Commission Implementing Regulation (EU) 2020/1991 of 27 November 2020 granting a Union authorisation for the biocidal product family 'perform-IPA' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1991

of 27 November 2020

granting a Union authorisation for the biocidal product family 'perform-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 Article 44(5) thereof,

Whereas:

(1) On 19 April 2016, Schuelke & Mayr GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'perform-IPA' of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-AB023095-72 in the Register for Biocidal Products.

(2) 'perform-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 27 August 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 7 April 2020, the Agency submitted to the Commission an opinion[(2)], the draft summary of the biocidal product characteristics ('SPC') of 'perform-IPA' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'perform-IPA' is a biocidal product family within the meaning of Article 3(1)(s) 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) and (6) of that Regulation.

(6) On 27 April 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 'perform-IPA'.

(8) According to the opinion of the Agency, as regards the non-active substance diethyl phthalate contained in 'perform-IPA', it was not possible to conclude whether it meets the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100[(3)] within the period for the evaluation of the application. Further examination of diethyl phthalate should therefore take place. If it is concluded that diethyl phthalate is considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for 'perform-IPA' in accordance with Article 48 of Regulation (EU) No 528/2012.

(9) 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-0023656-0000 is granted to Schuelke & Mayr GmbH for the making available on the market and use of the biocidal product family 'perform-IPA' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 December 2020 until 30 November 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, 27 November 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) 2020/1991. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

perform-IPA

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

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0023656-0000

R4BP asset number: EU-0023656-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	perform-IPA

1.2. Product type(s)

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Schülke & Mayr GmbH
	Address	Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Authorisation number	EU-0023656-0000	
R4BP asset number	EU-0023656-0000	
Date of the authorisation	27 December 2020	
Expiry date of the authorisation	30 November 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Schülke & Mayr GmbH

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1991. (See end of Document for details)*

Address of manufacturer	Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Location of manufacturing sites	Robert-Koch-Str. 2, 22851 Norderstedt, Germany

Name of manufacturer	BOCHEMIE a.s.
Address of manufacturer	Lidická 326, 735 95 Bohumín Czech Republic
Location of manufacturing sites	Lidická 326, 735 95 Bohumín Czech Republic

Name of manufacturer	Imeco
Address of manufacturer	Boschstr. 5, 63768 Hösbach Germany
Location of manufacturing sites	Boschstr. 5, 63768 Hösbach Germany Neue Straße 2-4, 09471 Köningswalde Germany

Name of manufacturer	Tristel Solutions Limited
Address of manufacturer	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom
Location of manufacturing sites	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom

Name of manufacturer	Techtex
Address of manufacturer	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom
Location of manufacturing sites	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom

Name of manufacturer	A.F.P. GmbH
Address of manufacturer	Otto Brenner Straße 16, 21337 Lüneburg Germany
Location of manufacturing sites	Otto Brenner Straße 16, 21337 Lüneburg Germany

Name of manufacturer	Innovate GmbH
Address of manufacturer	Am Hohen Stein 11, 06618 Naumburg (Saale) Germany
Location of manufacturing sites	Am Hohen Stein 11, 06618 Naumburg (Saale) Germany

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH
Address of manufacturer	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany
Location of manufacturing sites	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany

Name of manufacturer	Sterisol AB
Address of manufacturer	Kronoängsgatan 3, 592 23 Vadstena Sweden
Location of manufacturing sites	Kronoängsgatan 3, 592 23 Vadstena Sweden

Name of manufacturer	Rudolf Dankwardt GmbH
Address of manufacturer	Gutenbergring 50-52, 22848 Norderstedt Germany
Location of manufacturing sites	Gutenbergring 50-52, 22848 Norderstedt Germany Lagerstr. 15, 19249 Jessenitz - Werk / Lübtheen Germany

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

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH (formerly Sasol)
Address of manufacturer	Römerstraße 733, 47443 Moers Germany
Location of manufacturing sites	Römerstraße 733, 47443 Moers Germany Shamrockstr. 88, 44643 Herne 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	Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam-Pernis Netherlands

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max