged over 30 days	5.37E-04 mg/kg wwt
Local PEC in groundwater	1.66 µg/L

Atmospheric compartment:

Table 74: Local PECs in air

	Local PEC
Scenario 1	2.56E-03 mg/m^3

Metabolites

Propan-2-ol is readily biodegradable. Therefore it is expected to be totally mineralised to carbon dioxide and water. No further consideration is required.

Primary and secondary poisoning

Primary poisoning for the intended use-patterns is not expected. Secondary poisoning is not expected for propan-2-ol, based on the conclusion in the Assessment Report which is considered to be applicable.

8.2.1: Risk characterisation

Atmosphere

Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion.

PEC air = 2.56E-03 mg/m^3. As stated in the Assessment Report, a quantitative risk assessment cannot be performed for the air compartment as no PNECair exists.

The Assessment Report discusses the potential for propan-2-ol to cause issues due to long-range transport since it has a half-life longer than 2 days, but also indicates that according to the EU TGD, effects on stratospheric ozone and acidification are not expected due to the lack of halogen, nitrogen or sulphur atoms and propan-2-ol is not listed as a substance of concern in Regulation 1005/2009 on substances that deplete the ozone layer. The potential for global warming cannot be characterised as there is no information available in the absorption spectrum in the range 800-1200 nm.

The Assessment Report also goes on to state that "due to the intended use of the b.p. for product type 2 which is limited to indoor application and on basis of the available substance information the environmental risk of propan-2-ol for the atmosphere can be assumed as low".

The statements from the Assessment Report are considered valid for use in this report based on similar application use-pattern and product type.

Conclusion

There is **no concern** to the atmospheric compartment from use of the propan-2-ol products in accordance with label instructions.

Sewage treatment plant (STP)

Table 75:PEC/PNEC values

Scenario	**PEC_{STP}**	**$PNEC_{STP}$**	**$PEC/PNEC_{STP}$**
Scenario 1	0.0637 mg/L	10 mg/L	**0.006**

Conclusion

There is **no concern** to the STP compartment from use of the propan-2-ol products in accordance with label instructions.

Aquatic compartment

Table 76:PEC/PNEC values

Scenario	PEC_{water}	$PNEC_{water}$	$PEC/PNEC_{water}$
Scenario 1	6.37E-03 mg/L	2.82 mg/L	**0.002**
	PEC_{sed}	**$PNEC_{sed}$**	**$PEC/PNEC_{sed}$**
Scenario 1	5.44E-03 mg/kg_{wwt}	2.41 mg/kg wwt	**0.002**

Conclusion

There is **no concern** to the aquatic compartment from use of the propan-2-ol products in accordance with label instructions.

Terrestrial compartment

Table 77:PEC/PNEC values

Scenario	PEC_{soil}	$PNEC_{soil}$	$PEC/PNEC_{soil}$
Scenario 1	5.37E-04 mg/kg_{wwt}	0.496 mg/kg_{wwt}	**0.001**

Conclusion

There is **no concern** to the terrestrial compartment from use of the propan-2-ol products in accordance with label instructions.

Groundwater

Table 78:PEC/PNEC values

Scenario	PEC_{gw}	Trigger value groundwater
Scenario 1	1.66 µg/L	0.1 µg/L

Conclusion

Based on **first tier assessment** (PECporewater), there is **concern** to groundwater from use of the propan-2-ol products in accordance with label instructions.

At WG-VII-2018, it was agreed that for alcohols in general used in PT 2,4 with a release path via air, no assessment for the groundwater compartment is needed. In these situations, FOCUS PEARL is unlikely to provide realistic concentrations and no risk for groundwater is assumed, based on expert judgement. Several reasons why the calculated PECs are likely an overestimation:

- The whole fraction released to outdoor air is assumed to be emitted within 1000m vicinity of the emission source, and to agricultural soils only. However, for the intended uses, emission will mostly take place in urban areas with sealed soil.
- Reaction of the a.s. with photo-chemically produced OH and NO3 radicals in the atmosphere is currently not considered.
- FOCUS PEARL can take volatilization into account when a.s. specific diffusion coefficients to air and water are available. These parameters are not available since they are not part of the core data set required for active substances under evaluated under the BPR. Therefore, the current model may overestimate the groundwater concentration.

Therefore, FOCUS PEARL was not run to refine PEC_{GW} values, but the exceedance of the trigger value for the intended uses of the products is considered acceptable.

8.2.2: Primary and secondary poisoning

Primary poisoning

Conclusion

Based on approach in Assessment Report, there is **no concern** from primary poisoning from use of the propan-2-ol products when used in accordance with label instructions.

Secondary poisoning

Conclusion

Based on approach in Assessment Report, there is **no concern** from secondary poisoning from use of the propan-2-ol products when used in accordance with label instructions.

8.2.3: Mixture toxicity

An assessment of mixture toxicity is not required since none of the non-active components are classified for ecotoxic effects and are not expected to enhance the toxicity of the active.

8.2.4: Aggregated exposure (combined for relevant emission sources)

The guidance is still under development. This will therefore be performed when guidance is available in order to ensure a harmonised approach across dossiers.

9: Measures to protect man, animals and the environment

The biocidal product should be kept away from heat, hot surfaces, sparks, open flames and other ignition sources. It should be stored in a cool, well-ventilated area.

The biocidal product should be handled in accordance with good industrial hygiene and safety practice. Personal protective equipment should be used as required and gloves are recommended. The product should only be used with adequate ventilation.

The biocidal product should not be allowed to enter the drainage system or surface or ground water.

10: Assessment of a combination of biocidal products

The biocidal product is not intended to be used in combination with other biocidal products.

11: Comparative assessment

According to Article 23 of the BPR, this would be performed by the evaluating authority. However, propan-2-ol is not considered a candidate for substitution and therefore a comparative assessment should not be required.

Annexes

Annex 1:List of studies for the biocidal product

Table 79:List of studies for the biocidal product

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
3.1 3.2 3.3 3.4.1.1 3.4.1.3	2015/343AM	[redacted]	2016	Stability studies on the test item "ClearKlens IPA VH1 (spray bottle)"	Diversey Europe Operation BV	X	
3.4.1.2	2016/29 AM	[redacted]	2018	Shelf-Life stability study at 25°C for 24 months on the test item 'Clearklens IPA VH1 (Sterile Can 1000 mL)'	Diversey Europe Operation BV	X	
3.4.1.2	2016/30 AM	[redacted]	2018	Shelf-Life stability study at 25°C for 24 months on the test item 'ClearKlens IPA VH1 (airless spray)'	Diversey Europe Operation BV	X	
3.4.1.2	2015/220 AM	[redacted]	2017	Shelf-life stability study at 25°C for 24 months on the test item 'Clearklens IPA VH1 (sterile trigger 900 ml) '	Diversey Europe Operation BV	X	
3.4.1.2	2015/252 AM	[redacted]	2017	Shelf-Life stability study at 25°C for 24 months on the test item 'Clearklens IPA VH1 (spray bottle) '	Diversey Europe Operation BV	X	
3.4.1.2	2015/308 AM	[redacted]	2018	Shelf-life stability study at 25°C for 24 months on the test item 'Clearklens IPA VH1 (5L pouch) '	Diversey Europe Operation BV	X	
3.4.1.3 3.9	S-2016-00251 AM	[redacted]	2016	Low temperature stability study at 0°C for 1 weeks and viscosity on the test item "ClearKlens IPA VH1 (Sterile Can 1000ml)"	Diversey Europe Operation BV	X	
3.5.13	-	[redacted]	2016	Evaporation study "ClearKlens IPA (VH1 FM003774)"	Diversey Europe Operation BV	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
3.5.13	-	[redacted]	2016	Evaluation of spray pattern on different test items	Diversey Europe Operation BV	X	
3.8	201600613	[redacted]	2016	Surface Tension on the Sample ClearKlens IPA VH1 (Sterile Can 1000ml)	Diversey Europe Operation BV	X	
5.1	S-2015-02695 AM	[redacted]	2015	Set up and validation of a GC method for the quantification of the active ingredient isopropanol in the test item "ClearKlens IPA VH1 (Sterile Can 1000ml)"	Diversey Europe Operation BV	X	
6.7	L17/0015.1	[redacted]	2017	Bactericidal Activity of VH01 ClearKlens IPA in the quantitative suspension test according to DIN EN 1276:2009 (Phase 2, Step 1)	Diversey Europe Operation BV	X	
6.7	SN 19836 EN 1276	[redacted]	2016	VH01 ClearKlens IPA: EN 1276 Quantitative suspension test - bactericidal activity (phase 2, step 1)	Diversey Europe Operation BV	X	
6.7	L17/0015.2	[redacted]	2017	Yeasticidal Activity of VH01 ClearKlens IPA in the quantitative suspension test according to DIN EN 1650:2013 (Phase 2, Step 1)	Diversey Europe Operation BV	X	
6.7	SN 19836 EN 1650	[redacted]	2016	VH01 ClearKlens IPA: EN 1650 Quantitative suspension test - fungicidal activity (phase 2, step 1)	Diversey Europe Operation BV	X	
6.7	SN 19836 EN 13697	[redacted]	2016	VH01 ClearKlens IPA: EN 13697 (2015) Quantitative non-porous surface test - bactericidal and fungicidal activity (phase 2, step 2)	Diversey Europe Operation BV	X	
6.7	L17/0015.3	[redacted]	2017	Yeasticidal Activity of VH01 ClearKlens IPA in the quantitative surface test according to DIN EN 13697:2015 (Phase 2, Step 2)	Diversey Europe Operation BV	X	
10	-	[redacted]	1992	Degradation rates in the environment: extrapolation of standardized tests	Diversey Europe Operation BV	X	

Annex 2:Calculations for exposure assessment

1: Scenario 1: Mopping:

1.1: Tier 1: Dermal exposure

According to the Surface Disinfection (manual) Model 1, the potential hand exposure is 1030 mg/min, body exposure is 87.6 mg/min and the application duration is 5 minutes per room. Hence, the potential external dermal dose of product is equal to 16764 mg ((1030+87.6) mg/min x 5 min x 3 applications/ day). This is equivalent to a mass of propan-2-ol of 10729 mg.

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (10729 mg x 25%) / 60 kg bw

= **44.7 mg/kg bw/day**

1.2: Tier 2: Dermal exposure

The time taken for the product (10729 mg propan-2-ol) to evaporate from the surface of the skin is calculated as follows:

Evaporation time:

= t (s) = (m T R / (M ß p A)) x K,

where:

t = evaporation time (seconds)

m = mass of compound (10729 mg)

R = gas constant (8.314 J K/mol)

T = temperature in Kelvin (298.15 K, equal to 25 ºC, room temperature)

M = molar mass of compound (60.09 g/mol for IPA)

ß = coefficient of mass transfer in the vapour phase (8.7 m/h)

p = vapour pressure of compound (5780 Pa for IPA)

A = applied area (410 cm^2 – surface area of two palms or the whole of one hand)

K = conversion factor (3.6 x 10^4)

Therefore:

Evaporation time = 773 s = 12.88 min = 0.215 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm2/h x 0.215 h x 410 cm2) / 60 kg bw

= 1.25 mg/kg bw/day

1.3: Tier 3: Dermal exposure with the use of gloves

A 95% protection factor can be applied to the systemic dermal dose of propan-2-ol to account for the use of protective gloves. Therefore, this equals a dose of **0.062 mg/kg bw/day** of propan-2-ol (1.25 mg/kg bw/day x 5%).

2: Scenario 2: Wiping with a cloth following pouring:

2.1: Tier 1: Dermal exposure

According to BEAT, the indicative hand exposure is 2950 µL/min. For an exposure duration of 30 minute, 20 product applications/ day, product density of 0.87 and an propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 2950 µL/min x 30 min x 20 applications/day x 0.87 x 64%

= 985536 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of IPA in contact with skin x Dermal absorption) / Bodyweight

= (985536 mg x 25%) / 60 kg bw

= **4106 mg/kg bw/day**

2.2: Tier 2: Dermal exposure

The time taken for the product (985536 mg propan-2-ol) to evaporate from the surface of the skin (410 cm^2 – surface area of one adult palm) is calculated using the evaporation time equation described previously.

Therefore:

Evaporation time = 70991 s = 19.7 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm2/h x 19.7 h x 410 cm2) / 60 kg bw

= 114.4 mg/kg bw/day

2.3: Tier 3: Dermal exposure with the use of gloves

A 95% protection factor can be applied to the systemic dermal dose of propan-2-ol to account for the use of protective gloves. Therefore, this equals a dose of **5.72 mg/kg bw/day** of propan-2-ol (114.4 mg/kg bw/day x 5%).

3: Scenario 3: Wiping with a cloth following spraying:

3.1: Tier 1: Dermal exposure during **spraying**:

According to Consumer product spraying dusting Model 2, the indicative hand and forearm exposure is 36.1 mg/min. For an exposure duration during spraying of 10 seconds, 80 product applications/ day and a propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 36.1 mg/min x 0.167 min x 80 applications/day x 64%

= 308 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of IPA in contact with skin x Dermal absorption) / Bodyweight

= (308 mg x 25%) / 60 kg bw

= **1.28 mg/kg bw/day**

Tier 1: Dermal exposure during **wiping**:

According to BEAT, the indicative hand exposure is 214 µL/min. For an exposure duration during wiping of 1 minute, 80 product applications/ day, product density of 0.87 and a propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 214 µL/min x 1 min x 80 applications/day x 0.87 x 64%

= 9532 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of IPA in contact with skin x Dermal absorption) / Bodyweight

= (9532 mg x 25%) / 60 kg bw

= **39.72 mg/kg bw/day**

3.2: Tier 2: Dermal exposure during **spraying**

The time taken for the product (308 mg propan-2-ol) to evaporate from the surface of the skin (974.4 cm^2 – surface area of one hand and forearm) is calculated using the evaporation time equation described previously.

Therefore:

Evaporation time = 9.33 s = 0.0026 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 $mg/cm^2/h$ x 0.0026 h x 974.4 cm^2) / 60 kg bw

= **0.036 mg/kg bw/day**

Tier 2: Dermal exposure during **wiping:**

The time taken for the product (9532 mg propan-2-ol) to evaporate from the surface of the skin (205 cm^2 – surface area of one palm) is calculated using the evaporation time equation described previously.

Therefore:

Evaporation time = 1373 s = 0.38 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm2/h x 0.38 h x 205 cm2) / 60 kg bw

= 1.11 mg/kg bw/day

3.3: Tier 3: Dermal exposure with the use of gloves (**spraying**)

A 95% protection factor can be applied to the systemic dermal dose of propan-2-ol to account for the use of protective gloves. Therefore, this equals a dose of **0.0018 mg/kg bw/day** of propan-2-ol (0.036 mg/kg bw/day x 5%).

Tier 3: Dermal exposure with the use of gloves (**wiping**)

A 95% protection factor can be applied to the systemic dermal dose of propan-2-ol to account for the use of protective gloves. Therefore, this equals a dose of **0.056 mg/kg bw/day** of propan-2-ol (1.11 mg/kg bw/day x 5%).

4: Scenario 4: Glove disinfection:

The dermal exposure is negligible.

5: Scenario 5: Mopping:

For further details regarding the calculations, please refer to Scenario 1.

5.1: Tier 1: Dermal exposure

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (10729 mg x 25%) / 60 kg bw

= **44.7 mg/kg bw/day**

5.2: Tier 2: Dermal exposure

The time taken for the product (10729 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously:

Evaporation time = 772.8 s = 12.88 min = 0.215 h

Therefore, dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm2/h x 0.215 h x 410 cm2) / 60 kg bw

= 1.25 mg/kg bw/day

5.3: Tier 3: Dermal exposure with the use of gloves

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **0.062 mg/kg bw/day**.

6: Scenario 6: Wiping with a cloth following pouring:

For further details regarding the calculations, please refer to Scenario 2.

6.1: Tier 1: Dermal exposure

According to BEAT, the indicative hand exposure is 2950 µL/min. For an exposure duration of 30 minutes per application, 5 product applications/ day, product density of 0.87 and a propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 2950 µL/min x 30 min x 5 applications/day x 0.87 x 64%

= 246384 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (246384 mg x 25%) / 60 kg bw

= **1026.6 mg/kg bw/day**

6.2: Tier 2: Dermal exposure

The time taken for the product (246384 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously:

Evaporation time = 17748 s = 4.93 h

Therefore, dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm^2/h x 4.93 h x 410 cm^2) / 60 kg bw

= 28.6 mg/kg bw/day

6.3: Tier 3: Dermal exposure with the use of gloves

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **1.43 mg/kg bw/day**.

7: Scenario 7: Wiping with a cloth following spraying:

Please refer to Scenario 3 for all calculations and results.

8: Scenario 8: Glove disinfection:

The dermal exposure is negligible.

9: Scenario 9: Mopping:

For further details regarding the calculations, please refer to Scenario 1.

9.1: Tier 1: Dermal exposure

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (3576 mg x 25%) / 60 kg bw

= **14.9 mg/kg bw/day**

9.2: Tier 2: Dermal exposure

The time taken for the product (3576 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously:

Evaporation time = 258 s = 4.3 min = 0.07 h

Therefore, dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm2/h x 0.07 h x 410 cm2) / 60 kg bw

= **0.41 mg/kg bw/day**

9.3: Tier 3: Dermal exposure with the use of gloves

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **0.02 mg/kg bw/day**.

10: Scenario 10: Wiping with a cloth following pouring:

For further details regarding the calculations, please refer to Scenario 2.

10.1: Tier 1: Dermal exposure

According to BEAT, the indicative hand exposure is 2950 µL/min. For an exposure duration of 1 minute per application, 10 product application/ day, product density of 0.87 and a propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 2950 µL/min x 30 min x 10 application/day x 0.87 x 64%

= 492768 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (492768 mg x 25%) / 60 kg bw

= **2053 mg/kg bw/day**

10.2: Tier 2: Dermal exposure

The time taken for the product (492768 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously:

Evaporation time = 35495 s = 9.9 h

Therefore, dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm^2/h x 9.9 h x 410 cm^2) / 60 kg bw

= **57.3 mg/kg bw/day**

10.3: Tier 3: Dermal exposure with the use of gloves

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **2.87 mg/kg bw/day**.

11: Scenario 11: Wiping with a cloth following spraying:

For further details regarding the calculations, please refer to Scenario 3.

11.1: Tier 1: Dermal exposure during **spraying**:

Dermal exposure:

= 36.1 mg/min x 0.167 min x 10 applications/day x 64%

= 38.58 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of propan-2-ol in contact with skin x Dermal absorption) / Bodyweight

= (38.58 mg x 25%) / 60 kg bw

= **0.161 mg/kg bw/day**

Tier 1: Dermal exposure during **wiping**:

According to BEAT, the indicative hand exposure is 214 µL/min. For an exposure duration during wiping of 1 minute, 10 product applications/ day, product density of 0.87 and a propan-2-ol content of 64%, the potential dermal exposure to propan-2-ol is as follows:

Dermal exposure:

= 214 µL/min x 1 min x 10 applications/day x 0.87 x 64%

= 1192 mg propan-2-ol/person/day

Dermal systemic dose:

= (Mass of IPA in contact with skin x Dermal absorption) / Bodyweight

= (1192 mg x 25%) / 60 kg bw

= **4.96 mg/kg bw/day**

11.2: Tier 2: Dermal exposure during **spraying**

The time taken for the product (38.58 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously.

Therefore:

Evaporation time = 1.17 s = 0.00032 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm^2/h x 0.00032 h x 974.4 cm^2) / 60 kg bw

= **0.0019 mg/kg bw/day**

Tier 2: Dermal exposure during **wiping:**

The time taken for the product (1192 mg propan-2-ol) to evaporate from the surface of the skin is calculated using the evaporation time equation described previously.

Therefore:

Evaporation time = 171.7 s = 0.048 h

The internal dermal exposure can then be calculated based on the transdermal flux rate using the following calculation:

Dermal systemic dose:

= (Dermal flux rate x evaporation time x total skin surface) / bodyweight

= (0.85 mg/cm^2/h x 0.048 h x 205 cm^2) / 60 kg bw

= **0.139 mg/kg bw/day**

11.3: Tier 3: Dermal exposure with the use of gloves (**spraying**)

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **0.000095 mg/kg bw/day**.

Tier 3: Dermal exposure with the use of gloves (**wiping**)

Applying a 95% protection factor for the use of protective gloves, the dermal dose of propan-2-ol is **0.00695 mg/kg bw/day**.

12: Scenario 12: Glove disinfection:

The dermal exposure is negligible.

Annex 3:New information on the active substance

No new information on the active substance is available.

Annex 4:Residue behaviour

Information on the residue behaviour of propan-2-ol or the biocidal product is not required.

Annex 5:Summaries of the efficacy studies

The efficacy studies are summarised in 5.5 Efficacy data and in IUCLID Section 6.7.

Annex 6: ConsExpo Reports

ConsExpo Web – Parameters & Results (Oct 2019)

- Scenario 1 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	1056	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results
Inhalation

Mean event concentration	1.0×10^{1}	mg/m³
Peak concentration (TWA 15 min)	3.3×10^{2}	mg/m³
Mean concentration on day of exposure	3.4	mg/m³
Year average concentration	3.4	mg/m³
External event dose	1.7	mg/kg bw
External dose on day of exposure	1.7	mg/kg bw
Internal event dose	1.7	mg/kg bw
Internal dose on day of exposure	1.7	mg/kg bw/day
Internal year average dose	1.7	mg/kg bw/day

- Scenario 1 Tier 2

Parameters

Frequency	3	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	3	hour
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	352	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.26E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	22	m^2
Application duration	5	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	9.0	mg/m³
Peak concentration (TWA 15 min)	1.0×10^{2}	mg/m³
Mean concentration on day of exposure	3.4	mg/m³
Year average concentration	3.4	mg/m³
External event dose	5.6×10^{-1}	mg/kg bw
External dose on day of exposure	1.7	mg/kg bw
Internal event dose	5.6×10^{-1}	mg/kg bw
Internal dose on day of exposure	1.7	mg/kg bw/day
Internal year average dose	1.7	mg/kg bw/day

- Scenario 2 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	3200	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	3.1×10^{1}	mg/m³
Peak concentration (TWA 15 min)	9.9×10^{2}	mg/m³
Mean concentration on day of exposure	1.0×10^{1}	mg/m³
Year average concentration	1.0×10^{1}	mg/m³
External event dose	5.2	mg/kg bw
External dose on day of exposure	5.2	mg/kg bw
Internal event dose	5.2	mg/kg bw
Internal dose on day of exposure	5.2	mg/kg bw/day
Internal year average dose	5.2	mg/kg bw/day

- Scenario 2 Tier 2

Parameters

Frequency	20	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	160	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	10	m^2
Application duration	30	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	No	
Molecular weight matrix	50	g/mol
The product is used in dilution	No	
Amount of solution used	8	g
Weight fraction substance	0.64	
Room volume	25	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	0.335	m/min
Release area mode	Increasing	
Release area	0.5	m^2
Application duration	1	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	1.2×10^{1}	mg/m³
Peak concentration (TWA 15 min)	2.5×10^{1}	mg/m³
Mean concentration on day of exposure	1.0×10^{1}	mg/m³
Year average concentration	1.0×10^{1}	mg/m³
External event dose	2.6×10^{-1}	mg/kg bw
External dose on day of exposure	5.1	mg/kg bw
Internal event dose	2.6×10^{-1}	mg/kg bw
Internal dose on day of exposure	5.1	mg/kg bw/day
Internal year average dose	5.1	mg/kg bw/day

- Scenario 3 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	640	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	6.2	mg/m³
Peak concentration (TWA 15 min)	2.0×10^2	mg/m³
Mean concentration on day of exposure	2.1	mg/m³
Year average concentration	2.1	mg/m³
External event dose	1.0	mg/kg bw
External dose on day of exposure	1.0	mg/kg bw
Internal event dose	1.0	mg/kg bw
Internal dose on day of exposure	1.0	mg/kg bw/day
Internal year average dose	1.0	mg/kg bw/day

- Scenario 3 Tier 2

Parameters

Frequency	1	per day
Description	80 times per day should be added up	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	8	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	0.5	m^2
Application duration	0.17	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results (per application, For internal dose the application frequency of 80 applications per day should be accounted for)

Inhalation

Mean event concentration	8.1×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	2.4	mg/m³
Mean concentration on day of exposure	2.5×10^{-2}	mg/m³
Year average concentration	2.5×10^{-2}	mg/m³
External event dose	1.3×10^{-2}	mg/kg bw
External dose on day of exposure	1.3×10^{-2}	mg/kg bw
Internal event dose	1.3×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-2}	mg/kg bw/day
Internal year average dose	1.3×10^{-2}	mg/kg bw/day

- Scenario 4 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	209	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	2.0	mg/m³
Peak concentration (TWA 15 min)	6.5×10^{1}	mg/m³
Mean concentration on day of exposure	6.8×10^{-1}	mg/m³
Year average concentration	6.8×10^{-1}	mg/m³
External event dose	3.4×10^{-1}	mg/kg bw
External dose on day of exposure	3.4×10^{-1}	mg/kg bw
Internal event dose	3.4×10^{-1}	mg/kg bw
Internal dose on day of exposure	3.4×10^{-1}	mg/kg bw/day
Internal year average dose	3.4×10^{-1}	mg/kg bw/day

- Scenario 4 Tier 2

Parameters

Frequency	1	per day
Description	80 times per day should be summed up	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	2.61	g
Weight fraction substance	0.64	
Room volume	55	m^3
Ventilation rate	150	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	820	cm^2
Emission duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results (per application, For internal dose the application frequency of 80 applications per day should be accounted for

Inhalation

Mean event concentration	1.2×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	3.7×10^{-1}	mg/m³
Mean concentration on day of exposure	3.9×10^{-3}	mg/m³
Year average concentration	3.9×10^{-3}	mg/m³
External event dose	2.0×10^{-3}	mg/kg bw
External dose on day of exposure	2.0×10^{-3}	mg/kg bw
Internal event dose	2.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.0×10^{-3}	mg/kg bw/day
Internal year average dose	2.0×10^{-3}	mg/kg bw/day

- Scenario 5 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	512	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	8.5	mg/m³
Peak concentration (TWA 15 min)	2.7×10^2	mg/m³
Mean concentration on day of exposure	2.8	mg/m³
Year average concentration	2.8	mg/m³
External event dose	1.4	mg/kg bw
External dose on day of exposure	1.4	mg/kg bw
Internal event dose	1.4	mg/kg bw
Internal dose on day of exposure	1.4	mg/kg bw/day
Internal year average dose	1.4	mg/kg bw/day

- Scenario 5 Tier 2

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	3	hour
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	512	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	32	m^2
Application duration	15	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	2.2×10^{1}	mg/m³
Peak concentration (TWA 15 min)	2.4×10^{2}	mg/m³
Mean concentration on day of exposure	2.8	mg/m³
Year average concentration	2.8	mg/m³
External event dose	1.4	mg/kg bw
External dose on day of exposure	1.4	mg/kg bw
Internal event dose	1.4	mg/kg bw
Internal dose on day of exposure	1.4	mg/kg bw/day
Internal year average dose	1.4	mg/kg bw/day

- Scenario 6 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	800	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	1.3×10^{1}	mg/m³
Peak concentration (TWA 15 min)	4.3×10^{2}	mg/m³
Mean concentration on day of exposure	4.4	mg/m³
Year average concentration	4.4	mg/m³
External event dose	2.2	mg/kg bw
External dose on day of exposure	2.2	mg/kg bw
Internal event dose	2.2	mg/kg bw
Internal dose on day of exposure	2.2	mg/kg bw/day
Internal year average dose	2.2	mg/kg bw/day

- Scenario 6 Tier 2

Parameters

Frequency	5	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	160	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	10	m^2
Application duration	30	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	2.1×10^{1}	mg/m³
Peak concentration (TWA 15 min)	4.3×10^{1}	mg/m³
Mean concentration on day of exposure	4.4	mg/m³
Year average concentration	4.4	mg/m³
External event dose	4.4×10^{-1}	mg/kg bw
External dose on day of exposure	2.2	mg/kg bw
Internal event dose	4.4×10^{-1}	mg/kg bw
Internal dose on day of exposure	2.2	mg/kg bw/day
Internal year average dose	2.2	mg/kg bw/day

- Scenario 7 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	640	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	1.1×10^{1}	mg/m³
Peak concentration (TWA 15 min)	3.4×10^{2}	mg/m³
Mean concentration on day of exposure	3.6	mg/m³
Year average concentration	3.6	mg/m³
External event dose	1.8	mg/kg bw
External dose on day of exposure	1.8	mg/kg bw
Internal event dose	1.8	mg/kg bw
Internal dose on day of exposure	1.8	mg/kg bw/day
Internal year average dose	1.8	mg/kg bw/day

- Scenario 7 Tier 2

Parameters

Frequency	1	per day
Description	80 times per day should be added up	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	8	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	0.335	m/min
Release area mode	Increasing	
Release area	0.5	m^2
Application duration	0.17	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results (per application, For internal dose the application frequency of 80 applications per day should be accounted for

Inhalation

Mean event concentration	1.4	mg/m³
Peak concentration (TWA 15 min)	4.2	mg/m³
Mean concentration on day of exposure	4.4×10^{-2}	mg/m³
Year average concentration	4.4×10^{-2}	mg/m³
External event dose	2.2×10^{-2}	mg/kg bw
External dose on day of exposure	2.2×10^{-2}	mg/kg bw
Internal event dose	2.2×10^{-2}	mg/kg bw
Internal dose on day of exposure	2.2×10^{-2}	mg/kg bw/day
Internal year average dose	2.2×10^{-2}	mg/kg bw/day

- Scenario 8 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	104	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	1.7	mg/m³
Peak concentration (TWA 15 min)	5.5×10^{1}	mg/m³
Mean concentration on day of exposure	5.8×10^{-1}	mg/m³
Year average concentration	5.8×10^{-1}	mg/m³
External event dose	2.9×10^{-1}	mg/kg bw
External dose on day of exposure	2.9×10^{-1}	mg/kg bw
Internal event dose	2.9×10^{-1}	mg/kg bw
Internal dose on day of exposure	2.9×10^{-1}	mg/kg bw/day
Internal year average dose	2.9×10^{-1}	mg/kg bw/day

- Scenario 8 Tier 2

Parameters

Frequency	1	per day
Description	4o times/day should be summed up	

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	2.61	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	60	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	820	cm^2
Emission duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	2.2×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	6.3×10^{-1}	mg/m³
Mean concentration on day of exposure	6.8×10^{-3}	mg/m³
Year average concentration	6.8×10^{-3}	mg/m³
External event dose	3.4×10^{-3}	mg/kg bw
External dose on day of exposure	3.4×10^{-3}	mg/kg bw
Internal event dose	3.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.4×10^{-3}	mg/kg bw/day
Internal year average dose	3.4×10^{-3}	mg/kg bw/day

- Scenario 9 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	512	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	6.4×10^{1}	mg/m³
Peak concentration (TWA 15 min)	1.8×10^{3}	mg/m³
Mean concentration on day of exposure	2.1×10^{1}	mg/m³
Year average concentration	2.1×10^{1}	mg/m³
External event dose	1.1×10^{1}	mg/kg bw
External dose on day of exposure	1.1×10^{1}	mg/kg bw
Internal event dose	1.1×10^{1}	mg/kg bw
Internal dose on day of exposure	1.1×10^{1}	mg/kg bw/day
Internal year average dose	1.1×10^{1}	mg/kg bw/day

- Scenario 9 Tier 2

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	3	hour
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	160	g
Weight fraction substance	0.64	
Room volume	25	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	10	m^2
Application duration	15	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	1.7×10^{2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{3}	mg/m³
Mean concentration on day of exposure	2.1×10^{1}	mg/m³
Year average concentration	2.1×10^{1}	mg/m³
External event dose	1.1×10^{1}	mg/kg bw
External dose on day of exposure	1.1×10^{1}	mg/kg bw
Internal event dose	1.1×10^{1}	mg/kg bw
Internal dose on day of exposure	1.1×10^{1}	mg/kg bw/day
Internal year average dose	1.1×10^{1}	mg/kg bw/day

- Scenario 10 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	1600	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results:

Inhalation

Mean event concentration	2.0×10^{2}	mg/m³
Peak concentration (TWA 15 min)	5.5×10^{3}	mg/m³
Mean concentration on day of exposure	6.7×10^{1}	mg/m³
Year average concentration	6.7×10^{1}	mg/m³
External event dose	3.3×10^{1}	mg/kg bw
External dose on day of exposure	3.3×10^{1}	mg/kg bw
Internal event dose	3.3×10^{1}	mg/kg bw
Internal dose on day of exposure	3.3×10^{1}	mg/kg bw/day
Internal year average dose	3.3×10^{1}	mg/kg bw/day

- Scenario 10 Tier 2

Parameters:

Frequency	10	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	160	g
Weight fraction substance	0.64	
Room volume	25	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	10	m^2
Application duration	30	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results:

Inhalation

Mean event concentration	5.0×10^2	mg/m³
Peak concentration (TWA 15 min)	9.4×10^2	mg/m³
Mean concentration on day of exposure	2.1×10^2	mg/m³
Year average concentration	2.1×10^2	mg/m³
External event dose	1.0×10^1	mg/kg bw
External dose on day of exposure	1.0×10^2	mg/kg bw
Internal event dose	1.0×10^1	mg/kg bw
Internal dose on day of exposure	1.0×10^2	mg/kg bw/day
Internal year average dose	1.0×10^2	mg/kg bw/day

- Scenario 11 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	32	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	4.0	mg/m³
Peak concentration (TWA 15 min)	1.1×10^{2}	mg/m³
Mean concentration on day of exposure	1.3	mg/m³
Year average concentration	1.3	mg/m³
External event dose	6.7×10^{-1}	mg/kg bw
External dose on day of exposure	6.7×10^{-1}	mg/kg bw
Internal event dose	6.7×10^{-1}	mg/kg bw
Internal dose on day of exposure	6.7×10^{-1}	mg/kg bw/day
Internal year average dose	6.7×10^{-1}	mg/kg bw/day

- Scenario 11 Tier 2

Parameters

Frequency	10	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	8	g
Weight fraction substance	0.64	
Room volume	25	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Increasing	
Release area	0.5	m^2
Application duration	0.17	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	3.4×10^{1}	mg/m³
Peak concentration (TWA 15 min)	8.4×10^{1}	mg/m³
Mean concentration on day of exposure	1.1×10^{1}	mg/m³
Year average concentration	1.1×10^{1}	mg/m³
External event dose	5.3×10^{-1}	mg/kg bw
External dose on day of exposure	5.3	mg/kg bw
Internal event dose	5.3×10^{-1}	mg/kg bw
Internal dose on day of exposure	5.3	mg/kg bw/day
Internal year average dose	5.3	mg/kg bw/day

- Scenario 12 Tier 1

Parameters

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Instantaneous release	
Exposure duration	8	hour
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	26.1	g
Weight fraction substance	0.64	
Room volume	80	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	3.3	mg/m³
Peak concentration (TWA 15 min)	9.0×10^{1}	mg/m³
Mean concentration on day of exposure	1.1	mg/m³
Year average concentration	1.1	mg/m³
External event dose	5.4×10^{-1}	mg/kg bw
External dose on day of exposure	5.4×10^{-1}	mg/kg bw
Internal event dose	5.4×10^{-1}	mg/kg bw
Internal dose on day of exposure	5.4×10^{-1}	mg/kg bw/day
Internal year average dose	5.4×10^{-1}	mg/kg bw/day

- Scenario 12 Tier 2

Parameters

Frequency	10	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	45	minute
Product is substance in pure form	No	
Molecular weight matrix	15	g/mol
The product is used in dilution	No	
Amount of solution used	2.61	g
Weight fraction substance	0.64	
Room volume	25	m^3
Ventilation rate	8	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	4.27E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	820	cm^2
Emission duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Results

Inhalation

Mean event concentration	4.8	mg/m³
Peak concentration (TWA 15 min)	1.2×10^{1}	mg/m³
Mean concentration on day of exposure	1.5	mg/m³
Year average concentration	1.5	mg/m³
External event dose	7.5×10^{-2}	mg/kg bw
External dose on day of exposure	7.5×10^{-1}	mg/kg bw
Internal event dose	7.5×10^{-2}	mg/kg bw
Internal dose on day of exposure	7.5×10^{-1}	mg/kg bw/day
Internal year average dose	7.5×10^{-1}	mg/kg bw/day

Scenario 13
Parameters

Frequency	1	per week
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	1.33	minute
Product is substance in pure form	No	
Molecular weight matrix	50	g/mol
The product is used in dilution	No	
Amount of solution used	500	g
Weight fraction substance	0.64	
Room volume	1	m^3
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	20	°C
Vapour pressure	5.78E+03	Pa
Molecular weight	60	g/mol
Mass transfer coefficient	0.335	m/min
Release area mode	Constant	
Release area	0.002	m^2
Emission duration	1.33	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	Direct contact - Instant application	
Exposed area	410	cm^2
Weight fraction substance	0.64	
Product amount	0.01	g
Absorption model	Fixed fraction	
Absorption fraction	0.25	

Results

Inhalation

Mean event concentration	3.8×10^{1}	mg/m³
Peak concentration (TWA 15 min)	3.8×10^{1}	mg/m³
Mean concentration on day of exposure	3.5×10^{-2}	mg/m³
Year average concentration	5.0×10^{-3}	mg/m³
External event dose	1.7×10^{-2}	mg/kg bw
External dose on day of exposure	1.7×10^{-2}	mg/kg bw
Internal event dose	1.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-2}	mg/kg bw/day
Internal year average dose	2.5×10^{-3}	mg/kg bw/day

Dermal

Dermal load	1.6×10^{-2}	mg/cm²
External event dose	1.1×10^{-1}	mg/kg bw
External dose on day of exposure	1.1×10^{-1}	mg/kg bw
Internal event dose	2.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	2.7×10^{-2}	mg/kg bw/day
Internal year average dose	3.8×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	4.4×10^{-2}	mg/kg bw
Internal dose on day of exposure	4.4×10^{-2}	mg/kg bw/day
Internal year average dose	6.3×10^{-3}	mg/kg bw/day