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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1867

of 10 September 2025

granting a Union authorisation for the single biocidal product 'Sterillium liquid' 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 5 August 2024, BODE Chemie GmbH submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Sterillium liquid', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-MV099339-92 in the Register for Biocidal Products. The application referred to the single biocidal product 'I-HDL 02' (authorisation number EU-0027467-0023), which is a part of the related reference biocidal product family 'Knieler & Team Propanol Family'. The application also indicated the authorisation number of the related reference biocidal product family 'Knieler & Team Propanol Family' authorised by Commission Implementing Regulation (EU) 2022/1282 ([3]), with authorisation number EU-0027467-0000.

(2) The single biocidal product 'Sterillium liquid' contains propan-1-ol and propan-2-ol as the active substances, 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 4 December 2024, the Agency submitted to the Commission its opinion ([4]) and the draft summary of the biocidal product characteristics ('SPC') of 'Sterillium liquid' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.

(4) In its opinion, the Agency concludes that the proposed differences between the single biocidal product 'Sterillium liquid' and the related reference single biocidal product 'I-HDL 02', which is a part of the related reference biocidal product family 'Knieler & Team Propanol Family' are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([5]), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product 'Sterillium liquid' meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

([3]) Commission Implementing Regulation (EU) 2022/1282 of 8 July 2022 granting a Union authorisation for the biocidal product family 'Knieler & Team Propanol Family' (OJ L 195, 22.7.2022, p. 34, ELI: http://data.europa.eu/eli/reg_impl/2022/1282/oj).

([4]) European Chemicals Agency opinion of 4 December 2024 on the Union authorisation of the same single biocidal product 'Sterillium liquid', https://echa.europa.eu/opinions-on-union-authorisation.

([5]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

(5) On 20 December 2024, the Agency transmitted to the Commission the draft SPC of 'Sterillium liquid' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'Sterillium liquid'.

(7) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Knieler & Team Propanol Family'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0033788-0000 is hereby granted to BODE Chemie GmbH for the making available on the market and use of the same single biocidal product 'Sterillium liquid' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 5 October 2025 until 31 July 2032.

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, 10 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Sterillium liquid

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0033788-0000

R4BP asset number: EU-0033788-0000

1. ADMINISTRATIVE INFORMATION

1.1. **Trade name(s) of the product**

Trade name(s)	Sterillium liquid Manusept liquid Sterillium pur

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	BODE Chemie GmbH
	Address	Melanchthonstr. 27 22525 Hamburg DE
Authorisation number	EU-0033788-0000	
R4BP asset number	EU-0033788-0000	
Date of the authorisation	5 October 2025	
Expiry date of the authorisation	31 July 2032	

1.3. **Manufacturer(s) of the product**

Name of manufacturer	Bode Chemie GmbH
Address of manufacturer	Melanchthonstrasse 27 22525 Hamburg Germany
Location of manufacturing sites	BODE Chemie GmbH site 1 Melanchthonstraße 27 22525 Hamburg Germany

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

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals GmbH (formerly Oxea GmbH) site 1 OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX 77414 Bay City United States (the)

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 BASF SE, Carl-Bosch-Str. 38 67056 Ludwigshafen Germany

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH site 1 INEOS Solvent Germany GmbH, Römerstrasse 733 47443 Moers Germany INEOS Solvent Germany GmbH site 2 INEOS Solvent Germany GmbH, Shamrockstrasse 88 44623 Herne Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands (the)
Location of manufacturing sites	Shell Nederland Raffinaderij B.V. site 1 Shell Nederland Raffinaderij B.V. 3196 KK Rotterdam-Pernis Netherlands (the)

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	30 % (w/w)
Propan-2-ol		active substance	67-63-0	200-661-7	45 % (w/w)

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

AL Any other liquid.

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H226: Flammable liquid and vapour. H318: Causes serious eye damage. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. **Use description**

Table 1

Hygienic handrub, liquid

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: no data Scientific name: other Common name: Mycobacteria Development stage: no data Scientific name: other Common name: Yeasts Development stage: no data Scientific name: other Common name: Enveloped viruses Development stage: no data
Field(s) of use	Indoor use — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands — for professional use only

Application method(s)	Method: manual application Detailed description: Rubbing
Application rate(s) and frequency	Application rate: Dosage: At least 3 ml (use dispensers: for example, set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 seconds. Ready-to-use product. Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Industrial ; professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use under Section 5.2.

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

See general directions for use under Section 5.3.

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

See general directions for use under Section 5.4.

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 under Section 5.5.

4.2. **Use description**

Table 2

Surgical handrub, liquid

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: no data Scientific name: other Common name: Mycobacteria Development stage: no data Scientific name: other Common name: Yeasts Development stage: no data Scientific name: other Common name: enveloped viruses Development stage: no data
Field(s) of use	Indoor use Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: manual application Detailed description: Rubbing
Application rate(s) and frequency	Application rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example, set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 seconds. Ready-to-use product. Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml HDPE canister with HDPE screwed cap.

4.2.1. *Use-specific instructions*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use under Section 5.2.

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 under Section 5.3.

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

See general directions for use under Section 5.4.

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 under Section 5.5.

5. GENERAL DIRECTIONS FOR USE ([1])

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shoveling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to national legislation. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30 °C

Do not store at temperatures below 0 °C

Do not store near food, drink and animal feeding stuff. Keep away from combustible material.

6. OTHER INFORMATION

Not applicable.