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

DEC-AHOL® Product Family
Product type 2

Propan-2-ol

Case Number in R4BP: BC-XF025530-45

Evaluating Competent Authority: Netherlands

Date: August 2020

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1 CONCLUSION

The outcome of the assessment for the biocidal product family 'DEC-AHOL® Product Family ' is specified in the BPC opinion.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
DEC-AHOL® Product Family	Netherlands

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Veltek Associates, Inc. Europe
	Address	Branch Office Europe Rozengaard 1940 8212DT Lelystad Netherlands
Pre-submission phase started on	22 December 2015	
Pre-submission phase concluded on	18 February 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Veltek Associates, Inc.,
Address of manufacturer	15 Lee Blvd. Malvern PA19355 USA
Location of manufacturing sites	Same as above

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

Active substance	Propan-2-ol
Name of manufacturer	Exxon Mobil Chemical Company
Address of manufacturer	4045 Scenic Hwy, Baton Rouge, LA 70805 Louisiana, United States
Location of manufacturing sites	4045 Scenic Hwy, Baton Rouge, LA 70805 Louisiana United States

*Note: Dow Chemicals and Univar are suppliers of the active substance to Veltek, but Exxon Mobil is the manufacturer in all cases. The two distributors certify separately due

to the use of their own transport containers and vehicles. These certifications assure Veltek that the material is unchanged by the distributors handling and delivery routines.

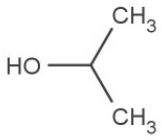
2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

Not applicable.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[1]

Quantitative and qualitative information on the composition of the biocidal product family can be found in Section 2.1.2.4.

1 Please delete as appropriate.

3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol; Isopropanol	2-propanol	Active substance	67-63-0	200-661-7	64.8	65.4
Refer to Confidential Annex		Non-active substance				

The purity of the substance is high (>99%). Therefore, the eCA has not distinguished between the technical substance / substance as manufactured (the substance according to the definition of 1907/2006/EC) and the pure active substance.

2.1.2.5 Information on technical equivalence

The applicant is a full member of the ASD Consortia for propan-2-ol. The applicant sources the active substance from Exxon Mobil in the United States. Decision number TAP-D-1218387-12-00/F confirms that the alternative source of propan-2-ol is considered technically equivalent compared to the reference source.

2.1.2.6 Information on the substance(s) of concern

There are no substances of concern or endocrine disruptors identified in the BPF.

2.1.2.7 Type of formulation

XX – Others, ready to use wipes AE - Aerosol Dispenser AL - Liquid (Trigger Spray, Pour on, Automatic Dispenser)

2.1.3 Hazard and precautionary statements

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

Meta SPC 1 - Wipes

Classification	
Hazard category	Flam. Liq. 2 Eye Irrit. 2 STOT SE3
Hazard statement	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking.

Labelling	
Signal words	Danger
Hazard statements	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 Avoid breathing vapours. P264 Wash … thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/doctor/… if you feel unwell. P337+P313 If eye irritation persists: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Propan-2-ol contributes to H336 and should appear on the label according to Art 18(3) of the CLP. Although it is recommended for products with H336, P271 is not prescribed. The BPF is specifically used in cleanrooms, which are already well-ventilated environments.

Meta SPC 2 – Aerosols (propellant)

Classification	
Hazard category	Aerosol 1 Eye Irrit. 2 STOT SE3
Hazard statement	H222 Extremely flammable aerosol H229 Pressurised container; may burst if heated H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking
Labelling	
Signal words	Danger

Hazard statements	H222 Extremely flammable aerosol H229 Pressurised container; may burst if heated H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignitions sources. No smoking. P211 Do not spray on an open flame or other ignition. P251 Do not pierce or burn even after use. P261 Avoid breathing vapours. P264 Wash … thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/doctor/… if you feel unwell. P337+P313 If eye irritation persists: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122° F P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Propan-2-ol contributes to H336 and should appear on the label according to Art 18(3) of the CLP. Although it is recommended for products with H336, P271 is not prescribed. The BPF is specifically used in cleanrooms, which are already well-ventilated environments.

Meta SPC 3 - Spray

Classification	
Hazard category	Flam. Liq. 2 Eye Irrit. 2 STOT SE3
Hazard statement	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking
Labelling	
Signal words	Danger

Hazard statements	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapours/spray. P264 Wash … thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/doctor/… if you feel unwell. P337+P313 If eye irritation persists: Get medical advice/attention. P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Propan-2-ol contributes to H336 and should appear on the label according to Art 18(3) of the CLP. Although it is recommended for products with H336, P271 is not prescribed. The BPF is specifically used in cleanrooms, which are already well-ventilated environments.

Meta SPC 4 – Aerosols (invertaspray)

Classification	
Hazard category	Aerosol 1 Eye Irrit. 2 STOT SE3
Hazard statement	H222 Extremely flammable aerosol H229 Pressurised container; may burst if heated H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking
Labelling	
Signal words	Danger
Hazard statements	H222 Extremely flammable aerosol H229 Pressurised container; may burst if heated H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking

Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignitions sources. No smoking. P211 Do not spray on an open flame or other ignition. P251 Do not pierce or burn even after use. P261 Avoid breathing vapours. P264 Wash … thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/doctor/… if you feel unwell. P337+P313 If eye irritation persists: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122° F P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Propan-2-ol contributes to H336 and should appear on the label according to Art 18(3) of the CLP. Although it is recommended for products with H336, P271 is not prescribed. The BPF is specifically used in cleanrooms, which are already well-ventilated environments.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Meta SPC 1

Table 1. Use # 1.1 – Disinfection of hard non-porous surfaces; Wipes (individual wipes and multi-pack wipes)

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant wipe for use in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities for the disinfection of hard non-

	porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.
Application method(s)	Wiping of surfaces
Application rate(s) and frequency	Product may be used multiple times a day, if required. Contact time: 2 min Individual wipe: 15.2 x 15.2cm wipe - 4 wipes per m^2 30.5 x 30.5 cm wipe - 1 wipes per m^2 45.7 x 45.7cm wipe - 1 wipes per m^2 Multi pack wipe: 30.5cm x 30.5cm - 1 wipes per m^2
Category(ies) of users	Industrial
Pack sizes and packaging material	Pre-saturated 70% (v/v) propan-2-ol and water for injection (WFI) wipes. *Individual wipes* Wipe is composed of 100% continuous filament polyester fibre. The wipes are packaged in individual heat-sealed plastic bags made of low density polyethylene. Pack sizes are detailed below: 15.2cm x 15.2cm wipe - 100/case, Non- Sterile 15.2cm x 15.2cm wipe - 100/case, Sterile 30.5cm x 30.5cm wipe - 100/case, Sterile 45.7cm x 45.7cm wipe - 100/case, Sterile *Multi pack wipes* Wipe is composed of 100% continuous filament knitted polyester fibre; 20 wipes per pack; folded together in a re-closable bag package. Pack sizes are detailed below: 100% polyester 30.5cm x 30.5cm wipe - 200/case, Non-sterile 100% polyester 30.5cm x 30.5cm wipe - 200/case, Sterile

2.1.4.2 Use-specific instructions for use

Use product only in cleanrooms which are classified according to ISO 14644-1 in class 1 to 9 or according to GMP EU classification in Grade A to D. Pre-clean and dry surfaces prior to disinfection. Only use wet wipes. Remove one or two wipes at a time for individual wipes and one wipe at a time for multipack wipes. Make sure to wet surfaces completely. Allow to take effect for at least 2 minutes . Discard wipe after use in a closed container and for multipack wipes close the package after opening. Individual wipe:

15.2 x 15.2cm wipe - 4 wipes per m^2 30.5 x 30.5 cm wipe - 1 wipes per m^2 45.7 x 45.7cm wipe - 1 wipes per m^2 Multi pack: 30.5cm x 30.5cm - 1 wipes per m^2

2.1.4.3 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

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

See general directions for use

2.1.4.7 Use description

Meta SPC 2

Table 3. Use # 2.1 – Disinfection of hard non-porous surfaces; Aerosols (propellant)

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria, yeasts.
Field of use	Indoors. Disinfectant for use in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.

Application method(s)	Aerosol spraying on surfaces
Application rate(s) and frequency	Maximal application 35 mL/m² Product may be used multiple times a day, if required. Apply product by spraying from 15-20 cm distance for 20 seconds/m^2.Contact time: 2 min.
Category(ies) of users	Industrial
Pack sizes and packaging material	325 mL (11 oz) - aerosol can (aluminium coated on the inside with epoxy phenolic resin), nitrogen propellant

2.1.4.8 Use-specific instructions for use

Pre-clean and dry surfaces prior to disinfection. Spray the surface to be disinfected from a distance of 15-20 cm away. Thoroughly wet surface for 20 seconds/m^2, make sure to wet surfaces completely. Allow to take effect for at least 2 minutes . After the required contact time has been achieved, allow surface to air dry or wipe dry with sterilised cloth or wipe. Clothes or wipes treated with the product must be discarded in a closable container.

2.1.4.9 Use-specific risk mitigation measures

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

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

See general directions for use

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

Empty containers may be discharged as normal waste or recycled where possible.

Additional information: Handle empty containers with care because residual vapours are flammable.

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

See general directions for use

2.1.4.13 Use description

Meta SPC 3

Table 4. Use # 3.1 – Disinfection of hard non-porous surfaces; Trigger Spray, Liquid

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts.
Field of use	Indoors. Disinfectant for use in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.
Application method(s)	Trigger spraying on surfaces
Application rate(s) and frequency	Maximal application 35 mL/m² Product may be used multiple times a day, if required. Apply product by spraying from 15-20 cm distance. Use 40 squeezes / m^2. Contact time: 2 min.
Category(ies) of users	Industrial
Pack sizes and packaging material	*Trigger:* 473 mL (16 oz) - trigger spray - 12/case, sterile 946 mL (32 oz) - trigger spray - 12/case, sterile 473 mL (16 oz) - trigger spray - 12/case, non-sterile 946 mL (32 oz) - trigger spray - 12/case, non-sterile Bottles are made of high density polyethylene, the dip tube is polypropylene. The bottle cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer already on the bottle or provided separately for customer to put on themselves. If triggers are requested not installed, a polyethylene screw cap is supplied on the bottles. Bottles are individually triple bagged in cardboard boxes. Distributors distribute sealed cases, not individual bottles. *Bag in bottle- Trigger:* 500 mL – Bag in bottle trigger spray - 12/case, sterile 1000 mL (32 oz) - Bag in bottle trigger spray - 12/case, sterile Bottles are made of high density polyethylene, they provided with a polyethylene sprayer already on the bottle, the dip tube is polypropylene. The bag inside the bottle is Surlyn®

	(thermoplastic resins). Bottles are individually triple bagged in cardboard boxes. Distributors distribute sealed cases, not individual bottles.

2.1.4.14 Use-specific instructions for use

Pre-clean and dry surfaces prior to disinfection. Direct the spray onto the surface from a distance of 15-20cm away. Make sure to wet surfaces completely (40 squeezes / m^2). Allow to take effect for at least 2 minutes. After the required contact time has been achieved, allow surface to air dry or wipe dry with sterilised cloth or wipe, if necessary. Only small surfaces may be disinfected. Clothes or wipes treated with the product must be discarded in a closable container.

2.1.4.15 Use-specific risk mitigation measures

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

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

See general directions for use

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

Empty containers may be discharged as normal waste or recycled where possible. Additional information: Handle empty containers with care because residual vapours are flammable. Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

See general directions for use

Table 5. Use #3.2– Disinfection of hard non-porous surfaces (including floors); Wiping,

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	

Target organism (including development stage)	Bacteria, yeasts.
Field of use	Indoors. Disinfectant for use in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.
Application method(s)	Wetting of sterile wipe/cloth prior to wiping of surfaces
Application rate(s) and frequency	Maximal application 35 mL/m² Product may be used multiple times a day, if required. Contact time: 2 min.
Category(ies) of users	Industrial
Pack sizes and packaging material	*Squeeze bottle:* 473 mL (16 oz) – squeeze individually bagged- 12/case, sterile 473 mL (16 oz) – squeeze, bulk group in one large bag – 12/case, sterile. Bulk pack bottles are not individually bagged. Bottle is made of low density polyethylene *Drum or bottle:* 18.9 L (5 gallon drum) - container double bagged- 1/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, non-sterile Containers made of high density polyethylene

2.1.4.19 Use-specific instructions for use

Pre-clean and dry surfaces prior to disinfection. Thoroughly wet a sterile wipe/cloth with the product, make sure to wet surfaces completely. Allow to take effect for at least 2 minutes. After the required contact time has been achieved, allow surface to air dry or wipe dry with sterilised cloth or wipe, if necessary. Only small surfaces may be disinfected. Clothes or wipes treated with the product must be discarded in a closable container.

2.1.4.20 Use-specific risk mitigation measures

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

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

See general directions for use

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

Empty containers may be discharged as normal waste or recycled where possible. Additional information: Handle empty containers with care because residual vapours are flammable. Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

See general directions for use

Table 6. Use # 3.3 – Disinfection of cleanroom gloves

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant for use on non-porous gloves on hands in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Dispensing of liquid droplets on gloves
Application rate(s) and frequency	1.5 mL per glove Product may be used multiple times a day, if required. Contact time: 1 min.
Category(ies) of users	Industrial
Pack sizes and packaging material	946 mL (32 oz) bottle - 12/case, sterile 946 mL (32 oz) bottle - 12/case, non-sterile The bottle is low density polyethylene.

2.1.4.24 Use-specific instructions for use

Use product only in cleanrooms which are classified according to ISO 14644-1 in class 1 to 9 or according to GMP EU classification in Grade A to D. Hold gloved hands under spout sensor to catch liquid. Thoroughly rub to distribute liquid evenly and wet clean glove surfaces with product. Do not wipe off and allow to remain wet for a minimum of 1 minute. After the required contact time has been achieved, allow surface to air dry or wipe dry with sterilised cloth or wipe, if necessary. Clothes or wipes treated with the product must be discarded in a closable container. Do not use on bare hands.

2.1.4.25 Use-specific risk mitigation measures

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

2.1.4.26 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

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

Empty containers may be discharged as normal waste or recycled where possible. Additional information: Handle empty containers with care because residual vapours are flammable. Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

See general directions for use

2.1.4.29 Use description

Meta SPC 4

Table 7. Use # 4.1 – Disinfection of hard non-porous surfaces; Aerosols

Product Type	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals.

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant for use in manufacturing facilities including cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industry for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.
Application method(s)	Aerosol spraying on surface
Application rate(s) and frequency	Maximal application 35 mL/m² Product may be used multiple times a day, if required. Apply product by spraying from 15-20 cm distance for 20 seconds/m^2. Contact time: 2 min.
Category(ies) of users	Industrial
Pack sizes and packaging material	325 mL (11 oz) – Inverta-Spray® mist spray Aluminium coated inside with epoxy phenolic resin fitted with low density polyethylene bag liner (bag-on-valve), compressed air propellant.

2.1.4.30 Use-specific instructions for use

Pre-clean and dry surfaces prior to disinfection. Spray the surface to be disinfected from a distance of 15-20 cm away. Thoroughly wet surface for 20 seconds/m^2, make sure to wet surfaces completely. Allow to take effect for at least 2 minutes. After the required contact time has been achieved, allow surface to air dry or wipe dry with sterilised cloth or wipe. Clothes or wipes treated with the product must be discarded in a closable container.

2.1.4.31 Use-specific risk mitigation measures

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

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

See general directions for use

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

Empty containers may be discharged as normal waste or recycled where possible.

Additional information: Handle empty containers with care because residual vapours are flammable.

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

See general directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

See Use-specific instructions for use.

2.1.5.2 Risk mitigation measures

Use with adequate ventilation with an air change rate of 8 per hour or more.
Apply away from eyes and face.

Hand protection: Wear chemically resistant protective gloves.
Eye protection: Wear eye protection.

Avoid contact with eyes.
Do not breathe vapours.
Do not eat, drink or smoke when using this product.
Wash hands thoroughly after handling.

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

Symptoms/injuries after inhalation : May cause drowsiness or dizziness
Symptoms/injuries after skin contact: Repeated and/or prolonged skin contact may cause irritation, dryness or cracking.
Symptoms/injuries after eye contact: Causes serious eye irritation
Symptoms/injuries after ingestion: Symptoms reported in humans are nausea and vomiting due to local irritation and systemic effects like drunkenness, drowsiness, sometimes unconciousness and low blood sugar (especially in children). But according to the type of formulations (wipes, aerosol and spray) the systemic effects are less likely.
First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

Call a POISON CENTRE or a doctor.IF ON SKIN: Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Gently wash with plenty of soap and water. If symptoms develop, obtain medical attention.
IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor IF SWALLOWED: Rinse mouth. Give something to drink if conscious. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers may be discharged as normal waste or recycled where possible.
Additional information: Handle empty containers with care because residual vapours are flammable.
Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

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

Keep in a cool, well-ventilated place.
Keep away from open flames, hot surfaces and sources of ignition.
Protect from frost

Store at temperatures below 30°C (meta SPC1).

Store at temperatures below 40°C (meta SPCs 2, 3 and 4).

Shelf-life = 2 years

2.1.6 Other information

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129.28 mg/m³ for the professional user was agreed and used for the risk assessment of this product.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
ALCOH-WIPE® - Meta 1					
Plastic bag containing pre-saturated wipes. Wipe is composed	15.2cm x 15.2cm wipe - 100/case, Non- Sterile 15.2cm x 15.2cm wipe - 100/case, Sterile	Low density polyethylene	Heat sealed	Industrial	Yes

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)
of 100% continuous filament polyester fibre.	30.5cm x 30.5cm wipe - 100/case, Sterile 45.7cm x 45.7cm wipe - 100/case, Sterile Wipes are individually packaged				
PROCESS2WIPE® IPA 70 – Meta 1					
Plastic bag containing pre-saturated wipes. Bag is re-closable between uses. Wipe is composed of 100% continuous filament knitted polyester fibre.	30.5cm x 30.5cm 20 wipes per pack 200/case,Non-sterile 200/case,Sterile Wipes contain on average 13.8 g product (see Section 2.2.2)	Low density polyethylene	Re-closable bag. Closure is a peel open panel with an adhesive around the opening to permit resealing the package between uses.	Industrial	Yes
DEC-AHOL® AEROSOL WFI Formula – Meta 2					
Aerosol standard can. The propellant is nitrogen under pressure inside the can along with the product. When the nozzle is depressed the nitrogen pressure expels the product	325 mL (11 oz) - Mist spray, sterile Cans are individually triple bagged and shipped in cardboard boxes (24 per box). Distributors distribute sealed cases, not individual cans	Aluminium coated inside with epoxy phenolic resin (baked on) and painted outside.	The nozzles are high density polyethylene sitting on a nylon splined (molded) valve stem held together by a mounting cup of aluminum with a gasket made of BUNA that is crimped	Industrial	Yes

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)
through the dip tube and out through the nozzle.			onto the can opening. The dip tube is linear low density polypropylene.		
DEC-AHOL® WFI Formula – Meta 3					
Squeeze bottle	473 mL (16 oz) – squeeze individually bagged- 12/case, sterile 473 mL (16 oz) – squeeze, bulk group in one large bag – 12/case, sterile. Bulk pack bottles are not individually bagged	Bottle is made of low density polyethylene with a polypropylene dip tube that is closed at the end by a press-on cap	The closure is polypropylene moulded with screw threads.	Industrial	Yes
Drum	18.9 L (5 gallon drum) - container double bagged- 1/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, non-sterile. Distributors distribute sealed cases, not individual containers. Customers may request triple bags, if desired.	High density polyethylene with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge.	Polypropylene screw cap with liner covers the pouring opening. All bottle caps are screw caps and able to be re-applied onto the bottle.	Industrial	Yes
Trigger spray	473 mL (16 oz) - trigger spray -	High density polyethylene	The bottle cap is	Industrial	Yes

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)
	12/case, sterile 946 mL (32 oz) - trigger spray - 12/case, sterile 473 mL (16 oz) - trigger spray - 12/case, non-sterile 946 mL (32 oz) - trigger spray - 12/case, non-sterile Bottles are individually triple bagged in cardboard boxes. Distributors distribute sealed cases, not individual bottles.	, the dip tube is polypropylene.	polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer already on the bottle or provided separately for customer to put on themselves. If triggers are requested not installed, a polyethylene screw cap is supplied on the bottles.		
Bag in bottle- Trigger spray	500 mL - bag in bottle trigger spray 1 Liter- bag in bottle trigger spray	High density polyethylene or polypropylene, the dip tube is polypropylene, the bag is Surlyn® (thermoplastic resins)*	Bottles are provided with a polyethylene sprayer. The dip tube is polypropylen and the bag inside the bottle is Surlyn® (thermoplastic resins)	Industrial	Yes
DEC-AHOL® ASEPTI-CLEANSE – Meta 3					
Bottle	946 mL (32 oz)	Bottle is low	The	Industrial	Yes

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)
(automatic dispenser) This bottle contains a small molded internal dip tube whose sole function is to supply the pump with a constant flow of product once the fluid level falls below the intake. This bottle collapses as the product is pumped out of it.	bottle - 12/case, sterile 946 mL (32 oz) bottle - 12/case, non-sterile	density polyethylene	cover/lid (over the dispensing head) is polypropylene moulded. The nozzle and collar are polypropylene moulded to fit securely into the pump dispensing assembly. The dip tube is polypropylene.		
DEC-AHOL® AEROSOL WFI Formula Invertaspray – Meta 4					
Aerosol Inverta-spray® can. The product is filled into the can and the nozzle seals the can. The bag is surrounded in the can by air pressure. The pressure exerted on the bag pushes the product through the nozzle when it is depressed.	325 mL (11 oz) – mist spray, sterile. Cans are individually triple bagged and shipped in cardboard boxes (24 per box). Distributors distribute sealed cases, not individual cans	Aluminium coated inside with epoxy phenolic resin (baked on) and painted outside. The inside is fitted with low density polyethylene bag liner.	The nozzles are high density polyethylene sitting on a nylon splined (moulded) valve stem held together by a mounting cup of aluminium with a gasket made of BUNA that is crimped onto the can opening.	Industrial	Yes

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)
Air never comes out. The product is never in contact with the inside of the aluminium can.					

* Surlyn is a polyethylene/polymethacrylic acid copolymer. The methacrylic acid moieties are partly neturalized with zinc or sodium.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A reference list is presented in Annex 3.1.

2.1.8.2 Access to documentation

The applicant is a member of the ASD Consortia Propan-2-ol and has full access to the data available on the active substance, propan-2-ol ol. The applicant is listed on Art. 95 as an approved product supplier for biocide products containing propan-2-ol.

2.1.8.3 Similar conditions of use

Not applicable

2.2 Assessment of the biocidal product family

2.2.1 Intended uses as applied for by the applicant

Table 8. Use # 1 – Individual Wipes (Meta SPC 1)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant wipe for use in cleanroom areas of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Wiping
Application rate(s) and frequency	7 mL/m² Product is used as required which may be multiple times a day
Category(ies) of users	Industrial
Pack sizes and packaging material	Pre-saturated 70% IPA and water for injection (WFI) wipes that is individually packaged. Wipe is composed of 100% continuous filament polyester fibre. The wipes are packaged in individual heat-sealed plastic bags made of low density polyethylene. Pack sizes are detailed below: 15.2cm x 15.2cm wipe - 100/case, Non- Sterile 15.2cm x 15.2cm wipe - 100/case, Sterile 30.5cm x 30.5cm wipe - 100/case, Sterile 45.7cm x 45.7cm wipe - 100/case, Sterile

Table 9. Use # 2 – Multipack Wipes (Meta SPC 1)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant wipe for use in cleanroom areas of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Wiping
Application rate(s) and frequency	7 mL/m² Product is used as required which may be multiple times a day

Category(ies) of users	Industrial
Pack sizes and packaging material	Wipes are ready-to-use, saturated with 70% IPA and water for injection (WFI) wipes. Wipe is composed of 100% continuous filament knitted polyester fibre; 20 wipes per pack; folded together in a re-closable bag package. The closure is a peel open panel with an adhesive around the opening to permit re-sealing the package between uses. The pouch style bag has a filling port to add the IPA. This is only used for production to fill the product liquid and is not intended for any other purpose. Pack sizes are detailed below: 100% polyester 30.5cm x 30.5cm wipe - 200/case, Non-sterile 100% polyester 30.5cm x 30.5cm wipe - 200/case, Sterile

Table 10. Use # 3 – Aerosols (propellant) (Meta SPC 2)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant for use in manufacturing facilities including cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.
Application method(s)	Spraying
Application rate(s) and frequency	35 mL/m²
Category(ies) of users	Industrial
Pack sizes and packaging material	325 mL (11 oz) - Mist spray - 24/case, sterile Packaging materials: Aluminium coated inside with epoxy phenolic resin (baked on) and painted outside. The nozzles are high density polyethylene sitting on a nylon splined (moulded) valve stem held together by a mounting cup of aluminium with a gasket made of BUNA that is crimped onto the can opening. The propellant is nitrogen under pressure inside the can along with the product. When the nozzle is depressed the nitrogen pressure expels the product through the dip tube and out through the nozzle. The dip tube is linear low density polypropylene. Cans are triple bagged and shipped in cardboard boxes (24 per box). Distributors distribute sealed cases, not individual cans.

Table 11. Use # 4 – Trigger Spray (Meta SPC 3)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoors. Disinfectant for use in manufacturing facilities including cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.
Application method(s)	Spray
Application rate(s) and frequency	35 mL/m²
Category(ies) of users	Industrial
Pack sizes and packaging material	***Trigger:*** 473 mL (16 oz) - trigger spray - 12/case, sterile 946 mL (32 oz) - trigger spray - 12/case, sterile 473 mL (16 oz) - trigger spray - 12/case, non-sterile 946 mL (32 oz) - trigger spray - 12/case, non-sterile Bottles are made of high density polyethylene, the dip tube is polypropylene. The bottle cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer already on the bottle or provided separately for customer to put on themselves. If triggers are requested not installed, a polyethylene screw cap is supplied on the bottles. Bottles are individually triple bagged in cardboard boxes. Distributors distribute sealed cases, not individual bottles.

Table 12. Use # 5 – Squeeze bottle and Drum (Meta SPC 3)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces (including floors), materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, yeasts.
Field of use	Indoors. Disinfectant for use in manufacturing facilities including cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.
Application method(s)	Wetting of sterile wipe/cloth prior to wiping.
Application rate(s) and frequency	35 mL/m²
Category(ies) of users	Industrial

Pack sizes and packaging material	***Squeeze bottle:*** 473 mL (16 oz) – squeeze individually bagged- 12/case, sterile 473 mL (16 oz) – squeeze, bulk group in one large bag – 12/case, sterile Bulk pack bottles are not individually bagged. Bottle is made of low density polyethylene with a polypropylene dip tube that is closed at the end by a press-on cap. The closure is polypropylene molded with screw threads. Bottles are triple bagged in cardboard boxes. Distributors distribute sealed cases, not individual bottles. ***Drum and bottle:*** 18.9 L (5 gallon drum) - container double bagged- 1/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, sterile 3.79 L (1 gallon bottle) – each container double bagged- 4/case, non-sterile Containers made of high density polyethylene with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge. Polypropylene screw cap with liner covers the pouring opening. All bottle caps are screw caps and able to be re-applied onto the bottle. Distributors distribute sealed cases, not individual containers. Customers may request triple bags, if desired.

Table 13. Use # 6 – Liquid Dispenser (Meta SPC 3)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of cleanroom gloves
Target organism (including development stage)	Bactericidal and yeasticidal
Field of use	Indoors. Disinfectant for use on gloved hands in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Dispenser of liquid droplets
Application rate(s) and frequency	1 mL per glove
Category(ies) of users	Industrial
Pack sizes and packaging material	946 mL (32 oz) bottle - 12/case, sterile 946 mL (32 oz) bottle - 12/case, non-sterile The bottle is low density polyethylene. It is designed to fit for a specific machine that must be purchased separately. The cover/lid (over the dispensing head) is polypropylene moulded. The nozzle and collar are polypropylene moulded to fit securely into the pump dispensing assembly. It is a simple 'drop in' to place it into the machine. This bottle

	contains a small moulded internal dip tube whose sole function is to supply the pump with a constant flow of product once the fluid level falls below the intake. The dip tube aligns to the end of the pump assembly upon insertion. The dip tube is polypropylene. This bottle collapses as the product is pumped out of it.

Table 14. Use # 7 – Aerosol (invertaspray) (Meta SPC 4)

Product Type	Product type 2; disinfectant
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bactericidal, yeasticidal and fungicidal
Field of use	Indoors. Disinfectant for use in manufacturing facilities including cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.
Application method(s)	Spraying
Application rate(s) and frequency	35 mL/m²
Category(ies) of users	Industrial
Pack sizes and packaging material	325 mL (11 oz) – Inverta-Spray® mist spray -24 / case, sterile Aluminium coated inside with epoxy phenolic resin (baked on) and painted outside. The inside is fitted with low density polyethylene bag liner. The product is filled into the can and the nozzle seals the can. The bag is surrounded in the can by air pressure. The pressure exerted on the bag pushes the product through the nozzle when it is depressed. Air never comes out. The product is never in contact with the inside of the aluminium can. The nozzles are high density polyethylene sitting on a nylon splined (moulded) valve stem held together by a mounting cup of aluminium with a gasket made of BUNA that is crimped onto the can opening. Cans are individually triple bagged and shipped in cardboard boxes (24 per box). Distributors distribute sealed cases, not individual cans.

2.2.2 Physical, chemical and technical properties

Meta SPC 1 contains wipes, *meta* SPC 2 the aerosol, *meta* SPC 3 the AL formulations and *meta* SPC 4 the bag-on-valve spray.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Guideline not listed	Wipes 'PROCESS2 WIPE IPA 70'; 71% v/v propan-2-ol (measured)	Polyester wipes wetted with an 70% IPA/water solution. Testing supports meta 1.	[redacted], 2016/187 AM, key study
		Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	Transparent liquidTesting supports metas 2 & 4.	[redacted], 2016/188 AM, key study
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	Transparent liquid. Testing supports meta 3.	[redacted], 2016/189 AM, key study [redacted], 2016/186 AM, key study
		Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol (nominal)	Transparent fluid. Testing supports meta 3.	[redacted], 2009, Vel-2009-004, supporting study
Colour at 20 °C and 101.3 kPa	Guideline not listed	Wipes 'PROCESS2 WIPE IPA 70'; 71% v/v propan-2-ol (measured)	Clear, colourless. Testing supports meta 1	[redacted], 2016/187 AM, key study
		Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	Clear, colourless. Testing supports metas 2 & 4.	[redacted], 2016/188 AM, key study
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	Clear, colourless. Testing supports meta 3.	[redacted], 2016/189 AM, key study [redacted], 2016/186 AM, key study
		Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol (nominal)	Clear, colourless. Testing supports meta 3.	[redacted], Vel-2009-004, supporting study
Odour at 20 °C and	-	70% v/v propan-	Not determined	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
101.3 kPa		2-ol	for any formulation.	
	eCA remark: The applicant proposed P261 (Avoid breathing dust/fume/gas/mist/vapours/spray.). This was accepted as waiver (see BPR guidance).			
Acidity / alkalinity	-	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol (nominal)	The pH of solution contained on/in this wipe product would be expected to have the same pH as the liquid 'DECON-AHOL 70% WFI' product, since both products feature only 70% v/v propan-2-ol/water mixtures. Thus pH testing on 'DECON-AHOL 70% WFI' can be used to support the registration of this formulation.	-
	CIPAC MT 75.3	Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	pH=6.20 (1%, 20.0 °C). Testing supports metas 2 & 4.	[redacted], 2016/188 AM, key study
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	pH=6.1 (1%, 20.0 °C). Testing supports metas 1 & 3.	[redacted], 2016/189 AM, key study [redacted], 2016/186 AM, key study
	EPA OPPTS 830.7000. Whilst the preferred method – CIPAC MT 75.3 – was not used, this method is considered essentially	Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol (nominal)	pH= 5.8 (100%, 20 °C). Testing supports metas 1 & 3.	[redacted], VEL-2009-002, supporting study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	identical to the CIPAC method, and therefore testing valid.			
Relative density	-	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol (nominal)	The relative density of the liquid contained on / in this product would be expected to be the same as the 'DECON-AHOL 70% WFI' since both are 70% v/v IPA/water solutions. Thus testing on 'DECON-AHOL 70% WFI' can be used to support the registration of this formulation.	-
	OECD 109 (capillary stoppered pycnometer)	Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	0.8748 at 20 °C. Testing supports metas 2 & 4.	[redacted], 2016/188 AM, key study
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	0.8710 at 20 °C.. Testing supports metas 1 & 3.	[redacted], 2016/189 AM, key study [redacted], 2016/186 AM, key study
	EPA OPPTS 830.7300. Whilst this is not the preferred method, this method is considered valid for determining this property.	Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol (nominal)	0.87 g/mL at 21.4 °C. Testing supports metas 1 & 3.	[redacted], VEL-2009-002, supporting study
Storage stability test – **accelerated storage**	eCA remarks: Results from different storage stability studies can be found in tables below this one. The evaluation of these studies and how these studies can be used to support the different *meta*			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	SPCs can be found at page 57.			
	CIPAC MT 46.3	Liquid 'DEC-AHOL WFI FORMULA'; 70% v/v propan-2-ol (measured)	Stored in LDPE at 30°C for 18 weeks. Tested parameters: Appearance of test item, appearance of packaging, weight loss, pH, relative density, a.s. content. The test item and packaging was determined not to undergo any significant physical change following storage. Please see Table 2.2.2a for results. Testing supports metas 1, 2, 3 & 4.	[redacted], 2016/189 AM, key study
		Liquid 'DEC-AHOL 70% WFI FORMULA'; 71% v/v (measured) & Aerosol 'DECON-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	Stored as trigger spray and aluminium aerosol spray can at 40°C for 8 weeks. Tested parameter: a.s. content. No significant reduction in propan-2-ol content following storage. Please see Table 2.2.2b for results. Testing supports metas 1, 2, 3 & 4.	[redacted], VAI LAB-2016-004-78, supporting study
	eCA remark: Weight change of the aerosol bottles was not measured. Since long-term storage stability studies are available in which weight change is small, this is acceptable.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	SOP (comparable to CIPAC MT46)	Liquid 'DECON-AHOL 70%' and 'DEC-AHOL 70%'; 71% v/v propan-2-ol (measured, HDPE containers); 70% v/v propan-2-ol (measured, aersol).	Stored in HDPE and aluminium can at 40°C for 24 weeks. Tested parameters: Appearance of packaging, a.s. content. HDPE containers IPA content: Initial 70.80% v/v 8 weeks 71.74% v/v 24 weeks 71.46% v/v Alu. containers IPA content: Initial 69.80% v/v 8 weeks 71.19% v/v 24 weeks 70.33% v/v All containers were stable after storage. Testing supports metas 2, 3 & 4.	[redacted], SS19062018, key study
	CIPAC MT46	Dec-Ahol 70% bag-in-bottle (16 and 32oz). Lots SAMPLE100418A SAMPLE100418B SAMPLE110418C Bag in bottle: PP with surlyn resin internal bag and spray attachment. 70% v/v propan-2-ol (nominal).	Stored in irradiated (sterile) bag-in-bottle (see 2.1.7 for description of materials) for 24 weeks at 40°C. Tested parameters: appearance and appearance of packaging, a.s. content, density, acidity. Assay method:	[redacted] Study no JR050572019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			GC-FID *32oz bottle sample A* Initial: Colourless, clear, transparant Packaging normal 68.8% v/v IPA 0.014% H_2SO_4 0.874 g/mL After 24 weeks Colourless, clear, transparant Packaging normal 70.05% v/v IPA 0.020% H_2SO_4 0.873 g/mL 32oz bottle sample B Initial: Colourless, clear, transparant Packaging normal 70.9% v/v IPA 0.016% H_2SO_4 0.874 g/mL After 24 weeks Colourless, clear, transparant Packaging normal 71.3% v/v IPA 0.016% H_2SO_4 0.873 g/mL 32oz bottle sample C Initial: Colourless, clear, transparant Packaging normal 71.2% v/v IPA 0.014% H_2SO_4 0.873 g/mL	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 24 weeks Colourless, clear, transparant Packaging normal 71.1% v/v IPA 0.016% H_2SO_4 0.872 g/mL 16oz bottle Sample A Initial: Colourless, clear, transparant Packaging normal 71.3% v/v IPA 0.014% H_2SO_4 0.874 g/mL After 24 weeks Colourless, clear, transparant Packaging normal 70.7% v/v IPA 0.018% H_2SO_4 0.874 g/mL 16oz bottle Sample B Initial: Colourless, clear, transparant Packaging normal 71.0% v/v IPA 0.014% H_2SO_4 0.874 g/mL After 24 weeks Colourless, clear, transparant Packaging normal 71.2% v/v IPA 0.020% H_2SO_4 0.873 g/mL 16oz bottle Sample C	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Initial: Colourless, clear, transparant Packaging normal 71.4% v/v IPA 0.014% H_2SO_4 0.873 g/mL After 24 weeks Colourless, clear, transparant Packaging normal 70.6% v/v IPA 0.018% H_2SO_4 0.874 g/mL	
		eCA remark The study report indicates the pH was determined as part of the acidity determination, but the data was not included in the study report. Not all test methods were described in detail. The report refers to internal SOPs of the lab which were not provided for the density determination. The acidity was determined by titration using 0.02N NaOH and titrating to a pH of 8.5. The analytical method used for the determination of the IPA content is a GC-FID method using an SP-1000 packed column of approx. 2.4m. The method is not exactly the same as reported in 2.2.4, but uses the same principles. Due to the simple composition of the product, the method is expected to produce sufficiently reliable results to allow this study to be used. The spray characteristics were determined in a separate study (see below), but only after storage.		
		Dec-Ahol 70% bag-in-bottle (16 and 32oz). Lots SAMPLE100418A SAMPLE100418B SAMPLE110418C Bag in bottle: PP with surlyn resin internal bag and spray	After storage for 24 weeks at 40°C tested samples had the following spray characteristics: 32oz bottle: Discharge rate: 0.8814 – 1.0708 g per operation	[redacted] Study no GS29042019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		attachment. 70% v/v propan-2-ol (nominal).	Spray diameter at 20cm distance: 11.75 – 19.5 cm (109.36 – 290.65 cm^2 even coverage). No leakage, blockage or clogging. 16oz bottle: Discharge rate: 0.8888 – 0.8940 g per operation Spray diameter at 20cm distance: 11.25 – 14.5 cm (99.4 – 165.13 cm^2 even coverage). No leakage, blockage or clogging.	
		eCA remark Within the dataset for the 32oz bottles, one bottle shows a spray pattern which is not consistent with the other two samples. The discharge rate of all samples is comparable however and as the product only requires to wet the surface to be disinfected, the spray pattern is not considered an issue, especially as the report indicates the spray is evenly distributed over the surface. As no data is available on fresh samples, it is not possible to conclude there is no difference before and after storage. However, it is possible to conclude aged samples have acceptable spray characteristics.		
Storage stability test – **long term storage at ambient temperature**	ECHA "Guidance on the Biocidal Products Regulation" Volume I: Identity/physico-chemical	Wipes 'PROCESS2 WIPE IPA 70'; 71% v/v propan-2-ol (measured)	Plastic bag containing pre-satured polyester wipes stored at 25°. Tested parameters: Appearance of test item,	[redacted], 2016/187 AM, key study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	properties/analytical methodology y – Part A: Information Requirements, Version 1.1, November 2014.		appearance of packaging, weight loss Currently within specification – for interim results up to 24 months, see Table 2.2.2c. The study has been extended via amendment to last 36 months. The presence of an inert polyester matrix (the wipe) is not be expected to affect other applicable properties – i.e. propan-2-ol content & pH – so this data should be read-across from study 'C. Belussi, 2019, 2016/186 AM' on the liquid formula – see Table 2.2.2e for interim results.	
		Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol (measured)	Stored in at 25°C in coated aluminium aerosol can. Tested parameters: Appearance of test item, appearance of packaging, weight loss, pH, relative density, a.s. content. Additional parameters at t=0 and t=36 months:	[redacted], 2016/188 AM, key study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Spray and stream character, spray rate, valve clogging, can pressure at 20°C and 50°C. Currently within specification – for interim results up to 24 months, see Table 2.2.2d.	
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	White HDPE plastic bottle with spray trigger stored at 25°. Tested parameters: Appearance of test item, appearance of packaging, weight loss, pH, relative density, a.s. content. Additional parameters at t=0 and t=36 months: Spray and stream character, spray rate, valve clogging Currently within specification – for interim results up to 24 months see Table 2.2.2e.	[redacted], 2016/186 AM, key study
	Not listed	Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol (nominal)	Stored in commercial packaging at ambient temperature for 35.8 months Tested parameters: Appearance of the	[redacted], Vel-2009-004, supporting study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			test item, density, a.s. content, non-volatile residues. See Table 2.2.2f for results.	
		eCA remark: this study is not signed, the a.s. content is measured using a non-validated method and the packaging material is not provided. The results are therefore not used for evaluation.		
Determination of Evaporation (opening and removal effects), Average Wipe Liquid Content, Assay (during use period), Squeezable Liquid and Surface Drying Time During Simulated Use Period	No guidance available	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol (nominal)	Effect of evaporation of product during simulated use (opening the package 10 s every day for 20 work days): No significant weight loss due to evaporation -effect of removal of wipes on evaporation of the product from the package when one wipe is removed every day until the package is empty: Total evaporation 5.5 gram -a.s. content of the liquid squeezed from these wipes and amount of liquid contained in these wipes: Propan-2-ol content: 68.45-71.92%v/v. The distribution of propan-2-ol in the package tended to be less toward	[redacted], VAI LAB-2016-05-25, key study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the top of the stack and more toward the bottom Average amount of liquid per wipe: 13.8 g -Evaporation time for product squeezed from wipes, measured 15 times. 6-29s. Packaging seal keeps integrity after repeated use and propan-2-ol was not lost during use. The wipes delivered the product to the intended target without spreading to unintended locations and the product evaporated as intended. Testing supports meta 1.	
Determination of active substance content	No guidance available	Wipes 'PROCESS2 WIPE IPA 70'; 69% v/v propan-2-ol (measured)	Propan-2-ol content of liquid squeezed from wipe: 69.2±0.08%. Testing supports meta 1.	[redacted], S-2016-02176 AM, key study
		Wipes 'ALCOH-WIPE'; 73% v/v propan-2-ol (measured)	Propan-2-ol content of liquid squeezed from wipe: 73.0±0.03%. Testing supports meta 1.	[redacted], S-2016-02175 AM, key study
		eCA remark: The report is not signed and hence not used in the evaluation.		
Storage stability test – **low temperature**	Waiver	65% w/w	Propan-2-ol and water are fully	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
stability test for liquids			miscible at all concentrations. Neat propan-2-ol has a freezing point of around -88 °C. A 70% v/v propan-2-ol / water binary solution will have a melting point below -20 °C, consequently the product will be stable at low temperatures and testing is not required to confirm this. This waiver supports metas 1, 2, 3 & 4.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	65% w/w	As stated in the BPR assessment report, propan-2-ol does not absorb ultraviolet radiation (wavelengths above 290 nm). Consequently photolysis could not be a route of degradation of propan-2-ol, i.e. the stability of a binary propan-2-ol/water mixture will not be affected by luminous intensity. Additionally, many formulations are contained within opaque containers. This waiver supports metas 1, 2, 3 & 4.	-
Effects on content of the active substance	Waiver	65% w/w	The effect of temperature on	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and technical characteristics of the biocidal product – **temperature and humidity**			the products within this product family has been investigated as part of storage stability studies. It could not be expected that these products would be affected by humidity as they are sealed containers and have a high water content (30 %). This waiver supports metas 1, 2, 3 & 4.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	No guideline followed	Wipes 'PROCESS2 WIPE IPA 70'; 71% v/v propan-2-ol (nominal)	Study in progress. No change in appearance before & during ambient storage for 24 months. See Table 2.2.2c for results. Testing supports meta 1.	[redacted], 2016/187 AM, key study
		Aerosol 'DEC-AHOL AEROSOL'; 71% v/v propan-2-ol (measured)	Study in progress. No change in appearance before & during ambient storage for 24 months.. See Table 2.2.2d for results. Testing supports meta 2 & 4.	[redacted], 2016/186 AM, key study
		Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (measured)	No change in appearance before & after accelerated storage; No change in appearance before & during ambient storage	[redacted], 2016/189 AM, key study [redacted], 2016/186 AM, key study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			for 24 months. . See Tables 2.2.2a & 2.2.2e for results. Testing supports meta 3.	
Wettability	Not applicable for a ready to use liquid formulation			
Suspensibility, spontaneity and dispersion stability	Not applicable for a ready to use liquid formulation			
Wet sieve analysis and dry sieve test	Not applicable for a ready to use liquid formulation			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for a ready to use liquid formulation			
Disintegration time	Not applicable for a ready to use liquid formulation			
Particle size distribution, content of dust/fines, attrition, friability	MMAD trigger sprayer D10 (µm): 41 D50 (µm): 90 D90(µm): 232 After 12 weeks at 30°C D10 (µm): 37 D50 (µm): 87 D90(µm): 28			[redacted] 2020a [redacted] 2020b [redacted] 2020c
	MMAD aerosol can D10 (µm): 36 D50 (µm): 73 D90(µm): 136 After 12 weeks at 30°C D10 (µm): 35 D50 (µm): 71 D90(µm): 138 MMAD from aerosol can at decreased pressure (410 kPa) D10 (µm): 49 D50 (µm): 101 D90(µm): 212			[redacted] 2020a [redacted] 2020b [redacted] 2020c
	ECa remark: The accelerated storage conditions cannot be extrapolated to 2 years, as the products were stored for 12 weeks at 30°C, not the full 18 weeks. However, since no valve clogging is expected (given the composition of the products), this is acceptable for the trigger sprayer. The can pressure of the aerosol can only decrease during			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	storage (at constant temperature), not increase. Hence, it can be argued that the MMAD measurement at 410 kPa gives an indication of the MMAD after longer storage. A lower pressure generally results in larger droplets, which is a better case situation. As already mentioned in the PAR, valve clogging is not expected given the composition of the product. Hence, valve clogging will not influence the MMAD after storage. In our opinion it would not be of added value to request the MMAD after 18 weeks at 30°C. Therefore, the MMAD data are acceptable for the Dec-Ahol biocidal product family. More information on the MMAD can be found in the confidential annex.			
Persistent foaming	Not applicable for a ready to use liquid formulation			
Flowability/Pourability/Dustability	Not applicable for a ready to use liquid formulation			
Burning rate — smoke generators	Not applicable for a ready to use liquid formulation			
Burning completeness — smoke generators	Not applicable for a ready to use liquid formulation			
Composition of smoke — smoke generators	Not applicable for a ready to use liquid formulation			
Spraying pattern — aerosols	Spray and stream character (FEA 644); Spray rate (FEA 643); Valve clogging (FAO)	Liquid 'DEC-AHOL WFI FORMULA'; 70% v/v propan-2-ol (measured)	. <u>Initial results</u> Spray and stream character: cone like a spray,. The initial result is considered acceptable. See Table 2.2.2d for further results. Testing supports meta 2.	[redacted], 2016/188 AM, key study
Other technical characteristics: Determination of liquid content dispensed onto a surface	In-house method (VP-8045)	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol (nominal)	The volume of liquid dispensed by a pre-saturated wipe onto a hard, non-porous one square meter surface was. From six wipes tested, an average of 6.94 mL (min: 5.96mL, max: 7.36 mL) of liquid was dispensed onto	[redacted], VP-8045, key study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the surface. Therefore it can be concluded ≈7 mL of liquid will be dispensed by one wipe onto one square meter of surface during full coverage.	
Other technical characteristics: Drying times for nitrile gloves	In-house method	DEC-Ahol 70% IPA; 70% v/v propan-2-ol (nominal)	The drying times of medium-sized nitrile gloves were evaluated by visual inspection following application of the test item. To keep gloves wet for at least 60 seconds, 2 mL of formulation must be applied or the formulation must be re-applied to the gloves after 30 seconds.	[redacted], RWH07052018, key study
Physical compatibility	None identified			
Chemical compatibility	None identified			
Degree of dissolution and dilution stability	Not applicable for a ready to use liquid formulation			
Surface tension	-	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol	The surface tension of the liquid contained on / in this product would be expected to be the same as the 'DECON-AHOL 70% WFI' since both are 70% IPA/water solutions. Thus testing on 'DECON-AHOL 70% WFI' can be used to support the registration of	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			this formulation.	
	-	Aerosol 'DEC-AHOL AEROSOL'; 71% v/v propan-2-ol	The surface tension of the liquid contained in this product would be expected to be the same as the 'DECON-AHOL 70% WFI' since both are 70% IPA/water solutions. Thus testing on 'DECON-AHOL 70% WFI' can be used to support the registration of this formulation.	-
	OECD 115; EC A.5 Ring method	Liquid 'DECON-AHOL 70% WFI'; 71% v/v propan-2-ol (nominal)	26.1 mN/m at 20 °C, neat formulation. Testing supports metas 1, 2, 3 & 4.	[redacted], 201602082, key study
Viscosity	-	Wipes 'PROCESS2 WIPE IPA 70'; 70% v/v propan-2-ol	The viscosity of the liquid contained on / in this product would be expected to be the same as the 'DEC-AHOL WFI FORMULA' since both are 70% IPA/water solutions. Thus testing on 'DEC-AHOL WFI FORMULA' can be used to support the registration of this formulation.	-
	-	Aerosol 'DEC-AHOL AEROSOL'; 70% v/v propan-2-ol	The viscosity of the liquid contained in this product would be expected to be the same as the 'DEC-AHOL WFI FORMULA' since	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			both are 70% IPA/water solutions. Thus testing on 'DEC-AHOL WFI FORMULA' can be used to support the registration of this formulation.	
	EPA OPPTS 830.7100	Liquid 'DEC-AHOL WFI FORMULA'; 71% v/v propan-2-ol (nominal)	2.27 mPa.s at 20 °C; 1.25 mPa.s at 40 °C. Testing supports metas 1, 2, 3 & 4.	[redacted], VAI LAB-2016-002, key study
		eCA remark: Although no information on the method other than the equipment (Brookfiled DV-prime viscometer) is provided, it is not expected that the viscosity is shear dependent. Therefore, the data is accepted.		
	Cannon-Fenske viscometer (Ubbelohde)	Liquid 'DECON-AHOL 70% WFI'; 70% v/v propan-2-ol	3.73 mPa.s at 22.8 °C. Testing supports metas 1, 2, 3 & 4.	[redacted], VEL-2009-002, supporting study

Table 2.2.2a; Results of the shelf-life stability study at 30 °C for 18 weeks in commercial containers on the test item "'DEC-AHOL WFI FORMULA (Trigger spray 473 mL)", [redacted], 2016/189 AM. The bottles used in the study are made of LDPE and feature a PP spray trigger.

Storage time (weeks)		0	18
Test	Method	-	-
Appearance of the test item	Visual	Colourless transparent liquid	No variation
Appearance of the packaging	Visual	A white plastic bottle closed by a white and red spray trigger, within two sealed transparent plastic bags	No variation
Weight loss %	Gravimetric	-	0.156
pH (1% solution)	CIPAC MT 75.3	6.1	5.8
Relative density	OECD 109	0.8710	0.8739
Propan-2-ol content (% v/v)	S-2016-02173AM-MdP	70.32	71.34 (+0.02% of T0)

Table 2.2.2.b; Results of the shelf-life stability study at 40 °C for 8 weeks in commercial containers on the test item "'DEC-AHOL WFI Formula" (HDPE trigger

spray) and "DEC-AHOL Aerosol WFI Formula" (aluminum aerosol spray can), [redacted], VAI LAB-2016-004-78.

Storage time (weeks)			**0**	**4**	**8**
Test item	Test	Method	-	-	-
DEC-AHOL WFI Formula	Propan-2-ol content (%v/v)	GC-FID	70.8	70.67	71.74
DEC-AHOL Aerosol WFI Formula	Propan-2-ol content (%v/v)	GC-FID	69.8	68.67	71.19

Table 2.2.2c; Interim results of the shelf-life stability study at 25 °C for 36 months in commercial containers on the test item "'PROCESS2 WIPE IPA 70", [redacted], 2016/187 AM. The wipes used in this study are made of polyester and enclosed in a heat-sealed LDPE bags.

Storage time (months)		**0**	**6**	**12**	**18**	**24**	**36**
Test	Method	-	-	-	-	-	
Appearance of the test item	Visual	Polyester wipes wetted with 70% IPA/water solution	No variation	No variation	No variation	No variation	Pending
Appearance of the packaging	Visual	A bag contained in two sealed transparent plastic bags	No variation	No variation	No variation	No variation	Pending
Weight loss (%)	Gravimetric	-	1.675	3.491	5.275	6.947	Pending

Table 2.2.2d; Interim results of the shelf-life stability study at 25 °C for 36 months in commercial containers on the test item "'DEC-AHOL AEROSOL", [redacted], 2016/188 AM. The containers used in this study are aluminium coated inside with epoxy phenolic resin (baked on) and painted outside. The nozzles are HDPE sitting on a nylon splined (moulded) valve stem held together by a mounting cup of aluminium with a gasket made of BUNA that is crimped onto the can opening. The dip tube is LDPE. The propellant is nitrogen.

Storage time (months)		**0**	**6**	**12**	**18**	**24**	**30**	**36**
Test	Method	-	-	-	-	-	-	-
Appearance of the test item	Visual	Colourless transparent liquid	No variation	No variation	No variation	No variation	No variation	No variation
Appearan	Visual	A white	No	No	No	No	No	No

ce of the packaging		can within two sealed transparent plastic bags	variation	variation	variation	variation	variation	variation
Weight loss (%)	Gravimetric	-	0.035	0.094	0.063	0.071	0.127	0.118
pH (1% solution)	CIPAC MT 75.3	6.20	6.02	5.74	6.01	6.22	5.72	5.05
Relative density	OECD 109	0.8748	0.8753	0.8757	0.8751	0.8765	0.8760	0.8772
Propan-2-ol content (% v/v)	S-2016-02173AM-MdP	70.3%	69.698 (-0.5% of T0)	70.523 (+0.3 % of T0)	69.076 (-1.8% of T0)	70.504 (+0.3 % of T0)	69.526 (-1.1% of T0)	68.389 (-2.7% of T0)
Spray & stream character	FEA 644	Cone like a spray	-	-	-	-	Cone like a spray	Cone like a spray
Spray rate	Internal method	-	-	-	-	-	2.25 g/s	2.19 g/s
Vlave clogging	FAO	-	-	-	-	-	No clogging	No clogging
Can pressure at 20°C	FEA 604/606	-	-	-	-	-	755.92 ± 881.56 kPa	-
Can pressure at 50°C							770.30 ± 902.67 kPa	-

Table 2.2.2e; Interim results of the shelf-life stability study at 25 °C for 36 months in commercial containers on the test item "'DEC-AHOL WFI FORMULA (Trigger spray 273 mL)", [redacted], 2016/186 AM. The bottles used in this study are made of LDPE and feature a PP spray trigger.

Storage time (months)		**0**	**6**	**12**	**18**	**24**	**36**
Test	Method	-	-	-	-	-	-
Appearance of the test item	Visual	Colourless transparent liquid	No variation	No variation	No variation	No variation	No variation
Appearance of the packaging	Visual	A white plastic bottle closed by a white and red spray trigger,	No variation	No variation	No variation	No variation	No variation

		within two sealed transparent plastic bags					
Weight loss (%)	Gravimetric	-	0.09	0.14	0.28	0.31	0.50
pH (1% solution)	CIPAC MT 75.3	6.1	6.1	5.8	6.1	5.8	5.6
Relative density	OECD 109	0.8724	0.8729	0.8729	0.8737	0.8729	0.8695
Propan-2-ol content (% v/v)	S-2016-02173AM-MdP	70.9%	71.45 (+0.8% of T0)	71.58 (+1.0% of T0)	71.49 (+0.8% of T0)	71.75 (+2.6% of T0)	72.10 (+1.7% of T0)
Spray & stream character	FEA 644	Cone like a spray	Not measured				Cone like a spray
Spray rate* (g)	FEA 643	0.76	0.73	0.64	0.77	0.78	0.79
Valve clogging	FAO	No clogging	No clogging	No clogging	No clogging	No cloggine	No clogging

* the average amount of spray delivered with one complete operation of the trigger sprayer

Table 2.2.2f; Results of the shelf-life stability study at ambient temperature for 35.8 months in commercial containers on the test item "DECON-AHOL 70% WFI'; 70% w/w propan-2-ol", [redacted], Vel-2009-004.

Time on storage (months)		**0**	**0**	**0**	**35.8**	**35.6**	**35.6**
Batch number		C43N12	162067 A	162068 A	C43N12	162067 A	162068 A
Test	Method	-	-	-	-	-	-
Appearance of the test item	Visual examination	Clear, colourless fluid	Pass	Pass	Pass	Pass	Pass
Specific gravity (g/mL)	Pycnometer	0.872	0.882	0.882	0.872	0.883	0.883
Propan-2-ol content (v/v)	Distillation	71.2%	72.0%	72.0%	71.2%	71.5%	71.5%

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

The DEC-AHOL® product family contains wipe, aerosol and liquid (trigger spray, pour/spray on solution, automatic dispenser) disinfectant products, based on a nominal 70% propan-2-ol (IPA) water binary solution. The individual products supported are PROCESS2 WIPE® IPA 70, DEC-AHOL® ASEPTI-CLEANSE ALCOH-WIPE®, DEC-AHOL® AEROSOL WFI Formula, DEC-AHOL® WFI Formula and DEC-AHOL® WFI Formula Invertaspray.

PROCESS2 WIPE IPA 70 are polyester wipes wetted with 70% IPA/water binary solution packaged in heat-sealed LDPE bags. The following properties of the product were/will be determined before after ambient storage: test item and container appearance, weight loss. As the study is in progress final results are not yet available. Initial measurements and measurements taken following 24 months of storage have been provided. Currently the test item remains within specification. pH, relative density, viscosity and surface tension measurement should be read-across from the 'DEC-AHOL WFI Formula' determinations. Testing found that ≈7 mL of liquid will be dispensed by one wipe onto one square meter of surface during full coverage.

DEC-AHOL WFI Formula (Trigger Spray 473 mL) is a colourless transparent liquid packaged in a white LDPE bottle closed by a white and red PP spray trigger sealed in two transparent plastic bags. The pH of a 1% dilution in water was measured to be 6.1. The relative density was measured to be 0.8710 at 20 °C. The surface tension of the neat test item was measured to be 26.1 mN/m at 20 °C. The dynamic viscosity of the test item was measured to be 3.73 mPa.s at 22.8 °C, 2.27 mPa.s at 20 °C and 1.25 mPa.s at 40 °C. The following properties of the product were determined before and after accelerated storage in a study compatible with CIPAC MT 46.3: test item and container appearance, weight loss, pH, relative density and active substance content. The test item did not to undergo any significant physical change following storage at 30 °C for 18 weeks and is therefore considered stable when stored under these conditions. A 36-month ambient temperature storage stability study is currently in progress on this product, measuring the same properties as the accelerated storage stability study together with satisfactory operation of the trigger sprayer. Interim results are provided, which find the formulation to be stable.

DEC-AHOL AEROSOL is a colourless transparent liquid. The packaging was a white aluminium can. The can is contained in two sealed transparent plastic bags. The pH of a 1% dilution in water was measured to be 6.20. The relative density was measured to be 0.87 at 20 °C. The following properties of the product were/will be determined before, during and after ambient storage for 36 months: test item and container appearance, weight loss. The study is in progress, and initial measurements and measurements taken following 18 months of storage have been provided. The study is expected to finish 05/08/2019 and a final report expected shortly after. Currently the test item remains within specification. Surface tension and viscosity measurements should be read-across from the 'DEC-AHOL WFI Formula' determinations.

A non-GLP study was carried out on the bulk pack wipes to determine the evaporation (opening and removal effects), average wipe liquid content, assay (during use period), squeezable liquid and surface drying time during simulated use period. The study showed no significant weight loss due to evaporation over the simulated use period of the product. The seal integrity remained after repeated openings and closings. The propan-2-ol content was measured to be within specification and in range (68.45%v/v-71.92%v/v). The specified range for propan-2-ol is 68.0%-72.0% v/v, and opening and closing the bag did not result in the loss of active substance. Under the conditions of this test the propan-2-ol wipes delivered alcohol so that all surfaces started out wet. During this study, the time for a dry spot to appear did not decrease.

A non-GLP study was run to determine the drying times of medium-sized nitrile gloves by visual inspection following application of the product Dec-Ahol 70% v/v IPA. To keep gloves wet for at least 60 seconds, 2 mL of product must be applied. Or, the product must be re-applied to the gloves after 30 seconds.

eCA remark:
Data for storage at 40°C were provided. Hence, the product should be stored at temperatures below 40°C. For LDPE packaging, the storage temperature should be limited to 30°C.
The active substance content of the liquid squeezed from the wipes is within specification (see studies [redacted], S-2016-02176 AM and [redacted], VAI LAB-2016-05-25). Endpoints for the product with wipes can be read-across from the results obtained for the liquid.

To support the shelf life, worst case packages have been tested. An overview of accepted shelf life studies can be found in the table below.

Package description	**Accelerated shelf life studies**	**Long term shelf life studies**	**Validated test method for a.s. determination**
LDPE triggerspray	[redacted], 2016/189 AM	C. Belussi, 2019, 2016/186 AM	Yes
Aluminium aerosol spray can	[redacted], VAI LAB-2016-004-78	C. Belussi, 2019, 2016/188 AM	Polanuyer: no* C Belussi: yes
HDPE	[redacted], SS19062018	No study	No*
Aluminium can	[redacted], SS19062018	No study	No*
LDPE bag containing pre-satured polyester wipes		C. Belussi, 2019, 2016/187 AM	Yes
Bag-in-bottle (PP with surlyn resin internal bag)	[redacted]	No study	No*

* A GC-FID method was used, which is also used in the validated method. However, the conditions (column, flow rate, temperature, for [redacted], VAI LAB-2016-004-78 also the carrier gas) differed from the validated method. Changing the conditions may result in a change in retention times. Given the composition of products in this family, this will not lead to a misidentification of the peaks.

The data and studies do not fully comply with the requirements of the current BPR guidance. However, it should be taken into account that the product is a relatively simple and well documented mixture. The proposed packaging is expected to be resistant to its contents, with LDPE being a worst-case for the plastics. In addition, aluminium aerosol cans can be considered acceptable and the accelerated storage study with the bag-in-bottle are considered sufficient to address packaging stability.

For the bag-in-bottle and aerosol cans, data on the discharge rate, spray diameter and nozzle blockage were addressed after storage only. It is possible to conclude aged samples have acceptable spray characteristics and there is no reason to assume spray characteristics before storage are not acceptable.
Spray characteristics for the inverta cans (BOV system) can be extrapolated from the normal aerosol can (see confidential annex) and are acceptable.

The products of the family were tested at various elevated temperatures (30°C in LDPE, 40°C in other packs). Considering LDPE may be sensitive to heating, the storage temperature is limited to 30°C for the meta SPC containing LDPE packs. For the other

products, an upper limit of 40°C is accepted, although noting that these temperatures are above the product's flashpoint.

A shelf-life of 2 years is considered supported for all .
Data to support the satisfactory operation of the aerosol spray can after storage were provided in a late stage of the evaluation process as part of 36 month storage stability studies, along with data on the 36 month storage stability studies of the trigger sprayer. Data were included in the PAR but only used to assess the satisfactory operation of the aerosol spray can, not to extend the shelf life.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Theoretical assessment	Not applicable	None of the components are explosive or oxidizing and it is therefore concluded that the solution is unlikely to undergo rapid decomposition with the evolution of gases or release of heat and, therefore does not present a risk of explosion. It is also important to note that the product as a whole would not be expected to behave differently with regards to explosivity compared with individual constituents when combined.	[redacted]
Flammable gases	Not applicable to the formulation types covered by this submission, which do not include gases			
Flammable aerosols	meta 1 (wipes): classification under this CLP endpoint is not applicable since the formulation does not meet the definition of an aerosol			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	meta 2 (aerosol propellant): this formulation has been classified as CLP aerosol category 1, based on experience of handling and limited testing. CLP regulation (annex I, section 2.3.2.2) states "Aerosols containing more than 1% flammable components… which are not submitted to the flammability classification procedures in this section shall be classified as aerosols, Category 1." As the formulation contains more than 1% flammable components, the formulation has been classified as a Category 1 aerosol without further testing. This is an acceptable approach to classification under CLP regulation, and therefore considered acceptable under BPR regulation.			
	meta 3 (liquid fitted with a trigger sprayer): classification under this CLP endpoint is not applicable since the formulation does not meet the definition of an aerosol			
	meta 4 (aerosol invertaspray): this formulation has been classified as CLP aerosol category 1, based on experience of handling and limited testing. CLP regulation (annex I, section 2.3.2.2) states "Aerosols containing more than 1% flammable components… which are not submitted to the flammability classification procedures in this section shall be classified as aerosols, Category 1." As the formulation contains more than 1% flammable components, the formulation has been classified as a Category 1 aerosol without further testing. This is an acceptable approach to classification under CLP regulation, and therefore acceptable under BPR regulation.			
Oxidising gases	Not applicable to the formulation types covered by this submission, which do not include gases			
Gases under pressure	Not applicable to the formulation types covered by this submission, which do not include gases			
Flammable liquids	EPA OPPTS 830.6315	70% v/v	Flash point = 21 °C	[redacted], VAI 2009-003.
		The flash point has not been determined with a method as listed in CLP Annex 1, Table 2.6.3. No information on the test method itself, other than the apparatus (Flash Point Tester – Koehler, model 16200) is provided. Given the composition of the product, a flash point <23 °C (i.e. the classification limit) is to be expected.		
Flammable solids	Not applicable to this product as it is a liquid			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Self-reactive substances and mixtures	Theoretical assessment	Not applicable	The chemical structures of all of the constituents were examined for the presence of characteristic groups associated with self-reactivity, none were present and therefore the product would not be expected to be susceptible to rapid, exothermic chemical reaction.	[redacted]
Pyrophoric liquids	Waiver	Not applicable	For a liquid to be classified as pyrophoric under CLP, it has to ignite within 5 minutes of coming in to contact with air. Experience of handling and use confirms this is not to be the case, and propan-2-ol is not classified as pyrophoric. The presence of any inert matrix or nitrogen would not affect this conclusion.	
Pyrophoric solids	Not applicable to this product as it is a liquid			
Self-heating substances and mixtures	Theoretical assessment	Not applicable	In general, the phenomenon of self-heating applies only to solids. The	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids.	
Substances and mixtures which in contact with water emit flammable gases	Waiver	70% v/v	The products contains 30% water, and a review of the properties and composition of the products confirm this endpoint is not applicable.	
Oxidising liquids	Theoretical assessment	Not applicable	None of the components are oxidizing and will therefore be incapable of reacting exothermically with combustible materials. Additionally, as all of the constituents only contain oxygen that is chemically bonded to carbon or hydrogen, and no halogens are present, according to BPR guidance the oxidizing hazard class is not applicable to this formulation.	[redacted]
Oxidising solids	Not applicable to this product as it is a liquid			
Organic peroxides	Waiver	Not applicable	The components of	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the products do not contain any peroxide functional groups, nor could it be anticipated that peroxides groups would form.	
Corrosive to metals	Theoretical assessment	Not applicable	No functional groups present on any of the constituents of the solution would be considered acidic or basic, and no halogens are present. Theproduct as a whole would not be expected to behave differently with regards to this CLP endpoint compared with the combined individual constituents.It is therefore concluded that the formulation would not be considered for classification as a substance with "Corrosive to Metals" properties	[redacted]
Auto-ignition temperatures of products (liquids and gases)	Waiver	Not applicable	The self-ignition temperature listed in the active substance dossier is 399 °C. The self-ignition	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			temperature of the product cannot be below this value, based on the composition (see confidential annex).	
Relative self-ignition temperature for solids	Not applicable to this product as it is a liquid			
Dust explosion hazard	Not applicable to this product as it is a liquid			

Conclusion on the physical hazards and respective characteristics of the product
Many endpoints are not applicable to this product and due to the simple composition of the products within the family, the eCA considers it to be acceptable not a full dataset of tests is available. The flash point was measured to be 21 °C. The the boiling point of the active substance is 82.5°C (see AR of 2-propanol). The boiling point of the the product will be above 35 °C, so the liquid product is classified as a Flammable Liquid category 2 under EU CLP. An expert review of the other CLP endpoints concluded that the product is not classified under any other physchem EU CLP endpoints. The aerosol product / pressurized containers are classified as an category 1 flammable aerosol – an aerosol, as defined under EU CLP, cannot also be a flammable liquid.

2.2.4 Methods for detection and identification

Gas chromatography with flame ionization detector and 1-propanol as internal standard was used.

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*		
Active substanc	GC-FID, Identity	50%(n=2) equiv to	Range:	Acceptable – no	50 %:	100 .27	0.17 (n=6	Not determi	[redacted]

e	of the a.s. peak confirmed by GC/MS	0.55 mg/mL 100% (n=2) equiv 1.11 mg/mL 150% (n=2) equiv 1.66 mg/mL	50%-150% y=0.7549x-0.0018 R^2 = 1.0000	interference	99.99-100.31 100%: 100.26-100.46 150%: 100.17-100.40		RSD_r = 1.41)	ned	[redacted], S-2016-02173 AM

* %RSD = Precision

Analytical methods for monitoring									
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 *		
A method for the determination of propan-2-ol in air is presented in the active substance dossier and is considered adequate since the co-formulants in the biocidal product will not influence the behaviour of propan-2-ol should it be released into the environment. Methods for the determination of propan-2-ol in soil and water, as well and food and feed of plant and animal origin, are not considered necessary because no residues are expected. Methods for the determination of propan-2-ol in animal and human body fluids and tissues are not considered necessary since Propan-2-ol is neither classified as toxic or highly toxic, nor, according to GHS, as acute toxic (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).									

Conclusion on the methods for detection and identification of the product

The GC-FID method for the determination of the active substance propan-2-ol in the biocidal product DEC-AHOL WFI Formula (in trigger spray bottle 473 mL) has been validated with acceptable specificity, linearity, precision, accuracy and repeatability. Although the method is validated using the RTU liquid, the method is applicable for all products within the family (aerosol, wipes, trigger-spray bottle) as the same 70:30 propan-2-ol/water liquid formulation is used across the range.

A method for the determination of propan-2-ol in air is presented in the active substance

dossier and is considered adequate. Methods for the determination of propan-2-ol in animal and human body fluids and tissues are not considered necessary since propan-2-ol is neither classified as toxic or highly toxic, nor, according to GHS, as acute toxic (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). Methods for the determination of propan-2-ol in soil and water, as well and food and feed of plant and animal origin, are not considered necessary because no residues are expected.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The DEC-AHOL® Product Family contains disinfectant products for use in Product Type 2. The products are for use in manufacturing facilities including cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product industries. The ready-to-use products (aerosol spray, trigger spray, pour on) are intended for the disinfection of hard non-porous inanimate surfaces surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. A liquid dispenser is for use on gloved hands. The products are for Industrial use only and are bactericidal and yeasticidal.

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

The DEC-AHOL® Product Family contains disinfectant products which are intended to control bacteria and yeast on surfaces, materials, equipment in manufacturing facilities and cleanrooms found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The DEC-AHOL® Product Family contains disinfectant products based on the active substance propan-2-ol. The active substance is an alcohol which is an acute toxin to bacteria and yeasts.

2.2.5.4 Mode of action, including time delay

Alcohols, such as propan-2-ol, exhibit an unspecific mode of action. Propan-2-ol affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death. There is no time delay to the toxic effect.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use**	**Test substance**	**Test organism(s)**	**Test**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Staphylococcus aureus ATCC 6538 Pseudomonas aeruginosa*	EN 1276:2009) . Suspension test (Phase 2,	Concentration (%): 80% product Interfering substances: bovine albumin (0.03%). Contact time:	log R>5.30: 80% product, Clean, 2 min. 20°C	[redacted] *IUCLID 6.7-01*

			ATCC 15442 Escherichia coli ATCC 10536 Enterococcus hirae ATCC 10541	step 1)	2 mins, 5 mins and 10 mins Test temperature: 20°C		
Bactericide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Staphylococcus aureus ATCC 6538 Pseudomonas aeruginosa ATCC 15442 Escherichia coli ATCC 10536 Enterococcus hirae ATCC 10541*	EN 13697: 2001. Surface test (Phase 2, step 2)	Concentration (%): 25%, 50% and 100%. Interfering substances:clean conditions (0.03% bovine albumin) Contact time: 2 and 15 minutes. Test temperature: 20°C.	Log R>6.51 at 100 % under clean conditions (0.03% bovine albumin), 20°C and 2 minutes contact time.	[redacted] *IUCLID 6.7-02*
Yeasticide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Candida albicans ATCC 10231 Aspergillus niger ATCC 16404*	EN 1650:2008. Suspension test (Phase 2, step 1)	Concentration (%): 80% Interfering substances: clean conditions (0.03% bovine albumin) Contact time:2, 5 and 15 minutes Test temperature: 20°C	Log R>4.43 at 80% under clean conditions (0.03% bovine albumin), 20°C and 2 minutes contact time for *C. albicans.* Log R=4.28 at 80% under clean conditions (0.03% bovine albumin), 20°C and 5 minutes contact time for *A. niger.*	[redacted] *IUCLID 6.7-03*
Yeasticide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Candida albicans ATCC 10231 Aspergillus niger ATCC 16404*	EN 13697:2001. Surface test (Phase 2, step 2)	Concentration (%): 25 %, 50% and 100%. Interfering substances: clean conditions (0.03% bovine albumin) Contact time: 2 and 15 minutes Test temperature:	Log R>5.95 at 100% under clean conditions (0.03% bovine albumin), 20°C and 2 minutes contact time	[redacted] *IUCLID 6.7-04*

					20°C.	for *C. albicans.* Log R>4.18 at 100% under clean conditions (0.03% bovine albumin), 20°C and 15 minutes contact time for *A. niger.*	
Bactericide, Yeasticidal	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Staphylococcus aureus ATCC 6538 Pseudomonas aeruginosa ATCC 15442 Enterococcus hirae ATCC 10541 Candida albicans ATCC 10231*	EN 16615:2015. Surface test (Phase 2, step 2)	Concentration (%): 100% Interfering substances: No soil, cleanroom use. Contact time: 2 minutes Test temperature: 22.5 °C Wipe material: 100% continuous filament polyester fibre	Log R>4.25 *S. aureus,* Log R>5 *P. aeruginosa* and *E. hirae* at 100 % with no soil, 20°C and 2 minutes contact time extended to EN 16615. Log R>4.63 at 100 % product, with no soil, 22.5°C and 2 minutes contact time for yeast.	[redacted] *IUCLID 6.7-05*
Bactericide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Staphylococcus aureus ATCC 6538 Pseudomonas aeruginosa ATCC 15442 Escherichia coli ATCC 10536 Enterococcus hirae ATCC 10541*	EN 13697:2015. Surface test (Phase 2, step 2)	Concentration (%):25 %, 50% and 100%. Interfering substances: No soil, cleanroom use. Contact time: 30 and 60 seconds. Test temperature: Room temperature	Log R>6.74 at 100 % with no soil, 20°C and 1 minutes contact time.	[redacted] *IUCLID 6.7-06*
Yeasticide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Candida albicans ATCC 10231*	EN 13697:2015. Surface test (Phase 2,	Concentration (%):25 %, 50% and 100%. Interfering substances: No soil, cleanroom use. Contact time: 30 and 60 seconds.	Log R>3.75 at 100 % with no soil, 20°C and 30 sec contact time	[redacted] *IUCLID 6.7-07*

				step 2)	Test temperature: Room temperature.		
Bactericide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	*Staphylococcus aureus ATCC 6538 Pseudomonas aeruginosa ATCC 15442 Escherichia coli ATCC 10536 Enterococcus hirae ATCC 10541*	EN 1276:2009) . Suspension test (Phase 2, step 1)	Concentration (%): 97%, 80% and 25% product Interfering substances: bovine albumin (0.03%). Contact time: 30 seconds and 1 minute Test temperature: 20°C	Log R>5.03 at 80 % under clean conditions, 20°C and 30 seconds contact time	[redacted] *IUCLID 6.7-08*
Yeasticide	*PT2*	*Aqueous formulation of Propan-2-ol (70% v/v)*	Place holder *Candida albicans ATCC 10231*	EN 1650:2008+A1:2013 Suspension test (Phase 2, step 1)	Concentration (%):97%, 80% and 25% product Interfering substances: clean conditions (0.03% bovine albumin) Contact time: 30 seconds and 1 minute Test temperature: 20°C	Log R>4.36 at 80 % under clean conditions, 20°C and 30 seconds contact time	[redacted] *IUCLID 6.7-09*

Conclusion on the efficacy of the product family

Formulation does not change when applied via wipes (see IUCLID 3.4.1.2)

Meta SPC 1

Use 1.1 - Disinfection of hard non-porous surfaces; Wipes (individual wipes and multi-pack wipes)

Claim: Disinfection of pre-cleaned hard surfaces, bactericidal, yeasticidal, 2 minutes contact time

For use in cleanrooms found in non medical areas

Efficacy in support of the claim
EN1276: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-01)
EN1650: PASS, Yeasticidal, Clean conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-03)
EN16615: Greater than 4 log reduction, bacteria and yeast, Clean conditions (0g/l interfering substance – cleanroom use only) 2 minutes (IUCLID 6.7-05)
EN13697: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-02)
EN13697: PASS, Yeasticidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-04)

The data supports the claim in that the product produces reductions in populations of bacteria and yeast (Phase 2 Step 1, Phase 2 Step 2) commensurate with that expected in PT2 Non Medical Area uses
A wipe with a size of 30x30 cm contains sufficient liquid to wet a square meter (IUCLID 3.5.13-01). Therefore the specification4 wipes of 15x15 cm are necessary to wet a square meter is added in the use description.

Meta SPC 2

Use 2.1 - Disinfection of hard non-porous surfaces; Aerosols (propellant)

Claim: Disinfection of pre-cleaned hard surfaces, bactericidal and yeasticidal, 2 minutes contact time

Use: For use in manufacturing facilities including cleanrooms areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries.

Efficacy in support of the use
EN1276: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-01)
EN1650: PASS, Yeasticidal, Clean conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-03)
EN13697: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-02)
EN13697: PASS, Yeasticidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-04)

The data supports the claim in that the product produces reductions in populations of bacteria and yeast (Phase 2 Step 1, Phase 2 Step 2) commensurate with that expected in PT2 Non Medical Area uses.

Meta SPC 3

Use 3.1 - Disinfection of hard non-porous surfaces; Trigger Spray, Liquid

Use 3.2 - Disinfection of hard non-porous surfaces (including floors); Wiping

Claim: Disinfection of pre-cleaned hard surfaces. Bactericidal, yeasticidal, 2 minutes contact time

Use: For use in manufacturing facilities including cleanrooms areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries

Efficacy in support of uses (3.1, 3.2)
EN1276: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-01)
EN1650: PASS, Yeasticidal, Clean conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-03)
EN13697: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-02)
EN13697: PASS, Yeasticidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-04)

The data supports the claim in that the product produces reductions in populations of bacteria and yeast (Phase 2 Step 1, Phase 2 Step 2) commensurate with that expected in PT2 Non Medical Area uses.

Use 3.3 - Disinfection of cleanroom gloves

Claim: Disinfection of cleanroom gloves. Bactericidal, yeasticidal, 1 minutes contact time

Use: For use in cleanrooms found in non medical areas

Efficacy in support of use 3.3
EN 1276: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 30 seconds. (IUCLID 6.7-08)
EN 1650: PASS, Yeasticidal, Clean Conditions (0.3g/l bsa), 30 seconds. (IUCLID 6.7-09)
EN13697: PASS, Bactericidal, Clean Conditions, no soil (0.0g/l bsa), 1 minute. (IUCLID 6.7-06)
EN13697: PASS, Yeasticidal, Clean Conditions, no soil (0.0g/l bsa), 30 Seconds. (IUCLID 6.7-07)

The data supports the claim in that the product produces reductions in populations of bacteria and yeast (Phase 2 Step 1, Phase 2 Step 2) commensurate with that expected in PT2 Non Medical Area uses.

Meta SPC 4

Use 4.1 - Disinfection of hard non-porous surfaces; Aerosols

Claim: Disinfection of pre-cleaned hard surfaces

Use: For use in manufacturing facilities including cleanrooms areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries

Efficacy in support of the use
EN1276: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-01)
EN1650: PASS, Yeasticidal, Clean conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-03)
EN13697: PASS, Bactericidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-02)
EN13697: PASS, Yeasticidal, Clean Conditions (0.3g/l bsa), 2 minutes. (IUCLID 6.7-04)

The data supports the claim in that the product produces reductions in populations of bacteria and yeast (Phase 2 Step 1, Phase 2 Step 2) commensurate with that expected in PT2 Non Medical Area uses.

A DEC-AHOL® Product Family representative product containing 70% v/v propan-2-ol met the criteria required to pass the EN Norm EN 1276 under clean conditions (0.03% Bovine Albumin) with a 2 min and 30 sec contact time. The contact times and interfering substance were commensurate with the type of applications (including cleanrooms) envisaged for the product.

A series of assays were conducted on a DEC-AHOL® Product Family representative product containing 70% v/v propan-2-ol to determine the (bactericidal, and yeasticidal) disinfectant efficacy on a surface. EN 13697:2001 was the chosen methodology. The test concentrations were 100% (neat RTU), 50% and 25%. Contact times were 2 minutes and 15 minutes. An interfering substance, bovine serum albumin (0.03%), was included to simulate use under clean conditions. The product passed the requirements of at least a four log reduction against all bacteria within a contact time of 2 minutes.

Additionally, a further EN 13697 study was carried out to evaluate the performance of the product when used for short contact times and no soiling (cleanroom conditions). Contact times of 30s and 60s were evaluated. The product passed the required criteria (4 log reduction – all bacteria) at a concentration of 100% at the 60 seconds and met

the criteria for three of the four organisms at the 30 s time point. The fourth organism (*S.aureus*) recorded a result very close to the pass criteria (3.7 log reduction) within 30 s. These data support the use of the product where shorter than normal contact times may be experienced – for example when disinfection gloves at a glove station.

The availability of EN 1276 and EN 13697 efficacy test data showing suitable pass criteria support the bactericidal claim for the DEC-AHOL® Product Family products at 1 min (no soil) en 2 min (clean) contact time, respectively.

A DEC-AHOL® Product Family representative product containing 70% v/v propan-2-ol met the criteria required to 'pass' and be defined as Yeasticidal as determined by the EN Norm EN 1650 under clean conditions (0.03% Bovine Albumin) with a 2 minutes and 30 sec contact time in a suspension test designed for that purpose. The testing method was appropriate for the type of claim. The organisms were appropriate target organisms and the contact times and soil were commensurate with the type of applications envisaged for the product.

A DEC-AHOL® Product Family representative product containing 70% v/v propan-2-ol was tested according to EN 13697 in order to determine its efficacy against yeasts on surface application. The 'PASS' requirement for EN 13697 is for a greater than 99.9% reduction to be achieved within a 15 minute contact time. For yeasts the test was passed with at least a three log reduction in 2 minutes. Achieving such performance for *Candida albicans* is sufficient to support a yeasticidal claim for a disinfectant.

Additionally, a further EN 13697 study was carried out to evaluate the performance of the product when used for short contact times and no soiling (cleanroom conditions). Contact times of 30s and 60s were evaluated. This study was carried out against *Candida albicans* only. The product passed the required criteria (3 log reduction) at a concentration of 100% at the 30 second time point. These data support the use of the product where shorter than normal contact times may be experienced – for example when disinfectiing gloves at a glove station and support a claim of yeasticidal for short contact times.

The availability of EN 1650 and EN 13697 efficacy test data showing suitable pass criteria support the yeasticidal claim for the DEC-AHOL® Product Family products at 30 sec (no soil) and 2 minutes (clean conditions) contact time respectively.

A study was also carried out to assess the performance of a wipes product. The chosen methodology was EN 16615. EN 16615 is specifically designed to assess the performance of a (wipe) product on a non-porous surface with mechanical action. It was also specifically designed for use in medical areas. The members of the DEC-AHOL product family are not intended for use in medical areas. The test was carried out according to the EN 16615 protocol but the 'pass' criteria were taken from surface test requirements more representative of the intended use areas of the product (EN 13697). Consequently the product was considered as having met the required criteria if it achieved a 4 log reduction (bacteria) or a 3 log reduction (yeast). The wipes products are not intended for use outside of pharmaceutical cleanrooms and therefore interfering substance levels were set to zero. EN 16615 allows for the user to set the contact time to a point between 1 and 60 minutes. The test was carried out for a short contact time of 2 minutes. The wipe product under test – representative of other products in the family, met the above reduction criteria for a 2 minutes contact time.

Conclusion eCA EN16615, we do not agree with the approach to use 'pass' criteria

from 1 test to another. Considering the difference in test setup we are of the opinion that a log reduction in EN13679 may not represent equivalent efficacy as the same log reduction in an EN16615 and therefore the log reduction should not be direlcty reference from on test to another. However at the time of submission of the dossier the The BPR Efficacy Working Group document of may 2016 (appendix 4) was in place, stating a log 4 reduction for bacteria for both the EN13697 and the EN16615, therefore we agree that a log 4 reduction in the EN16615 for bacteria could be acceptable for this dossier.
For yeast the Log reduction present in the EN16615 is sufficient according to the current Guidance documents of 2018.

The 70% v/v Propan-2 -ol liquid is common to all members of the product family, including the wipes products. In order to support the read-across of this liquid for use in wipe products studies were completed to determine the composition and active substance content of liquid expressed back out of two impregnated wipe products. These data can be found in references IUCLID 3.4.1.2-07 and IUCLID 3.4.1.2-08.

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of propan-2-ol, the development of resistance is not expected. A natural resistance against sporulated bacteria is known where propan-2-ol is ineffective at any concentration. Strategies such as alternate with other disinfectant active substances and avoidance of over frequent use are efficient standard practices and should be applied also to biocide uses of propan-2-ol, in order to prevent any potential development of resistance.

2.2.5.7 Known limitations

There are no known limitations for the products included in the DEC-AHOL® Product Family.

2.2.5.8 Evaluation of the label claims

In general, propan-2-ol is known as an effective disinfectant and within the frame of authorising the DEC-AHOL® Product Family, the disinfection effect proven by the efficacy data supports the claim for bactericidal and yeasticidal action (see section "Conclusion on efficacy").

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

DEC-AHOL® Product Family disinfectant products are not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

A waiver is presented for skin corrosion and irritation (IUCLID Section 8.1), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin corrosive or irritating
Justification for the value/conclusion	Propan-2-ol (the active substance) is not classified as a skin corrosive or skin irritant. No other components in the products are classified as skin corrosive or skin irritants. The products do not therefore meet the criteria for classification for skin corrosion or skin irritation according to Regulation (EC) No 1272/2008. The pH of the mixture is not less than 2 or greater than 11.5 and therefore the mixtures are not considered corrosive. EUH066 (Repeated exposure may cause skin dryness or cracking) has been proposed for propan-2-ol in the CAR, and this hazard character is taken for the labelling of the BPF.
Classification of the product according to CLP	Not classified for skin corrosion/irritation. EUH066 is assigned for all *meta* SPCs.

Data waiving	
Information requirement	IUCLID Section 8.1
Justification	Data waiving: study scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Eye irritation

A waiver is presented for eye irritation (IUCLID Section 8.2), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye irritation Category 2; H319
Justification for the value/conclusion	Propan-2-ol (the active substance) is classified as an eye irritant (Cat. 2). No other components in the products are classified as eye irritants. According to Regulation (EC) No 1272/2008, a mixture which contains a total of 10 % or more of a substance or substances classified in Category 2 for eye irritation shall be classified in Category 2 for eye irritation. The pH of the mixture is not less than 2 or greater than 11.5 and therefore the mixtures are not considered eye damaging.

	Therefore, the products meet the criteria to be classified in Category 2 for eye irritation (CLP Cat. 2 H319).
Classification of the product according to CLP	Eye irritation Category 2; H319

Data waiving	
Information requirement	IUCLID Section 8.2
Justification	Data waiving: study scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Respiratory tract irritation

A waiver is presented for respiratory tract irritation (IUCLID Section 8.4), on the basis that conducting studies is scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating.
Justification for the conclusion	None of the components of the products are classified for respiratory irritation according to Regulation (EC) No 1272/2008. The products do not therefore meet the criteria for classification as respiratory irritants according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	IUCLID Section 8.4
Justification	Data waiving: study scientifically unjustified. None of the components of the products are classified for respiratory irritation according to Regulation (EC) No 1272/2008. Specific testing for respiratory irritation is not required and is not possible in the absence of any recognised and validated test method.

Skin sensitization

A waiver is presented for skin sensitization (IUCLID Section 8.3), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising

Justification for the value/conclusion	Propan-2-ol (the active substance) is not classified as a skin sensitiser. No other components in the products are classified as skin sensitisers. The products do not therefore meet the criteria for classification for skin sensitisation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	IUCLID Section 8.3
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Respiratory sensitization (ADS)

A waiver is presented for respiratory sensitization (IUCLID Section 8.4), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	None of the components of the products are classified for respiratory sensitisation according to Regulation (EC) No 1272/2008. The products do not therefore meet the criteria for classification as respiratory sensitizers according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	IUCLID Section 8.4
Justification	Data waiving: studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing. Specific testing for respiratory sensitisation is not required and is not possible in the absence of any recognised and validated test method.

Acute toxicity

Acute toxicity by oral route

A waiver is presented for acute toxicity by the oral route (IUCLID Section 8.5.1), on the basis that conducting studies would be scientifically unjustified (see table below).

Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route
Justification for the selected value	Data provided for propan-2-ol (the active substance) and considered in the CAR indicate very low acute oral toxicity and do not trigger classification for acute oral toxicity. No other components in the products are classified for acute oral toxicity. The products do not therefore meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.1
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Acute toxicity by inhalation

A waiver is presented for acute toxicity by inhalation (IUCLID Section 8.5.2), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route
Justification for the selected value	Data provided for propan-2-ol (the active substance) and considered in the CAR indicate very low acute inhalation toxicity and do not trigger classification for acute inhalation toxicity. No other components in the products are classified for acute inhalation toxicity. The products do not therefore meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	IUCLID Section 8.5.2
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Acute toxicity by dermal route

A waiver is presented for acute toxicity by the dermal route (IUCLID Section 8.5.3), on the basis that conducting studies would be scientifically unjustified (see table below). Classification of the products is addressed using available data on the individual components of the respective formulations. No human data are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by the dermal route.
Justification for the selected value	Data provided for propan-2-ol (the active substance) and considered in the CAR indicate very low acute dermal toxicity and do not trigger classification for acute dermal toxicity. No other components in the products are classified for acute dermal toxicity. The products do not therefore meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	IUCLID Section 8.5.3
Justification	Data waiving: Studies scientifically unjustified. The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Information on dermal absorption

The Competent Authority Report for propan-2-ol (the active substance) contains a number of *in vivo* studies of dermal absorption in rats and humans, including a study using a product containing 70% (w/w) propan-2-ol. For the purposes of risk assessment, the CAR proposes the use of a dermal flux value of (0.85 mg/cm^2/h) rather than the proportion (%) absorbed. As DEC-AHOL® product family is considered sufficiently similar (70% v/v), this value is considered appropriate for the DEC-AHOL® product family.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	propan-2-ol
Value(s)*	0.85 mg/cm^2/h
Justification for the selected value(s)	For the purposes of risk assessment, the CAR proposes the use of a dermal flux value of (0.85 mg/cm^2/h) rather than the proportion (%) absorbed. This value is considered appropriate for the DEC-AHOL® product family.

Data waiving	
Information requirement	IUCLID Section 8.6
Justification	Data waiving: Other justification. The Competent Authority Report for propan-2-ol (the active substance) contains a number of in vivo studies of dermal absorption

	in rats and humans, including a study using a product containing 70% propan-2-ol. This value is considered appropriate for the DEC-AHOL® product family.

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

There are no non active substances of concern that meet any of the criteria laid out in the EU SoC guidance (CA-Nov14-Doc.5.11).
MetaSPC 3 contains nitrogen as the co-formulant. However nitrogen is included in Annex I of the BPR. According to the SoC guidance active substance are identified as SoC, other than those included in Annex I of the BPR (criteria 2). There are no other co-formulant present in the BPF.

Available toxicological data relating to a mixture

The classification of the biocidal products can be addressed based on their constituents, as detailed in Regulation (EC) No 1272/2008 and without the need for additional testing.

Other

Food and feeding stuffs

Biocidal products in the DEC-AHOL® family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. Testing in this respect is not therefore necessary.

Effects of industrial processing and / or domestic preparation

Industrial processing and domestic preparation are not relevant to biocidal products in the DEC-AHOL® Product Family. Testing in this respect is not therefore necessary.

Other tests related to exposure to humans

The toxicity of the active substance propan-2-ol has been characterised in a comprehensive set of studies and the substance has been approved for use in biocidal products. The toxicity and hazard of the products is predicted to be low. The products require Category 3 for specific target organ toxicity after single exposure (CLP Cat. 3 H336). There are no concerns relating to the proposed use of the products and no additional studies are required.

Endocrine disruptor Assessment
According to the CAR for propan-2-ol, there is no indication of endocrine disrupting properties of the active substance. MetaSPC 1, 3 and 4 of the DEC-AHOL® Product Family contains only water as co-formulant. MetaSPC 2 contains nitrogen. Nitrogen is however not further considered for the ED assessment because high concentration of nitrogen is already present in the air as background. There is no alert of endocrine disruptor found for the co-formulant of the BPF.

2.2.6.2 Exposure assessment

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

Intended uses:

Products in the DEC-AHOL® family are ready-for-use, alcoholic disinfectant products which are intended to be used as under the general biocidal product category "private and public health area disinfectants": Product Type 2 (PT 2), in the sub-category: PT2.01: Disinfectants for medical equipment, biocidal products for accommodation for man or in industrial areas. Their use is restricted to disinfection of hard, non-porous environmental surfaces, materials and equipment (including cleanroom gloves) in cleanrooms in pharmaceutical, biopharmaceutical, diagnostic and medical device facilities. Treated surfaces are allowed to dry after the treatment time interval has elapsed. These products will not be used in private area (home, daycare, food or beverage preparation establishments). The products in this family all contain the active substance: propan-2-ol (CAS 67-63-0; EC 200-661-7) at a nominal concentration of 70% v/v and water (CAS 7732-18-5; EC 232-791-2) at a nominal concentration of 30% v/v.

These products are effective against bacteria and yeast. They are designed for use indoors, for the disinfection of cleanroom found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product industries. These products are therefore used in strictly controlled, occupational settings only. There is no consumer use of these products and they are not intended to be used in public areas; members of the public will be excluded from areas where these products will be used. The products are applied to surfaces as such (i.e. undiluted) and no post-application rinsing of surfaces is required, since the ingredients in these products are in the pure form and will leave no dry residue.

The products are produced in different packaging types: wipes, aerosol sprays, trigger sprays and liquids (delivered via a bottle or dispenser). The products can therefore be applied by wiping, pouring or spraying, and will be used according to different disinfection regimes.

The products in this family are intended for industrial use only and are provided ready-to-use. No dilution is required, although some decanting of products in meta SPC 3 packaged in bottles of 3.79 L and larger may be required. Since the active substance rapidly evaporates, there is no post application exposure in primary users. Primary exposures will therefore occur only during the decanting (meta SPC 3) and application of the product (i.e. dermal and inhalation exposure). Secondary exposure may occur in bystanders inhaling residues of the active substance in the room (e.g. other workers: non-users working in the same room where the product).

The DEC-AHOL® product family consists of the following metaSPCs:

Summary table of metaSPCs in the DEC-AHOL® product family

Product
META SPC 1: Wipes
META SPC 2: Aerosols
META SPC 3: Liquid Trigger Spray, Liquid Dispenser, Drum and Bottle
META SPC 4: Aerosols (InvertaSpray)

Human exposure:

In line with [redacted] an exposure assessment for human health has been carried out for the DEC-AHOL® product family, based on a tiered approach. In the first instance for each exposure scenario, a Tier 1 assessment reflecting worst-case assumptions (e.g. task duration, assuming no protective equipment is worn) has been carried out. If the risks to human health were considered to be acceptable following the comparison of the predicted dose of the active substance with the appropriate Acceptable Exposure Limit (AEL), then no further refinement of the exposure scenario was carried out. In the AEL concept, the exposure estimates should be compared with the AEL (where the AEL is determined as the NOAEL for the critical effect / an Assessment Factor (AF). If an unacceptable risk was identified for a particular exposure scenario, then a further refinement of the exposure / risk assessment has been carried out using additional parameters.

Biocidal products in the DEC-AHOL® product family are used only in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities. A cleanroom is an environment, typically used in industrial manufacturing settings (e.g. for the production of pharmaceutical products or scientific research), in which low levels of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapours must be critically maintained. A cleanroom is a specially designed and constructed room in which the air supply, materials of construction, and operating procedures, are regulated to control airborne particle concentrations to meet appropriate cleanliness levels and standards. Processes for controlling particles include the use of filtration systems such as wall mounted high efficiency particulate air (HEPA) filters, ceiling mounted filters and return air filter grilles. Cleanrooms will therefore have specialised ventilation systems in order to comply with national or international regulatory standards for the classification of air cleanliness. Air ventilation rates associated with cleanrooms will vary, ranging from 20- 720+ air changes per hour (ACH) and differ from more typical workplace settings where ventilation rates will be in the region of 3-10 ACH.

Due to the high volatility of the active substance, propan-2-ol, the primary concern for human health is the inhalation of vapours and the potential for acute neurological effects. However, vapours of propan-2-ol will be rapidly removed due to the enhanced ventilation systems. In accordance with HEAdhoc Recommendation 15[2] (part B. Cleanrooms) 'Tier 1' inhalation exposure assessments have been performed for routine small surface disinfections considering a ventilation rate of 8 ACH, whilst 'Tier 2' evaluations have used a ventilation rate of 20 ACH.For all scenarios, the room volume of the cleanrooms is assumed to be 55 m^3 (based on HEAdhoc Recommendation 15).

Workers who operate in cleanroom settings in pharmaceutical manufacturing processes will wear uniforms/gowns and hygienic gloves which are specifically designed to protect the sterile products from the contaminants and particles that humans carry and could be inadvertently introduced into products (e.g. an effective "barrier uniform" will be worn). While these uniforms are not intended to protect workers against chemical or other hazards, to some extent, they will protect the workers from splashes and direct

2 ECHA (2017) Recommendation no 15 of the BPC Ad hoc Working Group on Human Exposure: Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer.

contact with the disinfectants that are in use. Hence direct dermal contact with the disinfectant products will be limited in practise. However, it could also occlude the skin and prolong the retention time of highly volatile substances, such as propan-2-ol on the skin (TGD 2003, Part 1, p. 53).

Tier 1 assessments have been carried out assuming no personal protective equipment (PPE) or respiratory protective equipment (RPE) is used, in accordance with the BPR guidance.

In line with the conclusions in the Assessment Report for propan-2-ol, it is assumed that there is 100% absorption of the active substance, propan-2-ol, via the inhalation route whereas for the calculation of the systemic dose via the dermal route, a transdermal flux value of 0.85 mg/cm^2/hour has been used.

The potential for exposure to arise will occur in industrial workers only as a result of primary use and as secondary, indirect scenarios where workers may be bystanders when these products have been used.

The primary routes of exposure to propan-2-ol in industrial workers when using biocidal products in the DEC-AHOL® product family are the inhalation and dermal routes (exposure via the oral route is not envisaged during normal use by professionals). Propan-2-ol is a volatile substance with a relatively high vapour pressure of 5780 Pa at 25^{o}C and will rapidly volatilise from aqueous solutions under normal conditions of use. Primary and secondary exposures in industrial users are therefore expected to occur via the inhalation of vapours. Propan-2-ol concentrations in air will be influenced by the applied dose, the volume of the room in which the products are used, the temperature (influence on vapour pressure) and the air change rate. In addition to exposure via inhalation, direct exposure via the skin is possible when applying the biocidal products by industrial users. Secondary dermal exposures are not envisaged.

No exposures for the general public are envisaged as the products are only used strictly controlled, occupational settings.

The potential for exposure to propan-2-ol to arise from the use of biocidal products in the DEC-AHOL® product family, is summarised in the table below.

Summary table of the relevant paths of human exposure to propan-2-ol from the use of biocidal products in the DEC-AHOL® product family

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

List of scenarios

The following scenarios have been considered in the assessment of human health risks from the use of biocidal products in the DEC-AHOL® product family:

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Mixing/loading	**Primary:** Industrial user pours/decants the liquid product from a 3.79L container when filling a trigger spray reservoir.	Industrial
2	Mixing/loading	**Primary:** Industrial user pours/decants the liquid product from a 3.79L container when wetting a cloth/wipe prior to application.	Industrial
3	Application	**Primary:** Industrial user disinfecting hard surfaces using wiping tissues/cloth.	Industrial
4	Application	**Primary:** Industrial user disinfecting hard surfaces using an aerosol spray can, including leaving on to soak and wiping.	Industrial
5	Application	**Primary:** Industrial user disinfecting hard surfaces using a trigger spray bottle, including leaving on to soak and wiping.	Industrial
6	Application	**Primary:** Industrial user disinfecting gloved hands using a liquid dispenser (in an industrial/manufacturing setting.	Industrial
7	Indirect	**Secondary (indirect exposure):** Bystanders (workers)– inhalation of volatilised residues of propan-2-ol in air after application (e.g. other workers in an industrial/manufacturing setting).	Bystanders (workers)

Industrial exposure

This section considers exposures to propan-2-ol which may occur in Industrial users during the use of ready-for-use alcoholic disinfectant biocidal products in the DEC-AHOL® product family for the routine disinfection of hard surfaces in industrial/manufacturing settings.

Biocidal products in the DEC-AHOL® product family are produced in different formulation types: wipes, aerosol sprays, trigger sprays or liquids (delivery via a bottle or

dispenser). These products can therefore be applied by wiping, pouring or spraying and will be used according to different disinfection regimes. These products contain propan-2-ol at 70% v/v.). A content of % v/v is equivalent to a content of 65% w/w; however, the following risk assessments have been performed assuming a content of 70% w/w as a worst case. The products in this family are intended for industrial use only and are provided ready-to-use. Since the active substance evaporates, there is no post application exposure in primary users. Primary exposure will therefore occur only during the application of the product, via the dermal and inhalation routes.

The biocidal products will be applied to hard surfaces as ready-to-use wipes, by spraying (e.g. using an aerosol can or a trigger spray) or by saturating a sterile cloth/wipe which is subsequently used to wipe a hard surface. The products will be used so as to thoroughly wet the surfaces. The application rate is 35 mL/m^2 for surface disinfection regardless of the type of application. The surfaces will then be allowed to air dry for a minimum of 2 minutes (bactericidal and yeasticidal purposes). After the required contact time has been achieved, the surfaces will be wiped dry with a sterilised cloth, as necessary.

Dispenser type products in the family are designed to disinfect gloves hands. In this case, gloved hands will be held under a spout sensor to catch liquid. The user with then rub the liquid thoroughly to distribute it evenly on the gloved surfaces. The product will not be wiped off, but allowed to dry. The application rate is 1 mL per glove.

Scenarios [1] and [2]

Description of Scenarios [1] and [2]: Primary exposure to an industrial user pouring/decanting the liquid product prior to application.		
Primary application scenario: An industrial worker decants/pours the liquid product from a container (3.79 L bottle) prior to application when filling a trigger spray bottle [1] or squeeze bottle when wetting a sterile wipe/cloth [2] prior to wiping. The liquid product contains 70% v/v propan-2-ol and 30% v/v water. Models/assessment approach: - **Inhalation exposure**: ConsExpo Web: ***"Exposure to vapour";*** release mode: ***"evaporation from constant surface"*** (RIVM Cleaning Products Factsheet 5.4, default scenario: ***"liquid cleaners"*** p. 59, adapted for use in a controlled manufacturing scenario). - **Dermal exposure:** Generic algorithm for dermal exposure to volatile compounds (EU Technical Guidance Document (2003) Part 1 Appendix IF); algorithm based on transdermal flux		
	Parameters	**Value**
Tier 1	Vapour pressure propan-2-ol (Pa)	5780
	Temperature (◦C)	25
	Molecular weight propan-2-ol (g/mol)	60.1
	Molecular weight matrix (g/mol)	18

	Inhalation exposure	
	Exposure duration (mins)	0.75
	Product amount (g)	1651
	Weight fraction compound (propan-2-ol)*	0.7
	Room volume (m^3)	1
	Release area (cm^3)	20
	Ventilation rate (air changes/hr)	8
	Adult bodyweight (kg)	60
	Inhalation rate (m^3/hour)	1.25
	Absorption via inhalation (%)	100
	Exposure duration (mins)	0.75
	Mass transfer coefficient (m/h)	10
	Dermal exposure	
	Applied area: skin surface area; the hands (palms and backs of both hands) (cm^2)	820
	Exposure duration (mins)	0.75
	Dermal flux of propan-2-ol (mg/cm^2/hr)	0.85
Tier 2	Ventilation rate (air changes/hr)	20

* based on a conservative active substance concentration of 70% w/w, rather than 65% w/w (=70% v/v)

Further information and considerations on scenarios [1] and [2]

Industrial users will be required to conduct loading/pouring tasks prior to applying the liquid product as a surface disinfectant, for example when pouring the biocidal product from a 3.79 L container into a receiving vessel (trigger spray reservoir) or when wetting a sterile cloth may result in exposure to propan-2-ol via the dermal and inhalation routes.
The liquid product is applied as a surface disinfectant at a rate of 35 mL/m^2, therefore a 3.79L container contains sufficient product to treat an area of 108 m^2. It is considered unlikely that an individual would disinfect an area in excess of 108 m^2 per day using either a trigger sprayer or soaked wipe. In light of this assumed work rate exposure whilst decanting from a single 3.79 L container has been assessed.

Inhalation exposure to an industrial user decanting/pouring the liquid product has been estimated using the ConsExpo Web: *Inhalation-exposure to vapour – evaporation constant surface area* model (RIVM Cleaning Products Factsheet 5.4, default scenario: *"liquid cleaners"* p. 59, adapted for a cleanroom scenario). The ConsExpo Web exposure model defines an event in which compounds evaporate from a liquid contained within a bottle/container. This approach has been adapted to reflect the use of the liquid product in a controlled cleanrooms in manufacturing facility.

Inhalation exposure to vapour

It is assumed that the active substance, propan-2-ol, evaporates from a surface area of 20 cm^2 (approximating a 3.79 L container with an opening 5 cm in diameter) and that the user stays in the vicinity of the evaporating compound whilst pouring/decanting occurs. A room volume of 1 m^3 has been assessed in order to determine the concentration of propan-2-ol in the air immediately surrounding the exposed individual.

Inhalation exposure to propan-2-ol was estimated using the following additional parameters:

- **Exposure duration:** 0.75 min, as stipulated in HEAdhoc Recommendation 13[3] for the professional decanting of disinfection products. The value of 0.75 mins is derived from a study by [redacted] and represents the maxiumium task duration recorded for an individual loading a dishwasher with liquid detergents. This value is considered representative of the duration required to fill a trigger spray reservoir and/or wet a sterile cloth.
- **Product amount:** The value of 1651 g has been used to estimate inhalation exposure from a half full 3.79 L container. The selection of this value follows the assessment approach proposed in both HEAdhoc Recommendation 13 and the RIVM Cleaning Products Factsheet.
- **Mass transfer rate:** 10 m/h (default ConsExpo Web, HEAd hoc recommendation no. 15)

Inhalation exposure [1] decanting into a trigger spray bottle

Tier 1

The assessment of the parameters described above results in an estimated mean event in-air concentration and peak concentration (TWA 15 min) of 7 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 0.75 minute decanting event. Systemic exposure in adults exposed to an in-air concentration of 7 mg/m^3 propan-2-ol for a duration of 0.75 minutes is calculated as follows:

$SysD_o = (MC \times IR \times Abs_I \times ED) / BW$

Where:

$SysD_o$ = Systemic inhalation dose (mg/kg bw/day)
MC = Mean event in-air concentration (mg/m^3)
IR = Inhalation rate (m^3/hr)
Abs_i = inhalable absorption rate
ED = Exposure duration (hrs)
BW = bodyweight (kg)

Inhalation route $SysD_o$ = (7 mg/m^3 x 1.25 m^3/hr x 1 x 0.0125 hrs) / 60 kg

= **0.0018 mg a.s./kg bw/day**

Tier 2

[3] ECHA (2017) Recommendation no 13 of the BPC Ad hoc Working Group on Human Exposure: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3).

A refined assessment was performed considering an increased ventilation rate of 20 ACH. This resulted in an estimated mean event in-air concentration and peak concentration (TWA 15 min) of 6.6 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 0.75 minute decanting event.

Inhalation route $SysD_o$ = (6.6 mg/m^3 x 1.25 m^3/hr x 1 x 0.0125 hrs) / 60 kg

= **0.0017 mg a.s./kg bw/day**

Dermal exposure [1] decanting into a trigger spray bottle

Tier 1

As a worst-case assessment of dermal exposure during decanting/wetting activities, the systemic dermal exposure to propan-2-ol was calculated using the transdermal flux rate, taking into account the surface area of skin exposed and a decanting duration time of 0.75 minutes per event. The systemic dermal dose was calculated as follows:

$SysD_o$= (*DF x ED x SS) / BW*

Where:

$SysD_o$ = Systemic dermal dose (mg/kg bw/day)
DF= Dermal flux (mg/cm^2/hr)
ED = Exposure duration (hrs)
SS= Area of exposed skin (cm^2)
BW = bodyweight (kg)

Dermal route $SysD_o$ = (0.85 mg/cm^2/hr x 0.0125 hrs x 820 cm^2) / 60 kg

= **0.1452 mg a.s./kg bw/day**

In considering the product application rate it is expected that industrial users will conduct a single decanting operation daily when filling a trigger spray bottle.

Inhalation exposure [2]: An industrial user saturates a cloth/wipe prior to wiping

Tier 1

An industrial user may wet/saturate a cloth (prior to wiping) on multiple occasions per day. As described in Scenario [PT2-3] it is assumed that an industrial user will disinfect an area of 0.5 m^2 using a wet tissue or wipe on 10 separate occasions per day. It is also assumed that the user will wet the cloth/wipe (by holding the cloth to the open neck of the bottle and tipping the container) prior to each disinfection event. Systemic exposure in adults exposed to an in-air concentration of 7 mg/m^3 propan-2-ol for a duration of 7.5 minutes (10 x 0.75 minute wetting events) is calculated as follows:

$SysD_o$= (*MC x IR x* Abs_I *x ED) / BW*

Where:

$SysD_o$ = Systemic inhalation dose (mg/kg bw/day)

MC = Mean event in-air concentration (mg/m^3)
IR = Inhalation rate (m^3/hr)
Abs_i = inhalable absorption rate
ED = Exposure duration (hrs)
BW = bodyweight (kg)

Inhalation route $SysD_o$ = (7 mg/m^3 x 1.25 m^3/hr x 1 x 0.125 hrs) / 60 kg

= **0.018 mg a.s./kg bw/day**

Tier 2

A refined assessment was performed considering an increased ventilation rate of 20 ACH. This resulted in an estimated mean event in-air concentration and peak concentration (TWA 15 min) of 6.6 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 0.75 minute decanting event.

Inhalation route $SysD_o$ = (6.6 mg/m^3 x 1.25 m^3/hr x 1 x 0.125 hrs) / 60 kg

= **0.017 mg a.s./kg bw/day**

Dermal exposure [2]: An industrial user saturates a cloth/wipe prior to wiping.

Tier 1

Systemic dermal exposure to propan-2-ol may be calculated using the transdermal flux rate, taking into account the surface area of skin exposed and a task duration time of 7.5 minutes (10 x 0.75 minute cloth wetting events). The systemic dermal dose was calculated as follows:

$SysD_o$= (*DF x ED x SS) / BW*

Where:

$SysD_o$ = Systemic dermal dose (mg/kg bw/day)
DF= Dermal flux (mg/cm^2/hr)
ED = Exposure duration (hrs)
SS= Area of exposed skin (cm^2)
BW = bodyweight (kg)

Dermal route $SysD_o$ = (0.85 mg/cm^2/hr x 0.125 hrs x 820 cm^2) / 60 kg

= **1.452 mg a.s./kg bw/day**

eCA note
During the Peer Review phase, one Member State has requested to add an exposure assessment based on ARTtool to Scenario 1 and 2.

Duration	10 min
Non-exposure period	0 min
Product type	Liquids
Process temperature	298 k
Vapour pressure	5780 Pa
Liquid mole fraction	0.411 (70%)
Activity coefficient	1.406
Emission source	In the breathing zone (near field)
Activity class	- transfer of liquid products - falling liquid - 0.1-1 L/min - Open process - Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Control measures (near-field emission source)	- No localised controls
Process fully enclosed	No
Effective housekeeping practices in place	Yes
Work area	Indoors
Room size of the work area	Any size workroom
Ventilation rate	Only good natural ventilation
Secondary emission source	No secondary source

Using ARTtool, the mean conc 130 mg/m^3 was calculated (75th %ile). The systemic exposure via inhalation is then calculated to be
(130 mg/m3 x 1.25 m3/h x 0.0125 h x 100% absorption)/60 kgbw = 0.034 mg/kg bw per pouring. Total systemic exposure is therefore calculated to be
- Scenario 1: 0.034 (inhal)+0.1452(dermal) =0.179 mg/kg bw/d
- Scenario 2: 0.34 (inhal)+1.425 (dermal) =1.765 mg/kg bw/d

The combined scenarios will then be

Summary table: combined systemic exposure from industrialuses			
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated total uptake**
Scenarios 2 + 3	0.34+3.3 = 3.64	1.452+ 0.4937 = 1.946	5.586
Scenario 1 + 5	0.034+5 = 5.034	0.1452 + 0.576 =0.7212	5.755

Because the estimated total uptake are both below the AEL acute/medium-term/long-term professional workers (17.9 mg/kg bw/d), no adverse health effects are expected. The calculation with ARTtool will not be further mentioned in the PAR.

Description of Scenario [3] Industrial user disinfecting hard surfaces using a wet wiping tissue/cloth

Primary application scenario: An industrial user uses a wiping tissue/cloth to disinfect a surface or article. The surface is wiped thoroughly until visibly wet and is left for up to 10 mins. In accordance with the propan-2-ol CAR, it is assumed that an industrial user disinfects an area of 0.5 m^2 for a duration of one minute. The user repeats this disinfection task at 45 minute intervals over an 8 hour work shift (10 disinfection events occur per shift). The disinfection wipes contain 70% v/v propan-2-ol and 30% v/v water.

The parameters listed below represent a single disinfection event using either a pre-impregnated wipe or cloth saturated with the liquid product. Exposure to an individual performing 10 disinfection events over an 8 hour shift is considered below.

Models/assessment approach:

- **Inhalation exposure**: ConsExpo Web model : ***"Exposure to vapour";*** release mode: ***"evaporation from increasing surface"*** (RIVM Cleaning Products Factsheet 5.4, default scenario: ***"wet tissues"*** p. 63, adapted for use in a controlled cleanroom in manufacturing/industrial setting.

- **Dermal exposure:** Generic algorithm for dermal exposure to volatile compounds ([redacted] Part 1 Appendix IF); algorithm based on transdermal flux

	Parameters	**Value**
Tier 1	Vapour pressure propan-2-ol (Pa)	5780
	Molecular weight propan-2-ol (g/mol)	60.1
	Molecular weight matrix (g/mol)	18
	Application frequency (per day)	10
	Inhalation exposure	
	Release area (m^2)	0.5
	Product application rate (mL/m^2)	35
	Body weight (kg)	60 (HEEG opinion 17)
	Exposure event duration (min/application)	45
	Application duration (min/application)	2
	Product amount (g/application)	15.24
	Weight fraction compound (propan-2-ol)*	0.7
	Room volume (m^3)	55
	Ventilation rate (air changes/hr)	8
	Inhalation absorption (%)	100
	Inhalation rate (m^3/hr)	1.25 (HEEG Opinion 17)

	Mass transfer coefficient (m/hr)	10
	Dermal exposure	
	Applied area: skin surface area; the palm of one hand (cm^2)	205
	Application duration (mins)	1
	Dermal flux of propan-2-ol ($mg/cm^2/hr$)	0.85
Tier 2	Ventilation rate (air changes/hr)	20

* based on a conservative active substance concentration of 70% w/w, rather than 65% w/w (=70% v/v)

Further information and considerations on scenario [3]

Industrial users may be exposed to propan-2-ol when using alcoholic disinfection wiping tissues/cloths to disinfect hard surfaces in an industrial/manufacturing setting. The assessment considers the use of wiping tissues that may be either a ready-for use, disposable fabric wipes or a sterile cloth/wipe that has been wetted (immediately prior to application) by the user. Exposure to propan-2-ol in an individual wetting a cloth prior to disinfecting a surface is considered in Scenario 2-1 above. The work rate, use pattern and subsequent exposure to an individual applying the liquid product using a saturated cloth would not exceed that associated with the use of a pre-impregnated 'wet wipe'.

Potential exposures to propan-2-ol may occur via the dermal route (e.g. to the hands when applying the wipes to surfaces during cleaning operations) and via the inhalation of vapours of the active substance which has volatilised from the wipe or the cleaned surface. It is expected that industrial users would use wiping tissues multiple times during a working shift, and that the use of these products would occur daily.

For an industrial user disinfecting hard surfaces using single use wiping tissues (PT2), [redacted], p.106, recommends using the ConsExpo 4.1 default scenario for "disinfectants for use indoors, wiping" and the RIVM Cleaning Product Factsheet 5.4 (report 320104003; 2006), scenario: **"wet tissues"**, p. 63.

The following approaches have been used to determine dermal and inhalation exposures respectively:

Inhalation exposure to vapour

Tier 1

In accordance with the modelling approach described in the propan-2-ol assessment report (AR)[4] inhalation exposure associated with the use of **"wet tissues"** has been assessed using the ConsExpo model: ***"Exposure to vapour - evaporation from increasing surface'.***

4 [redacted] Assessment Report for Propan-2-ol, Product Type 2. Evaluation of active substances: Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

The assessment of the parameters described above results in an estimated mean in-air event concentration of 21 mg/m^3 propan-2-ol (Consexpo Web output contained in Annex 3) during a single 45 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 21 mg/m^3 propan-2-ol for an 8 hour period (representing a worker performing 10 consecutive disinfection events) is calculated as follows: $SysD_o = (MC \times IR \times Abs_I \times ED) / BW$

Where:

$SysD_o$ = Systemic inhalation dose (mg/kg bw/day)
MC = Mean event in-air concentration (mg/m^3)
IR = Inhalation rate (m^3/hr)
Abs_i = inhalable absorption rate
ED = Exposure duration (hrs)
BW = bodyweight (kg)

Inhalation route $SysD_o$ = (21 mg/m^3 x 1.25 m^3/hr x 0.75 hour x 1) / 60 kg x 10 applications/day

= 3.3 **mg a.s./kg bw/day**

Tier 2

A refined assessment was performed considering an increased ventilation rate of 20 ACH. This resulted in an estimated mean event in-air concentration of 8.4 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 45 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 8.4 mg/m^3 propan-2-ol for an 8 hour period (representing a worker performing 10 consecutive disinfection events) is calculated as follows:

Inhalation route $SysD_o$ = (8.4 mg/m^3 x 1.25 m^3/hr x 0.75 hour x 1) / 60 kg x 10 applications/day

= **1.3 mg a.s./kg bw/day**

Dermal exposure

Tier 1

As a worst-case assessment of dermal exposure during disinfection activities, the systemic dermal exposure to propan-2-ol was calculated using the transdermal flux rate, taking into account the surface area of skin exposed and a total daily disinfection task duration of 10 minutes (10 x 1 minute disinfection tasks). The systemic dermal dose was calculated as follows:

$SysD_o = (DF \times ED \times SS) / BW$

Where:

$SysD_o$ = Systemic dermal dose (mg/kg bw/day)
DF= Dermal flux (mg/cm^2/hr)
ED = Exposure task duration (hrs)

SS= Area of exposed skin (cm^2)
BW = bodyweight (kg)

Dermal route $SysD_o$ = (0.85 mg/cm^2/hr x 0.17 hrs x 205 cm^2) / 60 kg

= **0.4937 mg a.s./kg bw/day**

Total systemic exposures were determined by adding the respective systemic doses determined via the dermal and the inhalation routes.

Description of Scenario [4] An industrial user disinfecting hard surfaces using an aerosol can and [5] An Industrial user disinfecting hard surfaces using a trigger spray

Primary application scenario: An industrial user uses an aerosol can spray [4] or a trigger spray bottle [5] to spray a 0.5 m^2 hard surface until wet, leaves the surface for up to 15 minutes (comment eCA: this 15 min assumption is based on fungicidal claim that was originally proposed by the applicant. The fungicidal claim was withdrawn in the course of evaluation phase. As 15 min represents a worse case than the remaining use with leave-on duration of 2 min, the calculation was not revised) and wipes dry with a sterilised cloth or wipe. The spray products respectively contain 70% v/v propan-2-ol and 30% v/v water.

The parameters listed below represent a single 45 minute disinfection event. Exposure to an individual performing 10 disinfection events over an 8 hour shift is considered below.

- **Inhalation exposure**: ConsExpo Web model: ***"Exposure to vapour";*** release mode: ***"evaporation from increasing surface"*** (RIVM Cleaning Products Factsheet 5.4, scenario: ***"spray cleaners"*** p. 61, adapted for a controlled manufacturing environment).

- **Dermal exposure:** Generic algorithm for dermal exposure to volatile compounds (EU Technical Guidance Document, (2003) Part 1 Appendix IF); algorithm based on transdermal flux

Inhalation exposure to aerosol formed during spraying application is not taken into consideration. Considering the very high vapor pressure propan-2-ol will quickly evaporate in air from applied surfaces. In addition, aerosol formed will sink quickly and will not be inhaled after application. This makes exposure duration to aerosol to be very short i.e. equals to the application duration of 10 sec per application. The exposure to vapour, on the other hand, assumes exposure duration of 45 min because vapourised propan-2-ol will be available in air also after application unless they are removed by ventilation. Because of these scenario assumptions the exposure to aerosol is negligible compared to that to vapour. Based on Consumer spraying and dusting model 2 (TNsG part 2, p 197) the air concentration of propan-2-ol as aerosols is about 10.5 mg/m^3 (and during trigger spraying. The systemic exposure to aerosol is calculated to be (10.5 mg/m^3 x 0,17 min/60 h x 1,25 m^3/h x 10 applications/day) /60 kg bw =0.006 mg/kg bw/day for scenario 5. This is far below the estimated exposure to vapour for the same scenario i.e. 5 and 2 mg/kg bw/day for Tier 1 and Tier 2 respectively.

	Parameters	Value
Tier 1	Vapour pressure propan-2-ol (Pa)	5780
	Molecular weight propan-2-ol (g/mol)	60.1
	Molecular weight matrix (g/mol)	18
	Frequency (per day)	10
	Inhalation exposure	
	Release area (m^2)	0.5
	Exposure event duration (min/acpplication)	45
	Product application rate (mL/m^2)	35
	Product amount – aerosol can/trigger spray (g/application)	15.24
	Weight fraction compound (propan-2-ol)*	0.7
	Room volume (m^3)	55
	Ventilation rate (air change/hr)	8
	Inhalation absorption (%)	100
	Inhalation rate (m^3/hr)	1.25 (HEEG Opinion 17)
	Application duration (single event) - spraying phase: aerosol can or trigger spray (mins)	0.17**
	Mass transfer coefficient (m/hr)	10
	Dermal exposure	
	Applied area: skin surface area; the palm of one hand (cm^2)	205
	Task duration - spraying phase: aerosol can or trigger spray (min/application)	0.17
	Task duration – soaking and wiping phase (min/application)	1
	Dermal flux of propan-2-ol (mg/cm2/hr)	0.85
Tier 2	Ventilation rate (air change/hr)	20

* based on a conservative active substance concentration of 70% w/w, rather than 65% w/w (=70% v/v)

** based on the application speed 20 seconds/m2 (use instruction), and the area treated is 0.5 m2 for this scenario, the spraying time needed is 10 seconds (=0.17 min)

Further information and considerations on scenario [4 and 5]

Industrial users may be exposed to propan-2-ol when using a spray-based product e.g. using an aerosol can (scenario 4) or a trigger spray bottle (scenario 5) to disinfect a hard surface or article in an industrial/manufacturing setting (e.g. a cleanroom). Scenarios 4 and 5 both involve the application of spray-based products (e.g. as an aerosol can or as a trigger spray respectively). Similar approaches have therefore been used, and

parameters specific to an aerosol can or a trigger spray respectively have been used where relevant.

In these scenarios, the worker will spray the surface until it is thoroughly wet, then leaves the surface or article for up to 15 minutes before wiping the surface dry with a sterilised cloth or wipe, as necessary. Spray type products contain 70% w/w propan-2-ol and 30% w/w water. No mixing and loading will be required as the products are packaged in ready-to-use spraying bottles. Potential exposures to propan-2-ol may occur via the dermal route (e.g. to the hands when spraying the product onto the surfaces or wiping the surface dry) and via the inhalation of vapours of the active substance which have volatilised during spraying or from the cleaned surface. These spraying products may be used according to different disinfection regimes in controlled industrial settings such as cleanrooms. As the worst case, it is expected that industrial users would use spraying products multiple times during a working shift, and that the use of these products would occur daily.

There are no models in the [redacted] which are specifically recommended for the spray disinfection of hard surfaces in an industrial setting such as a cleanroom. Exposures have been assessed taking into account the approach described in the RIVM Cleaning Products Factsheet p.61 for the scenario ***"spray cleaners",*** adapted to reflect the use of spraying products in a controlled industrial setting. The approach has also taken into account the high volatility of propan-2-ol and the use of the transdermal flux for the assessment of dermal exposure.

Three phases of operation can be distinguished for the use of spray disinfection products: firstly the products are sprayed onto the surface, then, the product is left to soak into the surface for several minutes and finally the surface is wiped with a cloth or wipe. The application time will be short and the direction of spraying will be away from the operator (e.g. directed into the surface). Due to the high vapour pressure of the active substance, propan-2-ol, inhalation exposure to vapours associated with spraying (and the subsequent soaking and wiping phases) has been assessed. Dermal exposure is expected to occur during the spraying phase. Once the product has been applied to the surface the active substance will rapidly evaporate such that exposures via dermal contact will be minimal. However, to account for any potential exposures arising from the wiping of wet surfaces, dermal exposures during the soaking and wiping phase of the disinfection task have been assessed.

The following approaches have been used to determine dermal and inhalation exposures respectively:

<u>Inhalation exposure to vapours (spraying, soaking and wiping phases):</u>

<u>Tier 1</u>

Considering the high volatility of propan-2-ol, the use of the ConsExpo model: ***"Exposure to vapour*** **- evaporation from increasing area'** is appropriate for assessing inhalation exposures during the spray application of products in the DEC-AHOL® family, including aerosol and trigger-based sprays.

The assessment of the parameters described above results in an estimated mean event in-air concentration of 32 mg/m^3 propan-2-ol (Consexpo Web output contained in Annex 3) during a 45 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 32 mg/m^3 propan-2-ol for an 8 hour

period (representing an industrial user performing 10 consecutive disinfection events) is calculated as follows:

$SysD_o = (MC \times IR \times Abs_I \times ED) / BW$

Where:

$SysD_o$ = Systemic inhalation dose (mg/kg bw/day)
MC = Mean event in-air concentration (mg/m^3)
IR = Inhalation rate (m^3/hr)
Abs_i = inhalable absorption rate
ED = Exposure duration (hrs)
BW = bodyweight (kg)

Inhalation route $SysD_o$ = ($32 mg/m^3 \times 1.25\ m^3/hr \times 1 \times 0.75$ hrs) / 60 kg x 10 applications

= **5 mg a.s./kg bw/day**

Tier 2

A refined assessment was performed considering an increased ventilation rate of 20 ACH. This resulted in an estimated mean event in-air concentration of 13 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 45 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 13 mg/m^3 propan-2-ol for an 8 hour period (representing a worker performing 10 consecutive disinfection events) is calculated as follows:

Inhalation route $SysD_o$ = ($13 mg/m^3 \times 1.25\ m^3/hr \times 0.75$ hour x 1) / 60 kg x 10 applications/day

= **2.0 mg a.s./kg bw/day**

Dermal exposure (spraying phase)

Tier 1

Systemic dermal exposure to propan-2-ol was calculated using the transdermal flux rate, taking into account the surface area of skin exposed and a spraying application task duration of 1.7 minutes (10 x 0.17 minute spray application tasks). The systemic dermal dose was calculated as follows:

$SysD_o = (DF \times ED \times SS) / BW$

Where:

$SysD_o$ = Systemic dermal dose (mg/kg bw/day)
DF= Dermal flux ($mg/cm^2/hr$)
ED = Exposure task duration (hrs)
SS= Area of exposed skin (cm^2)
BW = bodyweight (kg)

Dermal route $SysD_o$ = (0.85 mg/cm^2/hr x 0.003 hrs x 205 cm^2) / 60 kg x 10 applications

= **0.0823 mg a.s./kg bw/day**

Dermal exposure (wiping phase)

Systemic dermal exposure to propan-2-ol was calculated using the transdermal flux rate, taking into account the surface area of skin exposed and a wiping task duration of 10 minutes (10 x 1 minute wiping tasks). The systemic dermal dose was calculated as follows:

$SysD_o$= (DF x ED x SS) / BW

Where:

$SysD_o$ = Systemic dermal dose (mg/kg bw/day)
DF= Dermal flux (mg/cm^2/hr)
ED = Exposure task duration (hrs)
SS= Area of exposed skin (cm^2)
BW = bodyweight (kg)

Dermal route $SysD_o$ = (0.85 mg/cm^2/hr x 0.017 hrs x 205 cm^2) / 60 kg x 10 applications

= **0.4937 mg a.s./kg bw/day**

Total systemic exposures were determined by adding the respective systemic doses determined via the dermal and the inhalation routes.

Description of Scenario [6] Industrial user disinfecting gloved hands using a liquid dispenser

Primary application scenario: An industrial user disinfects gloved hands using a liquid dispenser. The worker holds their hands under a spout sensor to catch liquid and thoroughly rubs their hands to evenly distribute the liquid over the glove surfaces, before allowing to dry in the air. The liquid dispenser product contains 70% v/v propan-2-ol and 30% v/v water. Model/approach: ECHA Guidance Biocides (2015) – Scenario : *Hygienic and surgical hand disinfection in health care facilities by hand rubbing without rinsing.*

The parameters listed below represent a single 19 minute disinfection event. The exposure duration of 19 min was derived based on a working duration of 8 hours per day and disinfection frequency of 25 times a day (480 min /25 application).

The product amount used is 1.5 mL per glove, which results in 2625 mg (3 mL x relative density 0.875 g/mL) product per application.

- **Inhalation exposure**: ConsExpo: ***"Exposure to vapour";*** release mode: ***"instantaneous release"***.

- **Dermal exposure:** Considered negligible as the products are applied on impermeable gloves

	Parameters	**Value**
Tier 1	Not relevant (gloves are always worn)	
Tier 2	Vapour pressure propan-2-ol (Pa)	5780
	Molecular weight propan-2-ol (g/mol)	60.1
	Frequency of use (per day)	25 (HEAd hoc recommendation 1)
	Adult bodyweight (kg)	60
	Inhalation exposure	
	Exposure duration (min/application)	19
	Product amount (mg/application)	2625
	Room volume (m^3)	55
	Ventilation rate (air changes/hr)	8
	Inhalation absorption (%)	100
Tier 3	Ventilation rate (air changes/hr)	20

Further information and considerations on scenario [6]

Industrial users may be exposed to propan-2-ol when using a liquid dispenser containing an alcoholic disinfectant biocidal product from the DEC-AHOL® product family. The product is supplied in a low density polyethylene container that is designed to fit specific dispenser equipment. A cap is removed from the head of the container which is then placed into the machine. The nozzle and collar of the container are moulded to fit securely into the pump dispensing assembly. This bottle contains a small moulded internal dip tube whose sole function is to supply the pump with a constant flow of product once the fluid level falls below the intake. The dip tube aligns to the end of the

pump assembly upon insertion. The placing of the product container into the dispenser assembly is considered a negligible exposure scenario.

Potential exposures to propan-2-ol may occur via the dermal route (e.g. when applying the product over the surface of gloved hands and rubbing in well) and via the inhalation of vapours of the active substance which volatilises from the product when this is applied to the gloved hands. Note: the product is not intended to be applied to bare hands; it is for application to the gloves only (any dermal exposure would be accidental). Dermal exposure is considered negligible as the products are applied on impermeable gloves. It is expected that industrial workers could apply the product to the hands multiple times during a working shift, and that the use of these products would occur daily.

There are no models or approaches in [redacted] which directly address this scenario. However, the scenario is similar to one where a professional worker may use an alcoholic hand sanitising product directly onto the skin (e.g. a PT1 product). An approach is recommended for this scenario in Section 3.2.1 of [redacted] Professional worker: *Hygienic and surgical hand disinfection in health care facilities by hand rubbing without rinsing*. Taking into account these recommendations, the following approaches have been used to determine dermal and inhalation exposures respectively:

Inhalation exposure to vapour

Tier 2

[redacted] recommends that inhalation exposures to vapours arising from the application of a hand sanitising product are assessed used the ConsExpo 4.1: ***"Exposure to vapour"*** model. As a worst-case scenario, the model was been used in the ***"instantaneous"*** release mode as a first tier to screen the upper level of exposure. In this approach, it is assumed that all the active substance applied to the gloved hands per application (3 mL) is released at once into the room and is subsequently removed by ventilation to negligible levels before the next application. Due to the high volatility of the active substance, propan-2-ol, this is considered to give a reasonable approximation for the air concentration associated with the product use.

The assessment of the parameters described above results in an estimated mean in-air concentration of 12 mg/m^3 propan-2-ol (Consexpo Web output contained in Annex 3) during a 19 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 12 mg/m^3 propan-2-ol for an 8 hour period (representing an industrial user performing 25 consecutive disinfection events) is calculated as follows:

$SysD_o = (MC \times IR \times Abs_I \times ED) / BW$

Where:

$SysD_o$ = Systemic inhalation dose (mg/kg bw/day)
MC = Mean event in-air concentration (mg/m^3)
IR = Inhalation rate (m^3/hr)
Abs_i = inhalable absorption rate
ED = Exposure duration (hrs)
BW = bodyweight (kg)

Inhalation route $SysD_o$ = (12 mg/m^3 x 1.25 m^3/hr x 1 x 0.32 hrs) / 60 kg x 25 applications

= **2 mg a.s./kg bw/day**

Tier 3

A refined assessment was performed considering an increased ventilation rate of 20 ACH. This resulted in an estimated mean event in-air concentration of 5.3 mg/m^3 propan-2-ol (Consexpo Web output attached) during the 19 minute disinfection exposure event. Systemic (inhalation route) exposure in adults exposed to an in-air concentration of 5.3 mg/m^3 propan-2-ol for an 8 hour period (representing a worker performing 25 consecutive glove disinfection events) is calculated as follows:

Inhalation route $SysD_o$ = (5.3 mg/m^3 x 1.25 m^3/hr x 0.32 hour x 1) / 60 kg x 25 applications/day

= **0.89 mg a.s./kg bw/day**

Dermal exposure

Dermal exposure is negligible as the products are applied on impermeable gloves.

Scenario [7]

Secondary (indirect exposure): Bystanders (workers)– inhalation of volatilised residues of propan-2-ol in air after application (e.g. other workers in an industrial/manufacturing setting)

When biocidal products in the DEC-AHOL® product family are used in controlled industrial/manufacturing settings, secondary (indirect) exposures to propan-2-ol may occur in other workers who may be non-users but may be in the vicinity of areas where such products may be used (e.g. other workers or staff at the industrial settings). Secondary dermal exposures are not envisaged: the primary route of exposure will be inhalation of volatilised residues of propan-2-ol, arising from the use of these products.

Inhalation exposure to propan-2-ol in bystanders (industrial workers) is considered to be comparable to or lower than that experienced by primary users. Secondary (indirect exposure) has not therefore been considered further.

Summary table: Estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Mean event in-air propan-2-ol concentration (mg/m^3)**	**Estimated inhalation uptake (mg/kg bw /day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**

Primary exposure scenario [1] **Industrial user pours/decants the liquid product from a 3.79L container when filling a trigger spray reservoir**	Tier 1 No PPE	7	0.0018	0.1452	0.147
	Tier 2 No PPE 20 ACH	6.6	0.0017	0.1452	0.147
Primary exposure scenario [2] **Industrial user pours/decants the liquid product from a 3.79L container when wetting a cloth/wipe prior to application.**	Tier 1 No PPE	7	0.018	1.452	1.47
	Tier 2 No PPE 20 ACH	6.6	0.017	1.452	1.47
Primary exposure scenario [3] **Industrial user disinfecting hard surfaces using a wiping tissue/wet cloth.**	Tier 1 No PPE	21	3.3	0.4937	3.79
	Tier 2 No PPE 20 ACH	8,4	1.39	0.4937	1.79
Primary exposure scenario [4] **Industrial user disinfecting hard surfaces using an aerosol can[2]**	Tier 1 No PPE	32	5.0	0.0823+0.4937 =0.576	5.576
	Tier 2 No PPE 20 ACH	13	2.0	0.576	2.606
Primary exposure scenario [5] **Industrial user disinfecting hard surfaces**	Tier 1 No PPE	32	5.0	0.576	5.576

using a trigger spray[2]	Tier 2 No PPE 20 ACH	13	2.0	0.576	2.606
Primary exposure scenario [6] **Industrial user disinfecting gloved hands using a liquid dispenser**	Tier 1	Not relevant (gloves are always worn)			
	Tier 2 Gloves PPE	12	2.0	0	2.0
	Tier 3 Gloves PPE 20 ACH	5.3	0.89	0	0.89
Secondary exposure scenario [7] **Adult-bystander: inhalation of volatilised residues**	Tier 1 no PPE	≤32	≤5.0	NA	≤5.0
	Tier 2 No PPE 20 ACH	≤13	≤2.03	NA	≤2.03

Combined scenarios [2 and 3]

The following two combinations of scenarios are considered to be worst-case in terms of combined exposure in industrial workers using products in the DEC-AHOL® product family:

Scenario 2 – Industrial user pours/decants the liquid product from a 3.79 L container when wetting a cloth/wipe prior to application.

+

Scenario 3 – Industrial user disinfecting hard surfaces using a wiping tissue/wet cloth.

Scenario 1 – Industrial user pours/decants the liquid product from a 3.79L container when filling a trigger spray reservoir

+

Scenario 5 – Industrial user disinfecting hard surfaces using a trigger spray

The exposures predicted for these combined scenarios are summarised in the table below.

Summary table: combined systemic exposure from industrialuses

Scenarios combined	Estimated inhalation uptake (mg/kg bw /day)	Estimated dermal uptake (mg/kg bw /day)	Estimated total uptake (mg/kg bw /day)
Scenarios 2 and 3	0.018+3.3 = 3.318	1.452+ 0.4937 = 1.946	5.264
Scenario 1 and 5	0.0018+5 = 5.002	0.1452 + 0.576 =0.7212	5.723

The combined (Tier 1) scenarios described above (2+3 & 1+5) each consider systemic exposure in an individual exposed to the mean (45 minute) disinfection event (wiping or spray application) in-air concentration for a 450 minute (7.5 hr) period. This approach forms the risk envelop for a user who may alternate between wiping or spray applications throughout an 8 hr working shift.

Staff performing clean room disinfection activities would not perfom additional glove disinfections as the handling of the DEC-AHOL products (described in scenarios 3 & 5) would result in the disinfection of both the glove and the treated surface. It should also be noted that the purchase (and use) of the entire DEC-AHOL product family by a single cleanroom operator is highly unlikely (e.g a trigger sprayer and an aerosol would not be used in the same installation; a single spray application delivery device would be purchased).

Professional exposure

The DEC-AHOL® product family is used by industrial users only in industrial/manufacturing settings (pharmaceutical manufacture/clean rooms). Professional users (those using end-products outside industry) will not be exposed to the biocide product family.

Non-professional exposure

Biocidal products in the DEC-AHOL® product family are intended to be used by industrial users in industrial/manufacturing settings (e.g. cleanrooms). There are no non-professional uses of these products.

Exposure of the general public

Biocidal products in the DEC-AHOL® product family are intended to be used by industrial users only in industrial/manufacturing settings (e.g. cleanrooms) . These are strictly controlled environments and the general public will be excluded from entering these premises. Consideration of exposure of the general public is therefore not relevant to the use of these products.

Monitoring data

No surveys or study data using biocidal products in the DEC-AHOL® product family are available.

Dietary exposure

Biocidal products in the DEC-AHOL® product family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of dietary residues and dietary exposure is therefore not relevant to this product family.

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

Potential exposures during the manufacture of the active substance, propan-2-ol, and its formulation into the biocidal products in the DEC-AHOL® product family are considered under The Chemical Agents at Work Directive (98/24/EC, within 89/391/EEC) and are minimised by the use of automated processes and engineering controls integral to the processes and further reduced by the requirements to wear suitable protective equipment (including gloves, protective clothing and eye protection[5]) whenever exposure to the active substance or other ingredients is likely. These regulations competently control for operator exposure to the biocidal products in the DEC-AHOL® product family during production, formulation and disposal.

[5] The Personal Protective Equipment as Work Regulations 1992 (EU Directive 89/656/EEC)

2.2.6.3 Risk characterisation for human health

This section addresses the risk characterisation for human health associated with the uses of the products containing propan-2-ol as the active substance. The products contain propan-2-ol at concentration of 70% v/v.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AEC acute/medium-term/long-term general population	Human volunteer study ([redacted])	200 ppm	6.4	-	31.25 ppm for an exposure for 8 hours/d
AEL acute/medium-term/long-term general population	Human volunteer study ([redacted])	-	6.4	-	10.7 mg/kg bw/d
AEC acute/medium-term/long-term professional workers	Human volunteer study ([redacted])	200 ppm	3.8	-	52.6 ppm (≈129 mg/m^3) for an exposure for 8 hours/day
AEL acute/medium-term/long-term professional workers	Human volunteer study ([redacted])	-	3.8	-	17.9 mg/kg bw/d

Maximum residue limits or equivalent

No exisiting MRLs are known for propan-2-ol.

Risk for industrial users

Summary table: Estimated exposure from industrial uses					
Exposure scenario	**Tier**	**AEL (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**	**% of AEL**	**Acceptable (yes/no)**
Primary exposure scenario [1] **Industrial user pours/decants the liquid product from a 3.79L**	Tier 1	17.9	0.147	<1	Yes

container when filling a trigger spray reservoir	Tier 2	17.9	0.147	<1	Yes
Primary exposure scenario [2] **Industrial user pours/decants the liquid product from a 3.79L container when wetting a cloth/wipe prior to application.**	Tier 1	17.9	1.470	8	Yes
	Tier 2	17.9	1.469	8	Yes
Primary exposure scenario [3] **Industrial user disinfecting hard surfaces using a wiping tissue/wet cloth.**	Tier 1	17.9	3.794	22	Yes
	Tier 2	17.9	1.794	10	Yes
Primary exposure scenario [4] **Industrial user disinfecting hard surfaces using an aerosol can[2]**	Tier 1	17.9	5.576	31	Yes
	Tier 2	17.9	2.606	15	Yes
Primary exposure scenario [5] **Industrial user disinfecting hard surfaces using a trigger spray[2]**	Tier 1	17.9	5.576	31	Yes
	Tier 2	17.9	2.606	15	Yes
Primary exposure scenario [6] **Industrial user disinfecting gloved hands using a liquid dispenser**	Tier1				
	Tier 2 Gloves	17.9	2.0	11	Yes

	Tier 3	17.9	0.89	5	Yes
Secondary exposure scenario [7] **Adult- bystander: inhalation of volatilised residues[2]**	Tier 1	17.9	≤ 5	≤28	Yes

All scenarios demonstrate an acceptable level of exposure to an unprotected professional user perfroming disinfection tasks in a cleanroom environment in Tier 1 except for [6] glove disinfection. For [6] gloves are always used and Tier 2 calculation with gloves resulted in the acceptable risk.

Combined scenarios

Scenarios combined	**Tier**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenarios 2 and 3:	Tier 1	17.9	5.26	29	Yes
Scenarios 1 and 5	Tier 1	17.9	5.72	32	Yes

All combined scenarios demonstrate an acceptable level of exposure to an individual performing disinfection tasks in a cleanroom environment in Tier 1.

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.

- Apply away from eyes and face.
- Hand protection: Wear chemically resistant protective gloves.
- Eye protection: Wear eye protection. Avoid contact with eyes

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.

Conclusion

Based on the predicted exposure and risk characterisation for health effects, the use of biocidal products in the DEC-AHOL® product family as surface disinfectant by protected industrial users (gloves and eye protection) are not considered to pose unacceptable risk to human health when used in accordance with the use instructions specified in the SPC.

The use of Biocidal products as glove disinfectant by protected industrial workers (gloves and eye protection) in clean-rooms are not considered to pose unacceptable risk either. Similarly, exposures of adult bystanders are not considered to pose an unacceptable risk to human health.

Risk for professional users

The DEC-AHOL product family is used by industrial users only in clean rooms.
Professional users (those using end-products outside industry) will not be exposed to the biocide product family.

Risk for non-professional users

Biocidal products in the DEC-AHOL® product family are intended to be used by industrial users only in cleanrooms. There are no non-professional (consumer) uses of these products.

Risk for the general public

Biocidal products in the DEC-AHOL® product family are intended to be used by usersonly in cleanrooms. These are strictly controlled environments and members of the general public will be excluded from entering these premises. Consideration of exposures or risk assessments in members of the general public is therefore not relevant to the use of these products.

Risk for consumers via residues in food

Biocidal products in the DEC-AHOL® family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of dietary residues or a consumer dietary risk assessment is therefore not relevant to this product family.

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

Biocidal products in the DEC-AHOL® family contain only one active substance (i.e. propan-2-ol), and no substances of concern. The consideration of combined exposures to several active substances or substances of concern is not relevant to products in this product family.

2.2.7 Risk assessment for animal health

Biocidal products in the DEC-AHOL® family are not used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. The consideration of a risk assessment for animal health is therefore not relevant to this product family.

2.2.8 Risk assessment for the environment

The DEC-AHOL® product family consists of different formulation types: wipes, aerosol sprays, trigger sprays and liquids (delivered via a bottle or dispenser) all containing 70% v/v propan-2-ol, with identical areas of use in PT2 (general disinfection of hard surfaces and industrial areas). In all cases (spray application and wiping or use of already impregnated wipes) the disinfectant is a leave on product and should not be rinsed immediately afterwards. The application rate to surfaces is 35 mL/m^2 via the spray and liquid products. The wipe products contain a total amount of IPA ranging from 6 to 30 mL per wipe, depending on the size and type of wipe. However, due to the high sorbency of the wipe fabric, there will be very little IPA residue left on treated surfaces from the wipe during use, and consequently loss of IPA per wipe is very low and will not exceed that of the liquid/spray product application rate. The use frequency of wipes could be assumed to vary from 1 to 16 wipes per day with 30 minute intervals between applications, as per the Assessment Report for propan-2-ol (2015[6]). For risk assessment purposes, 35 mL/m^2 of active substance is assumed as a worst case daily application rate rather than the maximum application rate of 50 mL/m^2 specified in [redacted] given that this is the application rate specified for surface disinfection using the DEC-AHOL® products, regardless of the type of application (i.e. more specific information is available on the application rate of these products than what is presented in [redacted]

Propan-2-ol has been assessed under the EU Review programme and details of the evaluation are included in the Assessment Report for PT2. No new data are submitted over and above those evaluated under the EU review for this active substance.

Propan-2-ol was evaluated as PT2 in the Assessment Reports, although certain aspects of the use pattern may differ; therefore a new environmental risk assessment has been performed for the proposed uses.

2.2.8.1 Effects assessment on the environment

The PNECs agreed for propan-2-ol under the EU review and detailed in the AR (2015) are presented in Table 2.2.8.1-1. No further ecotoxicology data are submitted.

Table 2.2.8.1-1: Agreed PNECs for propan-2-ol

PNEC	PNEC (from AR 2015)	Justification
$PNEC_{STP}$	10 mg/L	Assessment factor of 100 applied to EC_{50} of >1000 mg/L
$PNEC_{aquatic, freshwater}$	2.82 mg/L	Assessment factor of 50 (as 2 long term studies available covering 3 trophic levels) applied to NOEC of 141 mg/L from the chronic Daphnia study.
$PNEC_{sediment, freshwater}$	2.41 mg/kg wwt	Equilibrium partitioning method (Koc = 3.3 l/kg)

6 Assessment Report for propan-2-ol, [redacted]

$PNEC_{terrestrial}$	0.496 mg/kg wwt	Equilibrium partitioning method
Marine water*	0.282 mg/L	Assessment factor of 500 (as 2 long term studies available covering 3 trophic levels) applied to NOEC of 141 mg/L from the chronic Daphnia study.
Marine water sediment*	0.241 mg/kg wwt	Equilibrium partitioning method
$PNEC_{secondary\ poisoning}$*	-	
Air	Not applicable	For the air compartment ecotoxicological data on animal species are not available and methods for determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed. Therefore, no quantitative estimation of PNECair for the active substance is possible.
* Not determined in [redacted] and therefore, where calculated, only included for completeness. Based on the intended use it can be concluded that the risk to the marine environment is considered to be negligible.		

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

The products are formulations of the active substance in water; therefore classification of the product with regard to environmental hazard is based on the data for the active substance. No further data on the formulation are submitted.

Further Ecotoxicological studies

No further ecotoxicology data are submitted.

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

No further data are submitted.

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

The products are intended for use indoors only, therefore there will be no direct exposure of the environment. However, according to the ESD for PT2 there could be exposure of the STP via waste water after wet washing of the treated area and subsequent exposure of surface water and agricultural land after spreading of sewage sludge. In addition, there may be emissions to air both from the STP and during product application, followed by subsequent deposition to soil and leaching to groundwater.

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

No further data on fate and behaviour in the environment are submitted.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

In the CAR on propan-2-ol (2015), the calculated concentrations in groundwater led to concern. Because no data on degradation in soils was available, a DT_{50} of 30 days (12°C) was assumed, which is the default for compounds that are readily biodegradable.

However, considering the environmental fate and behaviour of the active substance, it may be expected that propan-2-ol degrades more rapidly in soils.

The Handbook of Environmental Degradation Rates ([redacted])[7] lists the following half-lives for propan-2-ol in Soil of 24 to 168 hours, resulting from scientific judgement based upon estimated unacclimated aerobic aqueous biodegradation half-life.

Furthermore, [redacted][8] investigated the aerobic degradation of several organic substances in domestic waste water, including methanol and propan-2-ol, by means of the respirometric dilution method. The test yielded a BOD5 value of 1.236 g O_2/g test material, corresponding to 82.7% of ThOD at day 5 for methanol. The BOD5 of propan-2-ol was determined to be 1.680 g O_2/ g testing material, corresponding to 74.4% ThOD. These results indicate that biodegradation of methanol and propan-2-ol are comparable. Consequently, data on the biomineralization of methanol in soil may be used to approximate the degradation in soil of propan-2-ol.

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[7] [redacted]. Handbook of Environmental Degradation Rates. CRC Press. https://books.google.de/books?id=_0Ryd5Tis4gC.

[8] [redacted]. 'Untersuchungen Über Das Abbauverhalten Organischer Stoffe Mit Hilfe Der Respiratorischen Verdünnungsmethode'. Jb.«Vom Wasser 42: 271–305.

[redacted][9] studied the the formation of CO_2 from ^{14}C-labelled methanol in aerobic and anaerobic suspended soil was followed for estimation of biodegradation. The results demonstrated that methanol was readily biodegradable by the microorganisms present in soil, with 46.3% - 53.4% degradation after 5 days, based on CO_2 evolution.

These data indicate that the half-life of propan-2-ol in soil, whose degradation kinetics have been shown to be similar to those of methanol, is most likely significantly shorter than the assumed default value of 30 days.

Taken together, these data support the hypothesis that propan-2-ol is rapidly degraded in soil and therefore the DT_{50} is expected to be more in the range of hours or a few days, rather than the default value of 30 days.

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

No further data on distribution and dissipation in water and sediment are submitted.

Testing for distribution and dissipation in air (ADS)

No further data on distribution and dissipation in air are submitted.

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.

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.

2.2.8.2 Exposure assessment

The DEC-AHOL® product family consists of a variety of product formulation types: wipes, aerosol sprays, trigger sprays and liquids (delivered via bottle or dispenser) all of which contain 70% v/v propan-2-ol, with identical uses in PT2 (general disinfection of hard surfaces and industrial areas). A content of 70% v/v is equivalent to a content of 65% w/w; however, the risk assessment has been performed assuming a content of 70% w/v (or 0.7 kg/L) as a worst case. In all cases (spray application and wiping or use of already impregnated wipes) the disinfectant is a leave-on product and should not be rinsed immediately afterwards. A worst case daily application rate of 35 mL/m^2 has been specified for surface disinfection using the DEC-AHOL® products, regardless of the type of application (including wipes). Therefore for the purposes of the environmental risk

9 [redacted]. 'Biomineralization Rates of 14C-Labelled Organic Chemicals in Aerobic and Anaerobic Suspended Soil'. Chemosphere 16 (5): 1031–41. doi:10.1016/0045-6535(87)90040-3.

assessment, one representative worst case scenario has been applied and is considered sufficient to cover the whole product family.

General information

Assessed PT	PT 2
Assessed scenarios	Use of disinfectants in industrial areas
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC 2011 updated by the TAB (August 2018)
Approach	Average consumption
Distribution in the environment	Calculated in EUSES 2.1.2 based on the ECHA Guidance on the BPR: Part B+C, volume IV (2017) equations
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	None

Emission estimation

The local emission rate of 0.061 kg/day for wastewater and 0.551 kg/day for air were calculated using the "PT2-industrial areas" (emission scenario for calculating the releases of disinfectants used in industrial areas) from ECHAs "Environmental Emission Scenarios for Product Type 2: Private and public health area disinfectants and other biocidal products" amended according to the the TAB (August 2017).

The local emissions were calculated based on the application rate of 0.035 L/m^2 from the liquid/spray products, given that this is the highest application rate of the product family, and is therefore considered to be a reasonable representative worst case value for the product family. Although repeated applications may be made using the wipe products, the total amount of active substance that may be delivered by the wipes will not exceed that assumed by the liquid/sprays. The propan-2-ol CAR states that the distribution of releases between air and wastewater occur at a ratio of 90% and 10% respectively. The fraction released to wastewater was therefore set to 0.1 to derive the release to wastewater and the release to air calculated from this value (i.e. ($Elocal_{water}$ x 10) x 0.9). The 'active substance in product' used in emission calculation was set to 0.7 kg/L, based on 70% w/v active substance concentration (rather than the actual content of 65% w/w, i.e. 70% v/v) as a conservative worst-case approach. All other values used were default perameters (*i.e.* surface area to be disinfected, number of applications per day, and fraction of substance disintegrated during or after application (before release to the sewage system)).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks S/D/O/R***
Scenario: Private/public health disinfectant – industrial premises			
Max. application rate of biocidal product	0.035	[L/m^2]	D
Number of applications per day	1	-	D
Active substance in product	0.7	[kg/L]	S (based on a conservative active substance concentration of 70% w/v, rather than 65% w/w)
Fraction released to waste water	0.1	[-]	S**
Fraction released to air	0.9	[-]	S**
Area treated	25	[m^2]	D (AREAsurface for small scale applications according to TAB ENV 38, August 2017)
Number of emission days	260	[-]	D
*Set, Default, Output, Refined **Same assumption as in AR (2015)			

Calculations for Scenario 1: Private/public health disinfectant – industrial premises

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.061	Output from PT2 environmental emission estimation spreadsheet
Air	0.551	Calculated from emission rate to waste water

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Private/public health disinfectant – industrial premises	[yes]	[yes]	no	no	yes	yes	[yes]	[yes]	-

[] indicates indirect exposure

Input parameters (only set values) for calculating the fate and distribution in the environment from the AR (January 2015) except where stated			
Input	Value	Unit	Remarks
Molecular weight	60.09	g/mol	
Melting point	-89.5	°C	
Boiling point	82.5	°C	
Vapour pressure (at 25°C)	5780	Pa	
Water solubility (at 25°C)	1,000,000	mg/L	In the LoEP ([redacted]) it is just stated to be miscible with water. Value was used in the risk assessment in the AR as a worst case
Log Octanol/water partition coefficient	0.05	Log 10	
Organic carbon/water partition coefficient (Koc)	3.3	L/kg	From LoEP ([redacted]) estimated by QSAR-model for alcohols described in EU TGD (2003)
Henry's Law Constant	0.8	$Pa/m^3/mol$	temperature not given
Biodegradability	Readily biodegradable		
DT_{50} for hydrolysis in surface water	stable		

DT_{50} for photolysis in surface water	Not applicable, no absorption maximum > 290 nm		
DT_{50} for degradation in soil	30	d (at 12ºC)	DT_{50} of 30 days (12°C) assumed based on the default for readily biodegradability
DT_{50} for degradation in air	3.1	d	Calculated according to [redacted]
Bioaccumulation	BCF fish of 0.22 BCF earthworm 0.85	L/kg ww	Estimated values

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	All scenarios*	
Air	0.07	Source: Simple Treat 3.0 calculation
Water	12.6	
Sludge	0.03	
Degraded in STP	87.3	

* Values calculated in Simple Treat 3.0

Calculated PEC values

Summary table of calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Private/public health disinfectant – industrial premises (CAR soil DT_{50})	3.85 x 10-3	3.85 x 10^{-4}	3.29 x 10^{-4}	-	-	5.64 x 10^{-5}*	0.166	1.53 x 10^{-4}**

* Value includes emission via STP (slurry application) and emission deposition of airborn active substance released during application and waste water treatment. Note that the PEC was almost completely attributed to release during application. Emission via sewage sludge and evaporation is negligible due to the active substance's low sorption to organics and low Henry's law constant

** Value calculated in line with BPR Vol. IV Part B+C (2017)

Primary and secondary poisoning

Primary poisoning

The proposed uses of the product preclude any exposure via primary poisoning. The products are only intended for indoor use and are not applied in granular form. Moreover, propan-2-ol is readily biodegradable and is not anticipated to persist in the environment.

Secondary poisoning

The risk of secondary poisoning from the use of propan-2-ol products is considered to be negligible, as the active substance has a low potential for secondary poisoning. [redacted] states that the log Kow is low (0.05) and that the calculated bioaccumulation factors (BCFs) for fish and earthworms are 0.22 and 0.85 L/kg ww, respectively. [redacted] also highlights that there are no other indicators which point to an intrinsic potential for bioconcentration. The surface tension is 70.7 mN/m and therefore lies above the trigger value of ≤50 mN/m for surface active substances. Moreover, propan-2-ol is readily biodegradable and is not anticipated to persist in the environment.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: No hazard for air has been identified. As such, no risk to air is predicted, and PEC/PNEC ratios have not been derived.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Private/public health disinfectant – industrial premises	<0.001

Conclusion: From the assessment presented above, the use of propan-2-ol in PT2 does not pose an unacceptable risk to the local STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Private/public health disinfectant – industrial premises	<0.001	<0.001	-	-

Conclusion: From the assessment presented above, the use of propan-2-ol in PT2 does not pose an unacceptable risk to surface water and sediment.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Private/public health disinfectant – industrial premises	<0.001

Conclusion: From the assessment presented above, the use of propan-2-ol in PT2 does not pose an unacceptable risk to the terrestrial environment.

Groundwater

Calculated PECs in groundwater are slightly above the cut off value of 0.1 µg/L (according to the Drinking Water Directive and the Groundwater Directive) when calculated using the emission parameters of scenario 1 and using the default soil DT_{50} of 30 days at 12ºC as used in the CAR. However, considering the additional data discussed above (section 2.2.8.1, Testing for distribution and dissipation in soil (ADS)) shorter half-lives may be expected.

Furthermore, following discussions at WG-VII-2018 it was agreed that the following argument forms an acceptable weight of evidence approach to support FOCUS PEARL not offering an appropriate tier 2 refinement for these proposed uses of propan-2-ol.

For the environmental risk assessment, dry and wet deposition, expressed as DEPTtotal$_{ann}$, is assumed to be the main emission pathway to the soil and subsequently to the groundwater compartment due to the high volatility of propan-2-ol. The DEPTtotal$_{ann}$ is calculated by use of the OPS model (as described in the Guidance on the BPR IV ENV B, 2015), which assumes that the major fraction (90%) of the applied propan-2-ol is released to the ambient air and subsequently deposited in close vicinity (within a radius of 1000 m) to the source of emission. In the case of propan-2-ol this assumption represents an unrealistic worst-case and it can be considered highly unlikely that the assumed magnitude of exposure truly occurs under relevant field conditions.

- The FOCUS PEARL model was developed for the determination of groundwater concentrations related to the application of plant protection products (PPP) on agricultural land. Accordingly, the model assumptions for the nine locations rely on e.g. soil properties that are representative for agriculturally used areas in Europe. The unlimited applicability of the model for the very diverse field of biocidal applications is thus questionable. For biocidal applications where the release of active substances to the environment is related to the application of sewage sludge or manure/slurry to agricultural land, the applicability of FOCUS PEARL might be given. In the present case, where the products of the BPF are used in urban areas where a direct exposure to the urban environment is assumed, the model assumptions of FOCUS PEARL may not be accurate and the results of such a refinement should be evaluated with caution. The same applies, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, for which the model is might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.

This discussion is supported by the conclusion at the 21st BPC meeting that if not all nine scenarios show a safe use and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach.

An acceptable risk of propan-2-ol to groundwater is therefore expected.

Primary and secondary poisoning

Primary poisoning

The proposed uses of the product preclude any exposure via primary poisoning. The products are only intended for indoor use and are not applied in granular form. Moreover, propan-2-ol is readily biodegradable and is not anticipated to persist in the environment.

Secondary poisoning

Based on the low estimated BCF values in aquatic and terrestrial indicator species, propan-2-ol is not expected to accumulate in the environment. Moreover, propan-2-ol is readily biodegradable and is not anticipated to persist in the environment. The risk of secondary poisoning via ingestion of contaminated food by birds or mammals is therefore negligible.

Mixture toxicity

The products are a formulation of only the active substance in water. A mixture assessment is therefore not necessary.

Aggregated exposure (combined for relevant emission sources)

The uses within the product family fall within only a single PT2 emission scenario therefore an aggregated assessment of the biocidal uses is not required.

Propan-2-ol is also used in other biocidal PTs (1 and 4) and has a number of other non-biocidal uses. An aggregated exposure assessment was performed in [redacted] and the assessment is reproduced below.

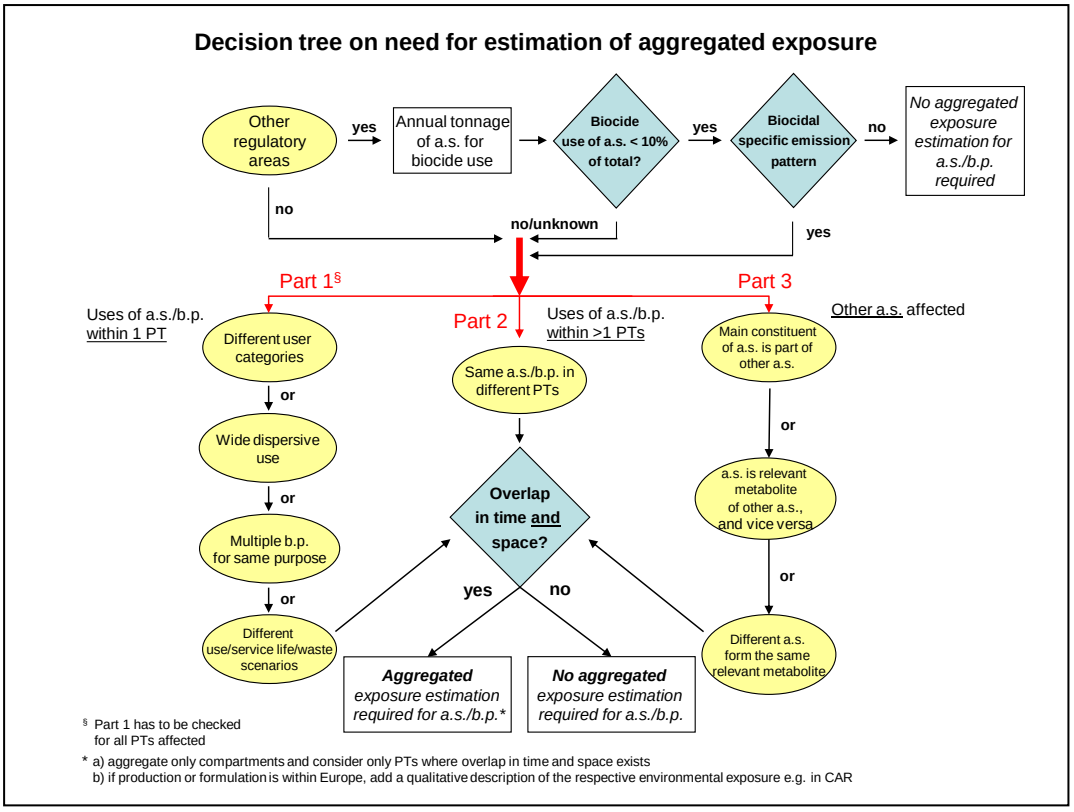

Figure 1: Decision tree on the need for estimation of aggregated exposure

"*Propan-2-ol is notified for Annex I inclusion in PT 1, 2, and 4. For all mentioned PTs, DE is RMS. The respective CA reports consider the following uses: PT 1 - skin and hand disinfectant in hospitals; PT 2 - disinfection of rooms, furniture and objects in the sanitary sector; PT 4 - assessment of small-scale applications (spraying of surfaces) / industrial kitchens / meat processing industry. As b.p. containing propan-2-ol are used in a wide dispersive way an aggregated environmental exposure assessment may be reasonable. According to the "Decision tree on the need for estimation of aggregated exposure" (BIP6.7 Decision Tree Agg Expo), the requirement for aggregated exposure estimations was checked for propan-2-ol. In summary, it has been concluded that no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced and no specific biocidal emission patterns are identified.*"

On this basis further consideration of aggregated exposure is not necessary.

Overall conclusion on the risk assessment for the environment of the product
The use of propan-2-ol as a disinfectant for PT2 is acceptable. The assessment demonstrated an acceptable risk for all compartments.

2.2.9 Measures to protect man, animals and the environment

Please refer to Section 2.1.5.2.

2.2.10 Assessment of a combination of biocidal products

Not relevant. The products are not intended to be used in combination with other products.

2.2.11 Comparative assessment

Not relevant. Propan-2-ol is not a candidate for substitution. As a result, a comparative assessment is not required.

3 Annexes[10]

a. List of studies for the biocidal product family

IUCLID Section No / Reference No	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
3.1-01 3.2-01 3.3-01 3.4.1.1-01	[redacted]	2017	ACCELERATED STORAGE TEST FOR 18 WEEKS AT 30°C ON THE TEST ITEM "DEC-AHOL WFI FORMULA (TRIGGER SPRAY 473 ML)" Eurofins Biolab S.r.l. Report number: 2016/189 AM GLP, unpublished	Y	Veltek Associates, Inc.
3.1-02 3.2-02 3.3-02 3.4.1.2-02 3.5.12-01	[redacted]	2019	SHELF-LIFE STABILITY STUDY AT 25OC FOR 36 MONTHS ON THE TEST ITEM "DEC-AHOL AEROSOL" Eurofins Biolab S.r.l. Report number: 2016/188 AM GLP, unpublished	Y	Veltek Associates, Inc.
3.1-03 3.4.1.2-03	[redacted]	2018	SHELF-LIFE STABILITY STUDY AT 25oC FOR 24 MONTHS ON THE TEST ITEM "PROCESS2 WIPE IPA 70" Eurofins Biolab S.r.l. Report number: 2016/187 AM GLP, unpublished	Y	Veltek Associates, Inc.

10 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.1-04	[redacted]	2009	Storage Stability – DECON-AHOL 70% WFI Technology Sciences Group Inc. Report number: Vel-2009-004 Non-GLP, unpublished	Y	Veltek Associates, Inc.
3.2-04 3.3-04 3.9-02	[redacted]	2009	Determination of pH, Viscosity, Density Technology Sciences Group Inc. Report number: Vel-2009-002 Non-GLP, unpublished	Y	Veltek Associates, Inc.
3.4.1.1-02	[redacted]	2016	Accelerated Storage Stability of DECAHOL WFI Formula Veltek Associates, Inc. (VAI) Chemical Laboratory Report number: VAI LAB-2016-004-78 Non-GLP, unpublished	Y	Veltek Associates, Inc.
3.4.1.1-03	[redacted]	2018	Decon-ahol 70%/Dec-ahol 70% Can and Bottle Stability in accelerated Condition Veltek Associates, Inc. (VAI) Chemical Laboratory Report number: SS19062018 Non-GLP, unpublished	N	Veltek Associated, Inc.
3.4.1.1-04	[redacted]	2019	Decon-Ahol/Dec-Ahol 70% Bag in Bottle Stability Report Veltek Associates, Inc. 15 Lee Boulevard, Malvern, PA 19355-1234 Study no JR05072019 GLP: no Unpublished	Y	Veltek Associated, Inc.

3.4.1.1-05	[redacted]	2019a	Decon/Dec-Ahol Bag in the Bottle Sprayer Test Veltek Associates, Inc. 15 Lee Boulevard, Malvern, PA 19355-1234 Study no GS29042019 GLP: no Unpublished	Y	Veltek Associated, Inc.
3.4.1.2-01 3.4.1.2-05	[redacted]	2019	SHELF-LIFE STABILITY STUDY AT 25OC FOR 36 MONTHS ON THE TEST ITEM "DEC-AHOL WFI FORMULA (TRIGGER SPRAY 473ML)" Eurofins Biolab S.r.l. Report number: 2016/186 AM GLP, unpublished	Y	Veltek Associates, Inc.
3.4.1.2-04	[redacted]	2016	Storage Stability – DECON-AHOL 70% WFI VAI Laboratories Report number: Vel-2009-004 Non-GLP, unpublished	Y	Veltek Associates, Inc.
3.4.1.2-06	[redacted]	2016	Determination of Evaporation (opening and removal effects), Average Wipe Liquid Content, Assay (during use period), Squeezable Liquid and Surface Drying Time During Simulated Use Period VAI Laboratories Report number: VAI LAB-2016-05-25 Non-GLP, unpublished	Y	Veltek Associates, Inc.

3.4.1.2-07	[redacted]	2016	Determination of the active ingredient isopropanol in the test item "PROCESS2 WIPE IPA 70" Eurofins Biolab Srl Report number: S-2016-02176 AM GLP, unpublished	Y	Veltek Associates, Inc.
3.4.1.2-08	[redacted]	2017	Determination of the active ingredient isopropanol in the test item "ALCOH-wipe" Eurofins Biolab Srl Report number: S-2016-02175 AM GLP, unpublished	Y	Veltek Associates, Inc.
3.5.13-01	[redacted]	2018	Determination of Liquid Content Dispensed Onto a Surface by Pre-Saturated Wiper Product Report number: VP-8045 Non-GLP, unpublished	N	Veltek Associates, Inc.
3.5.13-02	[redacted]	2018	Asepti-Cleans gloves study with 70% Decon-Ahol & Ster-Ahol VAI Laboratories Report number: RWH07052018 Non-GLP, unpublished	N	Veltek Associated Inc.
3.5	[redacted]	2020a	Spray Characterization: Following CIPAC MT 187 and ISO 13320:2009 guidelines for - Particle size analysis by laser diffraction Veltek-DEC-AHOL WFI Formula & DEC-AHOL AEROSOL WFI Formula ARE Labs Project – #10875.	N	Veltek Associated Inc.

3.5	[redacted]	2020b	Accelerated Aging: : VELTEK- DEC-AHOL WFI FORMULA & DEC-AHOL AEROSOL WFI FORMULA Following CIPAC MT 187 and ISO 13320:2009 guidelines for - Particle size analysis by laser diffraction	N	Veltek Associated Inc.
3.5	[redacted]	2020c	Effects of Hydrostatic Pressure on Emitted Particle Size from DEC-AHOL Aerosol Sample	N	Veltek Associated Inc.
3.8-01	[redacted]	2016	Surface Tension of the Sample DEC-AHOL WFI FORMULA (in Trigger Spray 473ml) Innovhub - Stazioni Spermentali per I'Industria Report number: 201602082 GLP, unpublished	Y	Veltek Associates, Inc.
3.9-02	[redacted]	2016	Viscosity of DEC-AHOL WFI Formula Veltek Associates, Inc. (VAI) Chemical Laboratory Report number: VAI LAB-2016-002 Non-GLP, unpublished	Y	Veltek Associates, Inc.
4.1-01 4.8-01 4.11-01 4.13-01 4.16-01	[redacted]	2016	Expert Statement on the EU CLP Characteristics of a Propan-2-ol/water Solution (70:30): Explosivity, Oxidising Properties, Self-Reacting, Self-Heating and Corrosive to Metals TSGE Consulting Limited Report number: TSGE_22-003-02_IPA_CLP Non-GLP, unpublished	Y	Veltek Associates, Inc.

4.6-01	[redacted]	2009	Determination of Flash Point Veltek Associates, Inc. Report number: VAI 2009-003 GLP, unpublished	Y	Veltek Associates, Inc.
5.1-01	[redacted]	2016	Method Validation for the Quantification of the Active Ingredient Isopropanol in the Test Item 'DEC-AHOL WFI' Formula (in Trigger Spray Bottle 473 mL) Eurofins Biolab Srl Report number: S-2016-02173 AM GLP, unpublished	Y	Veltek Associates, Inc.
6.7-01	[redacted]	2013	Suspension Bactericidal Effectiveness on DEC-AHOL Eurofins Biolab Report number: S-2013-0064-Ami GLP, unpublished	Y	Veltek Associates, Inc.
6.7-02	[redacted]	2014	Surface Bactericidal Effectiveness on DEC-AHOL Aerosol WFI Formula Eurofins Biopharma Product Testing Report number: S-2014-01371 Ami GLP, unpublished	Y	Veltek Associates, Inc.
6.7-03	[redacted]	2013	Suspension Fungicidal effectiveness on DEC-AHOL Eurofins Bioloab Report number: S-2013-01463-Ami GLP, unpublished	Y	Veltek Associates, Inc.

6.7-04	[redacted]	2014	Surface Fungicidal Effectiveness on DEC-AHOL aerosol WFI Formula Eurofins Biopharma Product Testing Report number: S-2014-01358 AMirev1 GLP, unpublished	Y	Veltek Associates, Inc.
6.7-05	[redacted]	2016	Bactericidal and Yeasticidal activity of Process2 Wipe IPA 70 Employing Mechanical Action on a Non-prorous Surface Eurofins Biolab Report number: S-2016-02253 AM GLP, unpublished	Y	Veltek Associates, Inc.
6.7-06	[redacted]	2016	Surface Bactericidal Effectiveness on Dec-Ahol WFI Formula (in Trigger Spray Bottle 473ml) Eurofins Biolab Report number: S-2016-02178 AM GLP, unpublished	Y	Veltek Associates, Inc.
6.7-07	[redacted]	2016	Surface Yeasticidal Effectiveness on DEC-AHOL WFI Formula (in Trigger Spray Bottle 473 ml) Eurofins Biolab Report number: S-2016-02179 AM GLP, unpublished	Y	Veltek Associates, Inc.
6.7-08	[redacted]	2018	Suspension bactericidal effectiveness in clean conditions on DEC-AHOL WFI formula Carluccio, S. Report number: S-2018-01150 AM GLP, unpublished	Y	Veltek Associates, Inc.

6.7-09	[redacted]	2018	Suspension fungicidal effectiveness in clean conditions on DEC-AHOL WFI formula Carluccio, S. Report number: S2018-001151 AM GLP, unpublished	Y	Veltek Associates, Inc.

b. Output tables from exposure assessment tools

Human health risk assessment

ConsExpo Web Report: Tier 1 Scenarios [1] and PT [2]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Pouring product from 3.79 L bottle into a trigger spray reservoir and/or when wetting a sterile cloth /wipe.
Inhalation Exposure model	**Exposure to vapour - Evaporation**
Exposure duration	0.75 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Product amount	1651 g
Weight fraction substance	0.7
Room volume	1 m^3
Ventilation rate	8 per hour
Inhalation rate	1.25 m^3/hr
Application temperature	25°C
Vapour pressure	5.78E+03 Pa
Molecular weight	60.1 g/mol
Mass transfer coefficient	10 m/h
Release area mode	Constant
Release area	20 cm^2
Emission duration	0.75 minute
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario		
Inhalation		
Mean event concentration	7	mg/m³
Mean concentration on day of exposure	0.0036	mg/m³
Peak concentration (TWA 15 mins)	7	mg/m³

ConsExpo Web Report: Tier 2: Scenarios [1] and [2]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Pouring product from 3.79 L bottle into a trigger spray reservoir and/or when wetting a sterile cloth /wipe.

Inhalation Exposure model	**Exposure to vapour - Evaporation**
Exposure duration	0.75 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Product amount	1651 g
Weight fraction substance	0.7
Room volume	1 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20°C
Vapour pressure	5.78E+03 Pa
Molecular weight	60.1 g/mol
Mass transfer coefficient	10 m/h
Release area mode	Constant
Release area	20 cm²
Emission duration	0.75 minute
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario		
Inhalation		
Mean event concentration	6.6	mg/m³
Mean concentration on day of exposure	0.0035	mg/m³
Peak concentration (TWA 15 mins)	6.6	mg/m³

ConsExpo Web Report: Tier 1: Scenario [3]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Disinfecting hard surfaces (0.5 m^2) using a wiping tissue/cloth.

Inhalation Exposure model	**Exposure to vapour - Evaporation**	
Exposure duration	45 minute	
Product in pure form	No	
Molecular weight matrix	18 g/mol	
The product is used in dilution	No	
Product amount	15.2 g	
Weight fraction substance	0.7	
Room volume	55 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	60.1 g/mol	
Mass transfer coefficient	10 m/h	
Release area mode	Increasing	
Release area	0.5 m^2	
Application duration	1 minute	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario		
Inhalation		
Mean event concentration	21	mg/m^3
Mean concentration on day of exposure	6.5	mg/m^3
Peak concentration (TWA 15 mins)	52	mg/m^3

ConsExpo Web Report: Tier 2: Scenario [3]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol

Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Disinfecting hard surfaces (0.5 m^2) using a wiping tissue/cloth.

Inhalation Exposure model	**Exposure to vapour - Evaporation**	
Exposure duration	45 minute	
Product in pure form	No	
Molecular weight matrix	18 g/mol	
The product is used in dilution	No	
Product amount	15.2 g	
Weight fraction substance	0.7	
Room volume	55 m^3	
Ventilation rate	20 per hour	
Inhalation rate	1.25 m^3/hr	
Application temperature	20°C	
Vapour pressure	5.78E+03 Pa	
Molecular weight	60.1 g/mol	
Mass transfer coefficient	10 m/h	
Release area mode	Increasing	
Release area	0.5 m^2	
Application duration	1 minute	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario		
Inhalation		
Mean event concentration	8.4	mg/m^3
Mean concentration on day of exposure	2.6	mg/m^3
Peak concentration (TWA 15 mins)	24	mg/m^3

ConsExpo Web Report: Tier 1: Scenario [4] and [5]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg

Task Description	Disinfecting hard surfaces (0.5 m^2) using an aerosol and/or trigger sprayer.

Inhalation Exposure model	**Exposure to vapour - Evaporation**
Exposure duration	45 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Product amount	15.2 g
Weight fraction substance	0.7
Room volume	55 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	60.1 g/mol
Mass transfer coefficient	10 m/h
Release area mode	Increasing
Release area	0.5 m^2
Application duration	0.17 minute
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario

Inhalation

Mean event concentration	32	mg/m^3
Mean concentration on day of exposure	9.9	mg/m^3
Peak concentration (TWA 15 mins)	79	mg/m^3

ConsExpo Web Report: Tier 2: Scenario [4] and [5]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Disinfecting hard surfaces (0.5 m^2) using an aerosol and/or trigger sprayer.

Inhalation Exposure model	**Exposure to vapour - Evaporation**
Exposure duration	45 minute
Product in pure form	No

Molecular weight matrix	18 g/mol	
The product is used in dilution	No	
Product amount	15.2 g	
Weight fraction substance	0.7	
Room volume	55 m^3	
Ventilation rate	20 per hour	
Inhalation rate	1.25 m^3/hr	
Application temperature	20°C	
Vapour pressure	5.78E+03 Pa	
Molecular weight	60.1 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 for scenario		
Inhalation		
Mean event concentration	13	mg/m^3
Mean concentration on day of exposure	4	mg/m^3
Peak concentration (TWA 15 mins)	36	mg/m^3

ConsExpo Web Report: Tier 1: Scenario [6]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Disinfecting of gloved hands.

Inhalation Exposure model	**Exposure to vapour – Instantaneous release**
Exposure duration	19 minutes
Product in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Product amount	2625 mg
Weight fraction substance	0.7
Room volume	55 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	60.1 g/mol	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario		
Inhalation		
Mean event concentration	12	mg/m³
Mean concentration on day of exposure	4	mg/m³
Peak concentration (TWA 15 mins)	14	mg/m³

ConsExpo Web Report: Tier 2: Scenario [6]

Substance Name	Propan-2-ol
Molecular weight	60.1 g/mol
Product Name	Decahol
Weight fraction substance	0.7
Population Name	Adult
Body weight	60 kg
Task Description	Disinfecting of gloved hands.

Inhalation Exposure model	**Exposure to vapour – Instantaneous release**
Exposure duration	19 minutes
Product in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Product amount	2625 mg
Weight fraction substance	0.7
Room volume	55 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	20°C
Vapour pressure	5.78E+03 Pa
Molecular weight	60.1 g/mol
Absorption model	Fixed fraction
Absorption fraction	1
Results for scenario	
Inhalation	

Mean event concentration	5.3	mg/m³
Mean concentration on day of exposure	1.7	mg/m³
Peak concentration (TWA 15 mins)	6.6	mg/m³

a. New information on the active substance

There is no new data submitted for the active substance propan-2-ol.

b. Residue behaviour

Residues in animal and human body fluids and tissues are not of concern, since propan-2-ol is not classified as toxic or highly toxic. Under normal conditions of use, direct contact with food or feedstuffs of plant or animal origin will not occur; therefore residue studies and supporting methods of analysis are not required. Residues of propan-2-ol in the environment are unlikely to occur. Propan-2-ol is readily biodegradable and will be rapidly broken down by micro flora in soil, water and in the STP. As such propan-2-ol is not expected to persist in the environment. Any limited emissions should be rapidly and completely degraded in a short time frame. Based on this no significant residues of propan-2-ol are expected in any environmental compartment.

c. Summaries of the efficacy studies (B.5.10.1-xx)

Efficacy study summaries are located in the IUCLID file under point 6.7