

COMMISSION IMPLEMENTING REGULATION (EU) 2021/552
of 30 March 2021
granting a Union authorisation for the biocidal product family ‘DEC-AHOL® Product Family’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 29 June 2016, Veltek Associates Inc. Europe submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘DEC-AHOL® Product Family’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-XF025530-45 in the Register for Biocidal Products.
- (2) ‘DEC-AHOL® Product Family’ contains propan-2-ol, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 9 December 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 2 July 2020, the Agency submitted to the Commission an opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘DEC-AHOL® Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘DEC-AHOL® Product Family’ is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 20 July 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘DEC-AHOL® Product Family’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 17 June 2020 on the Union authorisation of ‘DEC-AHOL® Product Family’ (ECHA/BPC/261/2020), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0024324-0000 is granted to Veltek Associates Inc. Europe for the making available on the market and use of the biocidal product family 'DEC-AHOL® Product Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 20 April 2021 until 31 March 2031.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

DEC-AHOL® Product Family

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0024324-0000

R4BP asset number: EU-0024324-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	DEC-AHOL® Product Family
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1.2. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Veltek Associates Inc. Europe
	Address	Rozengaard 1940, 8212DT Lelystad, Netherlands
Authorisation number	EU-0024324-0000	
R4BP asset number	EU-0024324-0000	
Date of the authorisation	20 April 2021	
Expiry date of the authorisation	31 March 2031	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Veltek Associates, Inc.
Address of manufacturer	15 Lee Blvd., PA19355 Malvern United States
Location of manufacturing sites	15 Lee Blvd., PA19355 Malvern United States

1.5. **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

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,8	65,4

2.2. **Type(s) of formulation**

Formulation(s)	AL – Any other liquid AE – Aerosol dispenser AL (any other liquid) – RTU wipe
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PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1
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1.2. **Suffix to the authorisation number**

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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2. **META SPC 1 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4	65,4

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL (any other liquid) – RTU wipe
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing vapours. Wash hands thoroughly after handling. Wear protective gloves. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a doctor if you feel unwell. If eye irritation persists: Get medical advice. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents in accordance with local/national regulations. Wear eye protection.

4. **AUTHORISED USE(S) OF THE META SPC 1**

4.1. **Use description**

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

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	<p>Common name: Bacteria Development stage: -</p> <p>Common name: Yeast Development stage: -</p>
Field(s) of use	<p>Indoor</p> <p>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.</p>
Application method(s)	Wiping of surfaces
Application rate(s) and frequency	<p>Ready to Use (RTU) Product may be used multiple times a day, if required. Contact time: 2 min</p> <p>Individual wipes: 15,2 cm × 15,2 cm wipe – 4 wipes per m² 30,5 cm × 30,5 cm wipe – 1 wipe per m² 45,7 cm × 45,7 cm wipe – 1 wipe per m²</p> <p>Multi pack wipes: 30,5 cm × 30,5 cm – 1 wipe per m²</p>
Category(ies) of users	Industrial
Pack sizes and packaging material	<p>Pre-saturated 70 % v/v propan-2-ol and water for injection (WFI) wipes.</p> <p>Individual wipes</p> <p>A wipe is composed of 100 % continuous filament polyester fibre. The wipes are packaged in individual heat-sealed plastic bags made of low density polyethylene.</p> <p>Pack sizes: 15,2 cm × 15,2 cm wipe – 100/case, non- Sterile 15,2 cm × 15,2 cm wipe – 100/case, sterile 30,5 cm × 30,5 cm wipe – 100/case, sterile 45,7 cm × 45,7 cm wipe – 100/case, sterile</p> <p>Multi pack wipes</p> <p>A wipe is composed of 100 % continuous filament knitted polyester fibre; 20 wipes per pack; folded together in a re-closable bag package.</p> <p>Pack sizes: 100 % polyester 30,5 cm × 30,5 cm wipe – 200/case, non-sterile 100 % polyester 30,5 cm × 30,5 cm wipe – 200/case, sterile</p>

4.1.1. *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 Good Manufacturing Practice (GMP) EU classification in grade A to D.

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 wipes:

15,2 cm × 15,2 cm wipe – 4 wipes per m²

30,5 cm × 30,5 cm wipe – 1 wipe per m²

45,7 cm × 45,7 cm wipe – 1 wipe per m²

Multi pack wipes:

30,5 cm × 30,5 cm – 1 wipe per m²

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Use 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 the product.

Wash hands thoroughly after handling.

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.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

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 unconsciousness and low blood sugar (especially in children). Because of the type of formulations (wipes, aerosol and spray) the systemic effects are however less likely.

First-aid measures general: Never give anything orally 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 that is comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Rinse skin with water/or shower. Remove all contaminated clothing immediately. Gently wash with plenty of soap and water. If symptoms develop, seek 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.

5.4. Instructions for safe disposal of the product and its packaging

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

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

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition. Store at temperatures below 30 °C.

Shelf-life: 2 years

6. OTHER INFORMATION

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	ALCOH-WIPE® PROCESS2WIPE® IPA70		Market area: EU Market area: EU		
Authorisation number	EU-0024324-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4

META SPC 2**1. META SPC 2 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 2 identifier**

Identifier	Meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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2. META SPC 2 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,8	64,8

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	AE – Aerosol dispenser
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Extremely flammable aerosol. Pressurised container: May burst if heated. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Avoid breathing vapours. Wash hands thoroughly after handling. Wear protective gloves. IF INHALED: Remove person to fresh air and keep comfortable for breathing.

	<p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a doctor if you feel unwell. If eye irritation persists: Get medical advice. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F. Dispose of contents in accordance with local/national regulations. Wear eye protection.</p>
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4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2. Use # 1 – Disinfection of hard non-porous surfaces; Aerosols (propellant)

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Common name: Bacteria Development stage: -</p> <p>Common name: Yeast Development stage: -</p>
Field(s) of use	<p>Indoor 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.</p>
Application method(s)	Aerosol spraying on surfaces
Application rate(s) and frequency	<p>Maximal application 35 mL/m² – RTU Product may be used multiple times a day, if required. Apply product by spraying from 15-20 cm distance for 20 seconds/m². Contact time: 2 min</p>
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)

4.1.1. Use-specific instructions for use

Clean and dry surfaces prior to disinfection. Spray the surface to be disinfected from a distance of 15-20 cm. Thoroughly wet surface with product for 20 seconds/m², 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. Cloths or wipes treated with the product must be discarded in a closed container.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽²⁾ OF THE META SPC 2**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Use 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 the product.

Wash hands thoroughly after handling.

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 unconsciousness and low blood sugar (especially in children). Because of the type of formulations (wipes, aerosol and spray) the systemic effects are however less likely.

First-aid measures general: Never give anything orally 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 that is comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Rinse skin with water/or shower. Remove all contaminated clothing immediately. Gently wash with plenty of soap and water. If symptoms develop, seek medical attention.

⁽²⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

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.

5.4. Instructions for safe disposal of the product and its packaging

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

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

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

Keep away from open flames, hot surfaces and sources of ignition.

Keep container tightly closed. Keep in a cool, well-ventilated place. Store at temperatures below 40 °C. Protect from frost.

Shelf-life: 2 years

6. OTHER INFORMATION

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	DEC-AHOL® AEROSOL WFI Formula		Market area: EU		
Authorisation number	EU-0024324-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,8

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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2. **META SPC 3 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4	65,4

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation(s)	AL – Any other liquid
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Wash hands thoroughly after handling. Wear protective gloves. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if easy to do. Continue rinsing. Call a doctor if you feel unwell. If eye irritation persists: Get medical advice. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents in accordance with local/national regulations. Avoid breathing spray. Wear eye protection.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 3. Use # 1 – Disinfection of hard non-porous surfaces; Trigger Spray, Liquid

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: - Common name: Yeast Development stage: -
Field(s) of use	Indoor 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/m ² – RTU 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 the triggers are not installed, a polyethylene screw cap is supplied on the bottles. Bottles are individually triple bagged in cardboard boxes. The product is only supplied to the users in sealed cases. Bag in bottle – Trigger: 500 mL (16 oz) – 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 are 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. The product is only supplied to the users in sealed cases.

4.1.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection. Direct the spray onto the surface from a distance of 15-20cm. Make sure to wet the surface completely (40 squeezes/m²). 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. Cloths or wipes treated with the product must be discarded in a closed container.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 4. Use # 2 – Disinfection of hard non-porous surfaces (including floors); Wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: - Common name: Yeast Development stage: -
Field(s) of use	Indoor 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 surface
Application rate(s) and frequency	Maximal application 35 mL/m ² – RTU 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

	<p>473 mL (16 oz) – squeeze, bulk group in one large bag – 12/case, sterile. Bulk pack bottles are not individually bagged.</p> <p>Bottle is made of low density polyethylene</p> <p>Drum or bottle:</p> <p>18,9 L (5 gallon drum) – container double bagged- 1/case, sterile</p> <p>3,79 L (1 gallon bottle) – each container double bagged- 4/case, sterile</p> <p>3,79 L (1 gallon bottle) – each container double bagged- 4/case, non-sterile</p>
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4.2.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection. Thoroughly wet a sterile wipe/cloth with the product, make sure to wet the 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. Cloths or wipes treated with the product must be discarded in a closed container.

4.2.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. **Use description**

Table 5. Use # 3 – Disinfection of cleanroom gloves

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Common name: Bacteria Development stage: -</p> <p>Common name: Yeast Development stage: -</p>

Field(s) of use	Indoor Disinfectant for use on gloved 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 – RTU 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

4.3.1. *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. Cloths or wipes treated with the product must be discarded in a closed container.

Do not use on bare hands.

4.3.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 3**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Use adequate ventilation with an air change rate of 8 per hour or more.

Apply away from eyes and face.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

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 the product.

Wash hands thoroughly after handling.

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 unconsciousness and low blood sugar (especially in children). Because of the type of formulations (wipes, aerosol and spray) the systemic effects are however less likely.

First-aid measures general: Never give anything orally 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 that is comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Rinse skin with water/shower. Remove all contaminated clothing immediately. Gently wash with plenty of soap and water. If symptoms develop, seek 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.

5.4. **Instructions for safe disposal of the product and its packaging**

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

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

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Keep container tightly closed. Keep in a cool, well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition. Store at temperatures below 40 °C.

Protect from frost.

Shelf-life: 2 years

6. **OTHER INFORMATION**

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

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	DEC-AHOL® WFI Formula DEC-AHOL® ASEPTI-CLEANSE		Market area: EU Market area: EU		
Authorisation number	EU-0024324-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4

META SPC 41. **META SPC 4 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC 4
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1.2. **Suffix to the authorisation number**

Number	1-4
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1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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2. **META SPC 4 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4	65,4

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation(s)	AE – Aerosol dispenser
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Extremely flammable aerosol. Pressurised container: May burst if heated. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Avoid breathing vapours. Wash hands thoroughly after handling. Wear protective gloves. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a doctor if you feel unwell. If eye irritation persists: Get medical advice. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F. Dispose of contents in accordance with local/national regulations. Wear eye protection.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 6. Use # 1 – Disinfection of hard non-porous surfaces; Aerosols

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: - Common name: Yeast Development stage: -
Field(s) of use	Indoor 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/m ² – RTU 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.

4.1.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection. Spray the surface to be disinfected from a distance of 15-20 cm. Thoroughly wet surface with product for 20 seconds/m², 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. Cloths or wipes treated with the product must be discarded in a closed container.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽⁴⁾ OF THE META SPC 4**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Use 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 the product.

Wash hands thoroughly after handling.

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.

⁽⁴⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

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 unconsciousness and low blood sugar (especially in children). Because of the type of formulations (wipes, aerosol and spray) the systemic effects are however less likely.

First-aid measures general: Never give anything orally 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 that is comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Rinse skin with water/or shower. Remove all contaminated clothing immediately. Gently wash with plenty of soap and water. If symptoms develop, seek 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.

5.4. Instructions for safe disposal of the product and its packaging

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

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

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

Keep away from open flames, hot surfaces and sources of ignition.

Keep container tightly closed. Keep in a cool, well-ventilated place. Store at temperatures below 40 °C.

Protect from frost.

Shelf-life: 2 years

6. OTHER INFORMATION

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	DEC-AHOL® AEROSOL WFI Formula Invertaspray		Market area: EU		
Authorisation number	EU-0024324-0004 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,4