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)

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,

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1147. (See end of Document for details)*

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1147. (See end of Document for details)*

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1147. (See end of Document for details)*

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.