

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.
- (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,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 28 February 2019 on the Union authorisation of ‘Pal IPA Product Family’ (ECHA/BPC/223/2019).

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

*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
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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)
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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 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

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

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

SECOND INFORMATION LEVEL — META SPC(S)

Meta SPC 11. **Meta SPC 1 administrative information**1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1 — Pal IPA Product Family Wipes
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1.2. **Suffix to the authorisation number**

Number	1-1
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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)
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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 Sub-stance	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
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3. **Hazard and precautionary statements of the meta SPC 1**

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	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTRE if you feel unwell. If eye irritation persists: Get medical advice. In case of fire: Use alcohol-resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to/container in accordance with local regulations.

4. Authorised use(s) of the meta SPC 1

4.1. Use description

Table 1. Use # 1 — Professional use

Product type	PT02 — Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeast Mycobacteria
Field(s) of use	Indoor Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of non-invasive medical devices, healthcare industries and other critical life science applications, and in industrial food and feed preparation areas
Application method(s)	Wiping
Application rate(s) and frequency	1 minute contact time for bacteria 1 minute contact time for mycobacteria 3 minute contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated 100 % polypropylene wipes in: — High-density polyethylene (HDPE) canister with Polypropylene (PP) lid – 150 wipes (0,5 L), 200 wipes (2 L), 240 wipes (2 L) — PP bucket with PP lid – 500 wipes (8 L), 1 000 wipes (8 L), 1 500 wipes (8 L) Impregnated 100 % polyester wipes in: — laminate film flow wrap packet sealed with PET/PE – 25, 50 or 100 wipes — Aluminium foil – 1 wipe

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use

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

5. **General directions for use ⁽¹⁾ of the meta SPC 1**

5.1. **Instructions for use**

Do not use on surfaces sensitive to alcohol.

Acceptable use temperature (10-20 °C)

For soiled surfaces, clean the surface carefully before application:

1. Follow agreed risk assessment policy guidelines regarding the use of Personal Protective Equipment.
2. Choose the dispenser type and dispense the wipe.
3. Wipe the surface in an S Shape moving from clean to dirty. Use the wipe flat not scrunched. Do not go over the same area twice with the same wipe.
4. Use a fresh wipe if your wipe becomes soiled or dry.
5. Make sure to wet surfaces completely
6. Used wipes must be disposed in a closed container
7. Allow the surface to dry before use.

5.2. **Risk mitigation measures**

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes.

When performing disinfection in areas where members of the public may be present, persons should be prevented from entering the room until the room has been well ventilated.

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

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

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

Dispose of contents/container in accordance with local regulations.

Do not flush wipes down the toilet. Do not macerate.

Residual alcohol should be emptied prior to disposal of container.

Discard used wipes in the appropriate waste bin following local agreed guidelines.

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

Store in a cool, dry, well-ventilated place in original container.

Keep container tightly closed.

Shelf-life: 2 years

6. **Other information**

Polypropylene or polyester wipes, 20-45 gsm, containing 1,7-7,5 ml product (0,93-4,12 g propan-2-ol)

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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

7. Third information level: individual products in the meta SPC 1**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Medipal Alcohol Disinfectant Wipes Pal Tech Precision 70 % IPA Wipes Pal TX IPA Surface Disinfectant Wipes				
Authorisation number	EU-0020463-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9