

Summary of product characteristics for a biocidal product family

Family name: Pal IPA Product Family

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0020463-0000

R4BP 3 asset reference number: IS-0021994-0000

Table Of Contents

Part I.- First information level	1
1. Administrative information	1
2. Product family composition and formulation	2
Part II.- Second information level - meta SPC(s)	3
1. Meta SPC administrative information - Meta SPC 1 - Pal IPA Product Family Wipes	3
2. Meta SPC composition	3
3. Hazard and precautionary statements of the meta SPC	4
4. Authorised use(s) of the meta SPC	4
5. General directions for use of the meta SPC	6
6. Other information	8
7. Third information level: individual products in the meta SPC	8

Part I.- First information level

1. Administrative information

1.1. Family name

Pal IPA Product Family

1.2. 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 NY57 Balbriggan Ireland

Authorisation number

EU-0020463-0000

R4BP 3 asset reference number

IS-0021994-0000

Date of the authorisation

24/12/2019

Expiry date of the authorisation

30/11/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Pal International Limited

Address of the 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	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the 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	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the 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 (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9 - 62,9

2.2. Type(s) of formulation

AL (any other liquid) - RTU wipe

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1 - Pal IPA Product Family Wipes

1.2. Suffix to the authorisation number

1-1

1.3 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 composition

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

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

Formulation(s)

AL (any other liquid) - RTU wipe

3. Hazard and precautionary statements of the meta SPC

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 CENTER 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

4.1 Use description

Use 1 - Professional use

Product type	<p>PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)</p> <p>PT04 - Food and feed area (Disinfectants)</p>
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Yeast Common name: Yeast Development stage: -</p> <p>Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage: -</p>
Field(s) of use	<p>Indoor</p> <p>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.</p>
Application method(s)	<p>Method: Wiping Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): Number and timing of application: 1 minute contact time for bacteria 1 minute contact time for mycobacteria 3 minute contact time for yeast</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Impregnated 100 % polypropylene wipes in:</p> <ul style="list-style-type: none"> - 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), 1000 wipes (8 L), 1500 wipes (8 L) <p>Impregnated 100 % polyester wipes in:</p> <ul style="list-style-type: none"> - 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 section 5.1

4.1.2 Use-specific risk mitigation measures

See section 5.2

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 section 5.3

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5.4

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 5.5

5. General directions for use of the meta SPC

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 (PPE).
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.

Hazard Statements and Precautionary statements in Icelandic:

H225: Mjög eldfimur vökvi

H319: Veldur alvarlegri augneringu

H336: Getur valdið sljóleika eða svima

P101: Ef leita þarf til læknis skal hafa ílát eða merkimiða tiltæk

P102: Geymist þar sem börn ná ekki til

P210: Haldið frá hitagjöfum, heitum flötum, neistagjöfum, opnum eldi og öðrum íkveikjuvöldum. Reykingar bannaðar.

P233: Ílát skal vera lukt.

P261: Gætið þess að anda ekki inn úða.

P264: Þvoið hendur vandlega eftir meðhöndlun.

P271: Notið eingöngu utandyra eða í vel loftræstu rými.

P280: Notið augnhlífur.

P303+P361+P353: BERIST EFNID Á HÚÐ (eða hár): Farið strax úr fötum sem óhreinast af efninu. Skolið húðina með vatni.

P304+P340: EFTIR INNÖNDUN: Flytjið viðkomandi í ferskt loft og látið hann hvílast í stellingu sem léttir öndun.

P305+P351+P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.

P312: Hringið í EITRUNARMÍÐSTÖÐ (s. 5432222/112) ef lasleika verður vart.

P337+P313: Ef augnering er viðvarandi: Leitið læknis.

P370+P378: Ef eldur kemur upp: Notið áfengisþolna froðu til að slökkva eldinn.

P403+ P235: Geymist á vel loftræstum stað. Geymist á köldum stað.

P405: Geymist á læstum stað.

P501: Fargið innihaldi/íláti á viðeigandi hátt.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Medipal Alcohol Disinfectant Wipes	Market area: EU
Pal Tech Precision 70% IPA Wipes	Market area: EU
Pal TX IPA Surface Disinfectant Wipes	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

IS-0021994-0001 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
