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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/550

of 26 March 2021

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Radicchio Rosso di Treviso' (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected geographical indication 'Radicchio Rosso di Treviso', registered under Commission Regulation (EC) No 1263/96 ⁽²⁾, as amended by Commission Regulation (EC) No 784/2008 ⁽³⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* as required by Article 50(2)(a) of that Regulation ⁽⁴⁾.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Radicchio Rosso di Treviso' (PGI) are hereby approved.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 1263/96 of 1 July 1996 supplementing the Annex to Regulation (EC) No 1107/96 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Regulation (EEC) No 2081/92 (OJ L 163, 2.7.1996, p. 19).

⁽³⁾ Commission Regulation (EC) No 784/2008 of 5 August 2008 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Radicchio Rosso di Treviso (PGI)] (OJ L 209, 6.8.2008, p. 7).

⁽⁴⁾ OJ C 418, 3.12.2020, p. 9.

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, 26 March 2021.

For the Commission
On behalf of the President
Janusz WOJCIECHOWSKI
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2021/551

of 30 March 2021

concerning the authorisation of turmeric extract, turmeric oil, turmeric oleoresin from *Curcuma longa* L. rhizome as feed additives for all animal species and turmeric tincture from *Curcuma longa* L. rhizome as a feed additive for horses and dogs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of turmeric extract, turmeric oil, turmeric oleoresin from *Curcuma longa* L. rhizome as a feed additives for all animal species and turmeric tincture from *Curcuma longa* L. rhizome for horses and dogs.
- (4) The applicant requested turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome in water for drinking should not be allowed.
- (5) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 May 2020 ⁽³⁾ that, under the proposed conditions of use turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome should be considered as irritants to skin and eyes and the respiratory tract and as skin sensitisers. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2020;18(6):6146.

- (7) The Authority concluded, that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome are recognised to flavour food and since their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (8) The assessment of turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised [as specified in the Annex to this Regulation].
- (9) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (10) The fact that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome are not authorised for use as flavourings in water for drinking, does not preclude their use in compound feed which is administered via water.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Use in water for drinking

The authorised substances specified in the Annex shall not be used in water for drinking.

Article 3

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 20 October 2021 in accordance with the rules applicable before 20 April 2021 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 20 April 2022 in accordance with the rules applicable before 20 April 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 20 April 2023 in accordance with the rules applicable before 20 April 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

Entry into force

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

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b163-eo	-	Turmeric essential oil	Additive composition Essential oil derived by steam distillation from the dried rhizomes of <i>Curcuma longa</i> L. Characterisation of the active substance Essential oil derived by steam distillation from the dried rhizomes of <i>Curcuma longa</i> L. as defined by the Council of Europe ⁽¹⁾ : — ar-Turmerone: 40-60 % — β-Turmerone (curlone): 5-15 % — ar-Curcumene: 3-6 % — β-Sesquiphellandrene: 3-6 % — α-Zingiberene: 1-5 % — (E)-Atlantone: 2-4 % CAS number 8024-37-1 ⁽²⁾ Einecs number 283-882-1 ⁽¹⁾ FEMA number 3085 ⁽¹⁾ CoE number 163 Liquid form	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and pre-mixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 % or milk replacers with a moisture content of 5,5 %: — all animal species except veal calves: 20 mg — veal calves: 80 mg (milk replacers)' 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded.	20.4.2031

			Analytical method ⁽³⁾ For the quantification of the phytochemical markers: ar-turmerone and beta-turmerone in the feed additive (turmeric oil): Gas chromatography coupled to mass spectrometry (GC-MS) (full scan mode) using Retention Time Locking (RTL) methodology (or standard substances of the phytochemical markers) with (or without) gas chromatography coupled to flame ionisation detection (GC-FID) based on the ISO 11024 standard method					5. The mixture of Turmeric essential oil with other authorised additives obtained from <i>Curcuma longa</i> L. shall be not be allowed in feeding-stuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
2b163-or		Turmeric oleoresin	Additive composition Oleoresin obtained by solvent extraction of dried rhizomes of <i>Curcuma longa</i> L. Characterisation of the active substance Oleoresin obtained by solvent extraction of dried rhizomes of <i>Curcuma longa</i> L. as defined by the Council of Europe ⁽⁴⁾ .	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg complete feedingstuff with a moisture content of 12 %:	20.4.2031

			Essential oil: 30-33 % (w/w) Total curcuminoids: 20-35 % (w/w) — Curcumin (I): 16-21 % (w/w) — Desmethoxycurcumin (II): 4-6 % (w/w) — Bis-desmethoxycurcumin (III): 3-5 % (w/w). Humidity: 12-30 % (w/w) Analytical method ⁽⁵⁾ For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric oleoresin): — Spectrophotometry — FAO JECFA Combined Compendium of Food Additive Specifications, 'Turmeric Oleoresin', monograph No 1 (2006)					— Chicken and laying hens: 30 mg — Other animal species: 5 mg'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded. 5. The mixture of Turmeric oleoresin with other authorised additives obtained from <i>Curcuma longa</i> L. shall be not be allowed in feeding-stuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
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2b163-ex		Turmeric extract	Additive composition Extract of dried rhizomes <i>Curcuma longa</i> L. using organic solvents. Characterisation of the active substance Extract of dried rhizomes <i>Curcuma longa</i> L. using organic solvents as defined by the Council of Europe ⁽⁶⁾. Total curcuminoids: ≥ 90 % (w/w) — Curcumin (I): 74-79 % (w/w) — Desmethoxycurcumin (II) 15-19 % (w/w) — Bis-desmethoxycurcumin (III) 2-5 % (w/w) Water: 0,30-1,7 % (w/w) Einecs number: 283-882-1 ⁽⁴⁾ FEMA number: 3086 ⁽⁴⁾ CAS number 8024-37-1 ⁽⁴⁾ CoE number: 163 Solid form (powder) Analytical method ⁽⁷⁾ For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric extract): — Spectrophotometry — FAO JECFA Combined Compendium of Food Additive Specifications, 'Curcumin', monograph No 1 (2006)	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 % and milk replacers with a moisture content of 5,5 %: all species and veal calves (milk replacers): 15 mg'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded. 5. The mixture of Turmeric extract with other authorised additives obtained from <i>Curcuma longa</i> L. shall be not be allowed in feeding-stuffs.	20.4.2031
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								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007)

⁽²⁾ The same identifier applies indiscriminately to different kinds of extracts and derivatives from *Curcuma longa* such as turmeric essential oil, turmeric extract and turmeric tincture.

⁽³⁾ Details of the analytical methods are available at the following address of the Reference Laboratory:<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽⁴⁾ Natural sources of flavourings – Report No 2 (2007)

⁽⁵⁾ Details of the analytical methods are available at the following address of the Reference Laboratory:<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽⁶⁾ Natural sources of flavourings – Report No. 2 (2007)

⁽⁷⁾ Details of the analytical methods are available at the following address of the Reference Laboratory:<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mL active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b163-t		Turmeric tincture	Additive composition Tincture produced by extraction of ground-dried rhizomes of <i>Curcuma longa</i> L. using a water/ethanol mixture (55/45 % v/v). Characterisation of the active substance Tincture produced by extraction of ground-dried rhizomes of <i>Curcuma longa</i> L. using a water/ethanol mixture (55/45 % v/v), as defined by the Council of Europe ⁽¹⁾ . Phenols (as gallic acid equivalent): 1 100–1 500 µg/mL Total curcuminoids ⁽²⁾ (as curcumin): 0,04 to 0,09 % (w/v) Curcumin (I): 83–182 µg/mL Desmethoxycurcumin (II): 80–175 µg/mL Bis-desmethoxycurcumin (III): 139–224 µg/mL	— Horses — Dogs	-	-	-	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — horses: 0,75 mL; — dogs: 0,05 mL'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded.	20.4.2031

			Essential oil: 1 176–1 537 µg/mL Dry matter: 2,62–3,18 % (w/w) Solvent (water/ethanol, 55/45):96-97,5 % (w/w) Liquid form CoE No 163 Analytical method ⁽³⁾ For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric tincture): — Spectrophotometry (based on European Pharmacopeia monograph 'Turmeric Javanese' (01/2008:1441))					5. The mixture of Turmeric tincture with other authorised additives obtained from <i>Curcuma longa</i> L. shall be not be allowed in feeding-stuffs. 6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007)

⁽²⁾ Determined by spectrophotometry as dicinnamoyl methane derivatives

⁽³⁾ Details of the analytical methods are available at the following address of the Reference Laboratory:<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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 algacides 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 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 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	Ready to Use (RTU) Product may be used multiple times a day, if required. Contact time: 2 min 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
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 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. 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 Multi pack wipes A wipe is composed of 100 % continuous filament knitted polyester fibre; 20 wipes per pack; folded together in a re-closable bag package. 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

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 algaecides 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.

	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.
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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 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/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
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 ^(*) 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.

^(*) 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 algaecides 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 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)	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 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)	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

	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
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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 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 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 algacides 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

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