



2024/2419

16.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2419

of 13 September 2024

granting a Union authorisation for the single biocidal product ‘Soft Care Med H5’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 29 March 2019, Diversey Europe Operations B.V. submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named ‘Soft Care Med H5’ of product-type 1 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-MF050448-40 in the Register for Biocidal Products.
- (2) ‘Soft Care Med H5’ contains propan-1-ol and propan-2-ol as the active substances, both included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 17 July 2023, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 14 December 2023, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Soft Care Med H5’ and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Soft Care Med H5’ is a single biocidal product within the meaning of Article 3(1), point (r), 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) of that Regulation.
- (6) On 3 January 2024, 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 ‘Soft Care Med H5’.
- (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, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>

⁽²⁾ ECHA opinion of 22 November 2023 on the Union authorisation of the single biocidal product ‘Soft Care Med H5’ (ECHA/BPC/401/2023), <https://echa.europa.eu/opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032018-0000 is granted to Diversey Europe Operations B.V. for the making available on the market and use of the single biocidal product 'Soft Care Med H5' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 6 October 2024 to 30 September 2034.

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, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Soft Care Med H5

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0032018-0000**R4BP asset number:** EU-0032018-0000**1. ADMINISTRATIVE INFORMATION****1.1. Trade name(s) of the product**

Trade name(s)	Soft Care Med H5 Soft Care Med DivoCare Alco P VR203 DivoCare Alco P Soft Care Alcoplus Soft Care Impact Med PrimeSource MED Soft Care Alcogel PrimeSource Alcoplus PrimeSource Alcogel PrimeSource Hand Sanitizer STAPLES Med STAPLES Alcogel STAPLES Alcoplus STAPLES Hand Sanitizer Optimax Hand Sanitizer Optimax Med Optimax Alcogel Optimax Alcoplus Trust MED
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht NL
Authorisation number	EU-0032018-0000	
R4BP asset number	EU-0032018-0000	
Date of the authorisation	6 October 2024	
Expiry date of the authorisation	30 September 2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	Diversey Europe Operations B.V.
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Address of manufacturer	Maarssebroeksedijk 2 3542 DN Utrecht, Netherlands (the)
Location of manufacturing sites	Diversey Europe Operations B.V. site 1 Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy Diversey Europe Operations B.V. site 2 Rembrandtlaan 414 7545 ZW Enschede, Netherlands (the) Diversey Europe Operations B.V. site 3 Cotes Park Industrial Estate DE55 4PA Somercotes, Alfreton, United Kingdom of Great Britain and Northern Ireland (the) Diversey Europe Operations B.V. site 4 Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura 28343 Valdemoro, Madrid, Spain Diversey Europe Operations B.V. site 5 Morschheimer Strasse 12 67292 Kirchheimbolanden, Germany
Name of manufacturer	Multifill B.V.
Address of manufacturer	Constructieweg 25a, P.O. Box 367 3640 Mijdrecht, Netherlands (the)
Location of manufacturing sites	Multifill B.V. site 1 Constructieweg 25a, P.O. Box 367 3640 AJ Mijdrecht, Netherlands (the)

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38 67056 Ludwigshafen, Germany
Location of manufacturing sites	BASF SE site 1 Carl-Bosch-Str. 38 67056 Ludwigshafen, Germany
Active substance	Propan-1-ol
Name of manufacturer	OXEA Corporation
Address of manufacturer	2001 FM 3057 TX 77414 Bay City United States (the)
Location of manufacturing sites	OXEA Corporation site 1 2001 FM 3057 TX 77414 Bay City United States (the)
Active substance	Propan-2-ol
Name of manufacturer	SASOL Solvents Germany, GmbH
Address of manufacturer	Anckelmannsplatz D-20537 Hamburg, Germany

Location of manufacturing sites	SASOL Solvents Germany GmbH site 1 Shamrockstrasse 88 D-44623 Herne, Germany SASOL Solvents Germany GmbH site 2 Römerstr. 733 D-47443 Moers, Germany
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Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334 3000 CH Rotterdam, Netherlands (the)
Location of manufacturing sites	Shell Chemicals Europe B.V. site 1 Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam-Pernis, Netherlands (the)

Active substance	Propan-2-ol
Name of manufacturer	Exxon Mobil Chemicals
Address of manufacturer	Hermeslaan 2 1831 Machelen, Belgium
Location of manufacturing sites	Exxon Mobil Chemicals site 1 ExxonMobil's Baton Rouge Refinery and Chemical Plant, 4045 Scenic Hwy LA 70805 Baton Rouge, United States (the) Exxon Mobil Chemicals site 2 Esso Refinery Fawley SO45 1TX Southampton, United Kingdom of Great Britain and Northern Ireland (the)

Active substance	Propan-2-ol
Name of manufacturer	Novapex
Address of manufacturer	21 Chemin de la Sauvegarde - 21 Ecully Parc - CS 33167 69134 Écully Cedex, France
Location of manufacturing sites	Novapex site 1 Novapex SAS Usine de Rousillon, Rue Gaston Monmousseau 38556 Saint Maurice l'Exil, France

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		active substance	71-23-8	200-746-9	2,96 % (w/w)
Propan-2-ol		active substance	67-63-0	200-661-7	70 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly flammable liquid and vapour. H336: May cause drowsiness or dizziness. H319: Causes serious eye irritation.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P370+P378: In case of fire: Use water to extinguish. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of contents to chemical waste. P103: Read carefully and follow all instructions.

4. AUTHORISED USE(S)

4.1. Use description

Table 1

PT01 - Hygienic hand rub

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data

	<p>Scientific name: no data Common name: limited spectrum viruses Development stage: no data Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data</p>
Field(s) of use	<p>indoor use outdoor use Ready to use disinfectant hand rub for hands for use in hospitals and other medical areas, institutional and industrial areas, restaurants and large-scale canteen kitchens and recreational areas. Not for domestic use.</p>
Application method(s)	<p>Method: Dispense Detailed description: For pump or pouch with pump:Dispense ready to use disinfectant by applying the product onto the hands. Rub to completely cover clean hands. For flip top or cap bottle:Pour the ready to use liquid into the palm of one cupped hand. Rub to completely cover clean hands.</p>
Application rate(s) and frequency	<p>Application rate: Adult: 3 ml (the amount of liquid should resemble the size of a large-sized coin) equal to 3 pumps with the dosing system Child under 12 years: 2 ml equal to 2 pumps with the dosing system Child under 6 years: 1 ml equal to 1 pump with the dosing system Dilution (%): Ready to use Number and timing of application: Professional user: Up to 25 applications per day Non-professional user: — Adults: Up to 11 applications per day — Children: Up to 3 applications per day</p>
Category(ies) of users	<p>industrial ; professional ; general public (non-professional)</p>
Pack sizes and packaging material	<p>Professional and industrial: Rigid container (flip top) high-density polyethylene (HDPE): 100, 150, 200, 500 ml Rigid container (pump or cap) (HDPE): 0,5, 0,6, 0,7, 0,75, 0,8, 0,9, 1, 1,3, 1,5, 2, 3, 5, 10, 20, 50, 100, 200, 900, 950, 1000 litres Flexible container (pouch with pump or cap) low-density polyethylene (LDPE): 0,8, 1,3, 2,5 litres Non-professional: Rigid container (flip top) (HDPE): 100, 150, 200, 500 ml Rigid container (pump or cap) (HDPE): 0,5, 0,6, 0,7, 0,75, 0,8, 0,9, 1, 1,3, 1,5, 2, 3, 5 litres Flexible container (pouch with pump or cap) (LDPE): 0,8, 1,3, 2,5 litres</p>

4.1.1. *Use-specific instructions*

Comply with the instructions for use.

The product needs to be used on visibly clean hands.

Step 1: Apply the following amount of disinfectant:

- Adult: 3 ml equal to 3 pumps with the dosing system
- Child under 12 years: 2 ml equal to 2 pumps with the dosing system
- Child under 6 years: 1 ml equal to 1 pump with the dosing system

Rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Keep wet for 30 sec against bacteria, yeast, tuberculosis bacilli and enveloped viruses or 2 minutes against limited spectrum viruses.

Do not rinse.

Repeat if renewed hand disinfection is required.

Children and toddler shall only perform hand disinfection under adult supervision: apply the amount for children/toddler at your own hand first and rub the product at child's/toddler's hand until both hands are totally dried (see 6-Step instructions). Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

Use by children only under supervision of an adult.

Do not use for children under 1 year.

Make sure that the user applies the product in an area where people will not be present for a longer period.

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*

Keep out of reach of children and non-target animals/pets

4.2. Use description

Table 2

PT01 - Surgical hand rub

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Limited spectrum viruses Development stage: no data Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data
Field(s) of use	indoor use Ready to use surgical disinfectant for hands and forearms for use in hospitals and other medical areas.
Application method(s)	Method: Dispense Detailed description: Dispense ready to use disinfectant by pumping at least 3 times (1 ml per pump) onto the hands (pump or pouch with pump) and rub to completely cover clean hands and arms. OR Pour the ready to use liquid into the palm of one cupped hand (flip top or cap bottle) applying sufficiently to completely cover clean hands and arms.
Application rate(s) and frequency	Application rate: Portions of 3 ml up to 12 ml in total Dilution (%): Ready to use Number and timing of application: Up to 4 applications per day
Category(ies) of users	professional
Pack sizes and packaging material	Rigid container (flip top) high-density polyethylene (HDPE): 100, 150, 200, 500 ml Rigid container (pump or cap) (HDPE): 0,5, 0,6, 0,7, 0,75, 0,8, 0,9, 1, 1,3, 1,5, 2, 3, 5, 10, 20, 50, 100, 200 litres Flexible container (pouch with pump or cap) low-density polyethylene (LDPE): 0,8, 1,3, 2,5 litres

4.2.1. Use-specific instructions

The product shall be used on visibly clean hands and arms.

Do not refill or decant products used as surgical hand rub.

For pump or pouch with pump:

Dispense by pumping at least 3 times (1 ml per pump) onto the hands and rub to completely cover clean hands and arms up to the elbow. Repeat the procedure and use multiple portions of 3 ml to keep hands and arms wet for 2 minutes.

Keep wet for 2 minutes against bacteria, yeast, tuberculosis bacteria and limited spectrum viruses.

Do not rinse.

Repeat if renewed hand disinfection is required. (Up to 4 applications per day).

For flip top or cap bottle:

Pour the liquid into the palm of one cupped hand, applying sufficiently to completely cover clean hands and arms up to the elbow. Repeat the procedure and use multiple portions of 3 ml to keep hands and arms wet for 2 minutes.

Keep wet for 2 minutes against bacteria, yeast, tuberculosis bacteria and limited spectrum viruses.

Do not rinse.

Repeat if renewed hand disinfection is required. (Up to 4 applications per day).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

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

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

See use specific instructions for the individual uses.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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

Inhalation: May cause drowsiness or dizziness.

Skin contact: No known effects or symptoms in normal use.

Eye contact: Causes severe irritation.

Ingestion: Ingestion might lead to nausea and vomiting due to local irritation and systemic effects like drunkenness, drowsiness, sometimes unconsciousness and low blood sugar (especially in children).

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

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.

Environmental precautions:

Avoid (direct) release (of undiluted product) to the environment/sewage system.

Dilute spills with water and mop up.

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

Dispose according to national or local regulations.

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

2 years shelf life

Store below 30°C

Store away from heat and direct sunlight.

6. OTHER INFORMATION
