COMMISSION IMPLEMENTING REGULATION (EU) 2023/1108

of 6 June 2023

granting a Union authorisation for the single biocidal product 'OP Plus' 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 23 April 2019, Laboratorium Dr. Deppe GmbH submitted to the European Chemicals Agency ('the Agency') an application 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 that Regulation, named 'OP Plus', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-JN051117-37 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.

(2) The same single biocidal product 'OP Plus' contains propan-1-ol and propan-2-ol as the active substances, which are 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 8 December 2021, the Agency submitted to the Commission an opinion ([3]) and the draft summary of the biocidal product characteristics ('SPC') of 'OP Plus' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.

(4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([4]), 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 meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

(5) On 20 October 2022, 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.

(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 'OP Plus'.

(7) 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]) 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).

([3]) ECHA opinion for 'OP Plus', 8 December 2021, https://echa.europa.eu/opinions-on-union-authorisation

([4]) 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).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027670-0000 is granted to Laboratorium Dr. Deppe GmbH for the making available on the market and use of the same single biocidal product 'OP Plus' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 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, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

OP Plus

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027670-0000

R4BP asset number: EU-0027670-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	OP Plus Nextsept MyClean HB plus MyClean HB basic Bavicid Hand

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorium Dr. Deppe GmbH
	Address	Hooghe Weg 35, 47906 Kempen Germany
Authorisation number	EU-0027670-0000	
R4BP asset number	EU-0027670-0000	
Date of the authorisation	27 June 2023	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	Laboratorium Dr. Deppe GmbH
Address of manufacturer	Hooghe Weg 35, 47906 Kempen Germany
Location of manufacturing sites	Laboratorium Dr. Deppe GmbH, Hooghe Weg 35, 47906 Kempen 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 Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States

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

Active substance	Propan-1-ol
Name of manufacturer	SASOL Chemie GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	Stockmeier Chemie GmbH & Co. KG
Address of manufacturer	Am Stadtholz 37, 33609 Bielefeld Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1, 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., 3196 KK Rotterdam-Pernis Netherlands Exxon Mobil, LA 70805 Baton Rouge United States

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	12,229
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751

2.2. Type of formulation

AL - Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. 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. Use only outdoors or in a well-ventilated area. 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. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1. Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Tuberculosis bacilli 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
Field(s) of use	Indoor — 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 s Dilution (%): 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, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions for use*

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

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 2. Use # 2 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data

	Scientific name: no data Common name: Tuberculosis bacilli 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
Field(s) of use	Indoor 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 s Dilution (%): 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, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap.

4.2.1. *Use-specific instructions for use*

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

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**

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, shovelling). 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 official regulations. 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.

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

Shelf-life: 24 months

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

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 feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**