II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1147

of 31 July 2020

granting a Union authorisation for the single biocidal product 'ClearKlens product based on IPA'

(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 26 May 2016, Diversey Europe Operations B.V. submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a single biocidal product named 'ClearKlens product based on IPA' 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-HD024462-61 in the Register for Biocidal Products.

(2) 'ClearKlens product based on IPA' 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 3 June 2019, 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 European Chemicals Agency ('the Agency').

(4) On 17 January 2020, the Agency submitted to the Commission an opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'ClearKlens product based on IPA' 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 'ClearKlens product based on IPA' is a 'single biocidal product' within the meaning of Article 3(1)(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 February 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 'ClearKlens product based on IPA'.

(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 11 December 2019 on the Union authorisation of 'ClearKlens product based on IPA' (ECHA/BPC/236/2019).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0022128-0000 is granted to Diversey Europe Operations B.V. for the making available on the market and use of the single biocidal product 'ClearKlens product based on IPA' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 24 August 2020 until 31 July 2030.

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, 31 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

ClearKlens product based on IPA

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0022128-0000

R4BP asset number: EU-0022128-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ClearKlens IPA ClearKlens IPA 70 % ClearKlens IPA 70 % v/v ClearKlens IPA VH1 ClearKlens IPA Airless ClearKlens IPA Pouch ClearKlens IPA Non Sterile ClearKlens IPA Non Sterile VH1 ClearKlens IPA SS ClearKlens IPA SS VH1 ClearKlens IPA RTU ClearKlens IPA RTU VH1 Texwipe® Sterile 70 % Isopropanol VH01 ClearKlens IPA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Maarssenbroeksedijk 2, 3542 DN, Utrecht, Netherlands
Authorisation number	EU-0022128-0000	
R4BP asset number	EU-0022128-0000	
Date of the authorisation	24.8.2020	
Expiry date of the authorisation	31.7.2030	

1.3. Manufacturer(s) of the product

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Maarssenbroeksedijk 2, 3542 DN Utrecht Netherlands
Location of manufacturing sites	Avenida Conde Duque 5, 7 y 9; Poligono Industrial La Postura, 28343 Valdemoro (Madrid) Spain Strada Statale 235, 26010 Bagnolo Cremasco (CR) Italy Cotes Park Industrial Estate, DE55 4PA Somercotes Alfreton United Kingdom Rembrandtlaan 414, 7545 ZW Enschede Netherlands Morschheimer Strasse 12, 67292 Kirchheimbolanden Germany

Name of manufacturer	Multifill BV
Address of manufacturer	Constructieweg 25a, 3640 AJ Mijdrecht Netherlands
Location of manufacturing sites	Constructieweg 25a, 3640 AJ Mijdrecht Netherlands

Name of manufacturer	Flexible Medical Packaging Ltd
Address of manufacturer	Unit 8, Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom
Location of manufacturing sites	Unit 8, Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom

Name of manufacturer	Ardepharm
Address of manufacturer	Les Iles Ferays, 07300 Tournon-sur-Rhône France
Location of manufacturing sites	Les Iles Ferays, 07300 Tournon-sur-Rhône France

Name of manufacturer	Entegris Cleaning Process (ECP) S.A.S
Address of manufacturer	395 rue Louis Lépine, 34000 Montpellier France
Location of manufacturing sites	395 rue Louis Lépine, 34000 Montpellier France

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

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents GmbH
Address of manufacturer	Anckelmannsplatz, D-20537 Hamburg Germany
Location of manufacturing sites	Shamrockstrasse 88, D-44623 Herne Germany Römerstrasse 733, D-47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334, 3000 CH Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601, 3196 KK Rotterdam-Pernis Netherlands

Active substance	Propan-2-ol
Name of manufacturer	Exxon Mobil Chemicals
Address of manufacturer	Hermeslaan 2, 1831 Machelen Belgium
Location of manufacturing sites	4045 Scenic Highway, LA 70805 Baton Rouge United States Southampton, SO45 1TX Hampshire United Kingdom

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	63,1

2.2. Type of formulation

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

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 spray. Wash hands thoroughly after handling. Store in a well-ventilated place. Keep cool. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. In case of fire: Use alcohol-resistant foam to extinguish.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – PT02: Non-porous hard surface disinfectant – professionals – mopping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Ready to use product for the disinfection of cleaned non-porous hard surfaces in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.

Application method(s)	Disinfection using a mop —
Application rate(s) and frequency	Apply 18,4 mL product/m² surface.
Category(ies) of users	Professional
Pack sizes and packaging material	Containers (High Density PolyEthylene (HDPE), Polypropylene (PP), Polyethylene (PE)): 1–20 L

4.1.1. *Use-specific instructions for use*

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the mop with the disinfectant and mop the surface. Wet the surface completely. Allow to take effect for at least 30 seconds.

Used mops must be stored in a closed container.

4.1.2. *Use-specific risk mitigation measures*

Apply the product only in a sufficiently ventilated room. The minimum air change rates required are:

— 60/h in pharmaceutical and cosmetics manufacturing facilities,

— 150/h in cleanrooms.

Do not use more than 18,4 mL product/m².

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 – PT02: Non-porous hard surface disinfectant – professionals – cloth

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Ready to use product for the disinfection of cleaned non-porous hard surfaces in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.
Application method(s)	Disinfection using a cloth
Application rate(s) and frequency	Apply 18,4 mL product/m² surface.
Category(ies) of users	Professional
Pack sizes and packaging material	— Containers (High Density PolyEthylene (HDPE), Polypropylene (PP), Polyethylene (PE)): 1–20 L — Containers (HDPE, PP, PE) with a pump: 200 L (cleanroom only) — Intermediate bulk containers (IBCs) with a pump (HDPE, PP, PE): 950 and 1 000 L (cleanroom only)

4.2.1. *Use-specific instructions for use*

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the cloth with the disinfectant and wipe the surface. Wet the surface completely. Allow to take effect for at least 30 seconds. In cleanrooms, the exact amount of required product can also be dispensed either using a low flow-rate spray lance or into a bucket via a system of pipes. Used cloths must be disposed of in a closed container.

4.2.2. *Use-specific risk mitigation measures*

Apply the product only in a sufficiently ventilated room. The minimum air change rates required are

— 8/h in laboratories,

— 60/h in pharmaceutical and cosmetics manufacturing facilities,

— 150/h in cleanrooms.

Do not use more than 18,4 mL product/m².

The following personal risk mitigation measure can be applied for wiping disinfection unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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 3. Use # 3 – PT02: Non-porous hard surface disinfectant – professionals – spraying

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Ready to use product for the disinfection of cleaned non-porous hard surfaces in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 8, 60 or 150 per hour or more.
Application method(s)	Disinfection using a trigger spray Wiping optional to spread the product.
Application rate(s) and frequency	Apply 18,4 mL product/m^2 surface.
Category(ies) of users	Professional
Pack sizes and packaging material	— Trigger spray pouch (PE): 0,9 – 20 L — Bag in bottle (multilayer coextruded five-layer Ethylene vinyl acetate (EVA)/EVA/Polyvinylidene dichloride (PVDC)/ EVA/EVA bag in a HDPE, PP or PE bottle): 0,9–2 L — Trigger Spray bottle (HDPE, PP, PE): 0,5–1,5 L — Airless trigger spray bottle (Low-density polyethylene (LDPE)): 0,25–1L

4.3.1. *Use-specific instructions for use*

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Spray the surface, wipe if necessary to spread the product. Wet the surface completely. Allow to take effect for at least 30 seconds. Used cloths must be disposed in a closed container.

Number of applications per type of packaging, necessary to obtain an application rate of 18,4 mL product/m^2 surface:

— Trigger spray pouch: apply 19 sprays/m^2 surface,

— Sterile trigger (bag in bottle): apply 16 sprays/m^2 surface,

— Trigger spray bottle: apply 14 sprays/m^2 surface,

— Airless trigger spray bottle: apply 21 sprays/m^2 surface.

4.3.2. *Use-specific risk mitigation measures*

Apply the product only in a sufficiently ventilated room. The minimum air change rates required are

— 8/h in laboratories,

— 60/h in pharmaceutical and cosmetics manufacturing facilities,

— 150/h in cleanrooms.

Do not use more than 18,4 mL product/m^2.

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.

4.4. **Use description**

Table 4. Use # 4 – PT02: Non-porous glove disinfectant – professionals – non-porous glove disinfection

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Ready to use product for the disinfection of clean non-porous gloves in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.
Application method(s)	Disinfection of non-porous gloves
Application rate(s) and frequency	Apply 3 mL of product to gloved hands.
Category(ies) of users	Professional
Pack sizes and packaging material	Automatic dosing: — Containers (HDPE, PP, PE): 1–20 L — Containers (HDPE, PP, PE) with a pump: 200 L (cleanrooms only) — IBCs with a pump (HDPE, PP, PE): 950 and 1 000 L (cleanrooms only)

	Manual dosing: — Trigger spray pouch (PE): 0,9–20 L — Bag in bottle (multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag in a HDPE, PP or PE bottle): 0,9–2 L — Trigger spray bottle (HDPE, PP, PE): 0,5–1,5 L — Airless trigger spray bottle (LDPE): 0,25–1 L

4.4.1. *Use-specific instructions for use*

Ready to use product for the disinfection of non-porous gloves.

Automatic and manual dosing:

Apply 3 mL of the product directly on clean gloved hands, distribute evenly and make sure to wet the surface completely. Allow to take effect for at least 30 seconds.

Number of applications per type of packaging, necessary to apply 3 mL of product on clean gloved hands:

— Trigger spray pouch: apply 3 sprays of the product on two hands,

— Sterile trigger (bag in bottle): apply 3 sprays of the product on two hands,

— Trigger spray bottle: apply 3 sprays of the product on two hands,

— Airless trigger spray bottle: apply 4 sprays of the product on two hands.

4.4.2. *Use-specific risk mitigation measures*

Apply the product only in a sufficiently ventilated room. The minimum air change rates required are

— 8/h in laboratories,

— 60/h in pharmaceutical and cosmetics manufacturing facilities,

— 150/h in cleanrooms.

4.4.3. *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.

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

See general directions for use.

4.4.5. *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.

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

5.2. **Risk mitigation measures**

Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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.

Eye contact: Causes severe irritation.

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTRE, doctor or physician if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation occurs and persists, get medical attention.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical attention or advice if you feel unwell.

Environmental precautions:

The product should not reach sewage water or drainage ditch undiluted or unneutralised.

Do not allow the product to enter drainage system, surface or ground water. Dilute with plenty of water.

Methods and material for containment and cleaning up. Absorb the product with liquid-binding material (sand, diatomite, universal binders, sawdust).

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

The product and its container must be disposed of in a safe way, in compliance with any relevant legislation on the disposal of hazardous waste. Dispose of or incinerate in accordance with the local regulations.

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

2 years shelf-life.

Keep only in original packaging.

Store away from direct sunlight and below 30 °C.

Store in a closed container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No: 67-63-0), for which a European reference value of 129,28 mg/m^3 for the professional user was agreed and used for the risk assessment of the product.