Commission Implementing Regulation (EU) 2019/2030 of 29 November 2019 granting a Union authorisation for the biocidal product family 'Pal IPA Product Family' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/2030

of 29 November 2019

granting a Union authorisation for the biocidal product family 'Pal IPA Product Family'

(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 29 June 2016, Pal Hygiene Products Limited, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Pal IPA Product Family' of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of United Kingdom had agreed to evaluate the application. The application was recorded under the case number BC-DY025578-07 in the Register for Biocidal Products.

(2) 'Pal IPA Product Family' 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 22 August 2018, 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 25 March 2019, the Agency submitted to the Commission an opinion[(2)], including the proposed terms and conditions of the authorisation, the draft summary of the biocidal product characteristics ('SPC') of 'Pal IPA Product Family' 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 'Pal IPA Product Family' 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 proposed terms and conditions and the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2030. (See end of Document for details)*

(6) On 4 June 2019, 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 'Pal IPA Product Family'.

(8) In the opinion the Agency also recommends that a long-term storage test at ambient temperature for wipes in their commercial packaging be conducted by the authorisation holder as a condition in the authorisation. The Commission agrees with that recommendation and considers that the submission of this test should be a condition relating to the making available on the market and use of the biocidal product family pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1)(d) of that Regulation on the basis of the existing data.

(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-0020463-0000 is granted to Pal Hygiene Products Limited for the making available on the market and use of the biocidal product family 'Pal IPA Product Family', subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in the Annex II.

The Union authorisation is valid from 24 December 2019 until 30 November 2029.

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, 29 November 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2030. (See end of Document for details)*

ANNEX I

TERMS AND CONDITIONS
(EU-0020463-0000)

The authorisation holder shall conduct a long-term storage test at ambient temperature for wipes in their commercial packaging.

By 31 July 2021 the authorisation holder shall submit the results of the test to the Agency.

ANNEX II

SUMMARY OF PRODUCT CHARACTERISTICS
FOR A BIOCIDAL PRODUCT FAMILY

Pal IPA Product Family

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-0020463-0000

R4BP asset number: EU-0020463-0000

PART I

FIRST INFORMATION LEVEL

1. **Administrative information**

1.1. **Family name**

Name	Pal IPA Product Family

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	Pal Hygiene Products Limited
	Address	Unit 5B & Unit 5H Fingal Bay Business Park, K32

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2030. (See end of Document for details)*

		NY57, Balbriggan, Co. Dublin, Ireland
Authorisation number	EU-0020463-0000	
R4BP asset number	EU-0020463-0000	
Date of the authorisation	24 December 2019	
Expiry date of the authorisation	30 November 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Pal International Limited
Address of manufacturer	Bilton Way, LE17 4JA Lutterworth, Leicestershire, United Kingdom
Location of manufacturing sites	Bilton Way, LE17 4JA Lutterworth, Leicestershire, United Kingdom

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

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11, 45131 Essen, Germany
Location of manufacturing sites	Baton Rouge Chemical Plant (BRCP), Exxon Mobil Chemical Plant, 4999 Scenic Highway, 70897 Baton Rouge, Louisiana, United States

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11, 45131 Essen, Germany
Location of manufacturing sites	Haven 3222, Vondelingenweg 601, 3196 KK Vondelingenplaat, 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
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/2030. (See end of Document for details)*

2.2. **Type(s) of formulation**

Formulation(s)	AL (any other liquid) - RTU wipe

PART II

SECOND INFORMATION LEVEL — META SPC(S)

Meta SPC 1

1. **Meta SPC 1 administrative information**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1 — Pal IPA Product Family Wipes

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **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)

2. **Meta SPC 1 Composition**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL (any other liquid) - RTU wipe

3. **Hazard and precautionary statements of the meta SPC 1**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation.