



2024/2409

16.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2409

of 13 September 2024

granting a Union authorisation for the single biocidal product ‘Hydroflex IPA 70 Biocide’ 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 20 September 2023, Hydroflex Group 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 ‘Hydroflex IPA 70 Biocide’, of product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012, referring to the single biocidal product “Isopropanol 70 Biocide” (authorisation number EU-0027707-0022), which is a part of the related reference biocidal product family ‘Brenntag GmbH Propan-2-ol Product Family’. The application was recorded under case number BC-BX088801-11 in the Register for Biocidal Products. The application also indicated the authorisation number of the related reference biocidal product family ‘Brenntag GmbH Propan-2-ol Product Family’ authorised by Commission Implementing Regulation (EU) 2022/2252 ⁽³⁾, with authorisation number EU-0027707-0000.
- (2) The single biocidal product ‘Hydroflex IPA 70 Biocide’ contains propan-2-ol as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 12 January 2024, the Agency submitted to the Commission its opinion ⁽⁴⁾ and the draft summary of the biocidal product characteristics (‘SPC’) of ‘Hydroflex IPA 70 Biocide’ 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 ‘Hydroflex IPA 70 Biocide’ and the related single biocidal product “Isopropanol 70 Biocide”, which is a part of the related reference biocidal product family ‘Brenntag GmbH Propan-2-ol Product 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 ‘Brenntag GmbH Propan-2-ol Product Family’ and subject to compliance with the draft SPC, the same single biocidal product ‘Hydroflex IPA 70 Biocide’ 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) 2022/2252 of 11 November 2022 granting a Union authorisation for the biocidal product family ‘Brenntag GmbH Propan-2-ol Product Family’ (OJ L 297, 17.11.2022, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2022/2252/oj).

⁽⁴⁾ European Chemicals Agency opinion of 12 January 2024 on the Union authorisation of the same single biocidal product ‘Hydroflex IPA 70 Biocide’, <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 4 April 2024, the Agency transmitted to the Commission the revised SPC of 'Hydroflex IPA 70 Biocide' 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 'Hydroflex IPA 70 Biocide'.
- (7) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Brenntag GmbH Propan-2-ol Product 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-0032170-0000 is granted to Hydroflex Group GmbH for the making available on the market and use of the same single biocidal product 'Hydroflex IPA 70 Biocide' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 6 October 2024 until 30 November 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, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Hydroflex IPA 70 Biocide

Product type(s)

PT02: Disinfectants and algacides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: EU-0032170-0000**R4BP asset number:** EU-0032170-0000**1. ADMINISTRATIVE INFORMATION****1.1. Trade name(s) of the product**

Trade name(s)	Hydroflex IPA 70 Biocide
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Hydroflex Group GmbH
	Address	Kiesacker 19 35418 Buseck DE
Authorisation number		EU-0032170-0000
R4BP asset number		EU-0032170-0000
Date of the authorisation		6 October 2024
Expiry date of the authorisation		30 November 2032

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

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway LA 70897 Baton Rouge, Louisiana United States (the)
Location of manufacturing sites	4999 Scenic Highway LA 70897 Baton Rouge, Louisiana United States (the)

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

Active substance	Propan-2-ol
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Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	Römerstrasse 733 47443 Moers Germany Shamrockstraße 88 44623 Herne Germany

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-2-ol		active substance	67-63-0	200-661-7	70 % (w/w)

2.2. Type(s) of formulation

Meta SPC 2: Ready-to-Use trigger spray

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. 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. P261: Avoid breathing spray. P271: Use only outdoors or in a well-ventilated area. P280: Wear eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER/doctor if you feel unwell. P337+P313: If eye irritation persists: Get medical advice. P337+P313: If eye irritation persists: Get medical attention. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of contents to in accordance with local regulations. P501: Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use 1 – Liquid Spray – Small surface disinfection – Professional user

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria (incl. Mycobacteria), Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	indoor use Disinfection of small non-porous surfaces, materials, equipment and furniture in private, public, healthcare, industrial areas and in areas for professional activities.
Application method(s)	Method: spraying Detailed description: -
Application rate(s) and frequency	Application rate: For surface disinfection a ready-to-use spray solution (20 ml/m ²) is applied on surfaces at room temperature. Dilution (%): - Number and timing of application: Application according to requirements, one application per use, 4 times per day. Small surface disinfection(other than healthcare): Bactericidal and yeasticidal: contact time at least 1 min In healthcare area: Bactericidal and yeasticidal: contact time at least 5 min
Category(ies) of users	professional
Pack sizes and packaging material	— Bottle HD-PE: 0,1L–2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) — Can HD-PE: 5L-60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)) — Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) — IBC container HD-PE: 1 000L; (Screw caps (HD-PE))

4.1.1. Use-specific instructions

- 1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for 1 minute (general surface disinfection) or 5 minutes (surfaces in healthcare area)
- 2) For use at room temperature.
- 3) Application according to requirements, one application per use, 4 times per day.

4.1.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and/or organisational measures:

The use of eye protection during refilling of the product is recommended.

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 – Liquid Spray - Disinfection for small food contact surfaces – Professional user

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	indoor use Disinfection of small non-porous surfaces in food sector or food processing industries (including breweries, dairy industry and meat industry).
Application method(s)	Method: spraying Detailed description: -
Application rate(s) and frequency	Application rate: For surface disinfection a ready-to-use spray solution (20 ml/m ²) is applied on surfaces at room temperature. Dilution (%): - Number and timing of application: Application according to requirements, one application per use, 4 times per day. Small surface disinfection: Bactericidal and yeasticidal: contact time at least 1 min In Breweries/meat industry: Bactericidal and yeasticidal: contact time at least 5 min In dairy industry: Bactericidal and yeasticidal: contact time at least 15 min

Category(ies) of users	professional
Pack sizes and packaging material	<ul style="list-style-type: none"> — Bottle HD-PE: 0,1L–2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) — Can HD-PE: 5L–60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)) — Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) — IBC container HD-PE: 1 000L;(Screw caps (HD-PE))

4.2.1. Use-specific instructions

- 1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for at least 1 min (general surface disinfection), 5 min (surface disinfection in breweries or meat industry) or at least 15 min (surface disinfection in dairy industry).
- 2) For use at room temperature.
- 3) Application according to requirements, one application per use, 4 times per day.

4.2.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is recommended.

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

- 1) Products must be shaken before use.
- 2) Do not apply more than 20 mL/m².
- 3) Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

- 1) Avoid contact with eyes.
- 2) For refilling a funnel must be applied.
- 3) The product must only be applied for disinfection of small surfaces.
- 4) Keep out of reach of children and pets.
- 5) Use only in well-ventilated areas.

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

- 6) Keep children and pets away from rooms where disinfection is taking place.
- 7) Provide adequate ventilation before children and pets enter treated rooms.

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

- 1) 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.
- 2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

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

- 1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
- 2) Do not let product enter drains.
- 3) Contact waste disposal services.
- 4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
- 5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

- 1) Store in a well-ventilated place.
- 2) Keep cool.
- 3) Keep container tightly closed.
- 4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 5) Shelf-life: 24 months

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.