

# Summary of product characteristics for a biocidal product family

**Family name:** Pal IPA Product Family

**Product type(s):** PT04 - Food and feed area (Disinfectants)

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

**Authorisation number:** IE/BPA 70666

**R4BP 3 asset reference number:** IE-0024880-0000

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## Part I.- First information level

### 1. Administrative information

#### 1.1. Family name

Pal IPA Product Family

#### 1.2. Product type(s)

PT04 - Food and feed area (Disinfectants)

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

#### 1.3. Authorisation holder

**Name and address of the authorisation holder**

Name	Holchem Ireland Limited
Address	Trinity House Charleston Road, Ranelagh Dublin 6 Dublin Ireland

**Authorisation number**

IE/BPA 70666

**R4BP 3 asset reference number**

IE-0024880-0000

**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 United Kingdom

**Location of manufacturing sites**

Bilton Way LE17 4JA Lutterworth United Kingdom

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

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	INEOS GmbH
<b>Address of the manufacturer</b>	Romerstrabe 733 47443 Moers Germany
<b>Location of manufacturing sites</b>	Romerstrabe 733 47443 Moers Germany

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Brenntag UK & Ireland (supplier of active substance), Albion House, Rawdon Park, Yeadon, Leeds, LS19 7XX
<b>Address of the manufacturer</b>	ExxonMobil Petroleum & Chemical B.V.B.A. (manufacturer of active substance), Polderdijkweg 3B B-2030 Antwerp Belgium
<b>Location of manufacturing sites</b>	Baton Rouge Chemical Plant (BRCP), Exxon Mobil Chemical Plant, 4999 Scenic Highway 70897 Baton Rouge United States

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Brenntag UK & Ireland (supplier of active substance), Albion House, Rawdon Park, Yeadon, Leeds, LS19 7XX
<b>Address of the manufacturer</b>	Shell Chemicals Europe B.V. (manufacturer of active substance), PO Box 2334 3000 CH Rotterdam Netherlands
<b>Location of manufacturing sites</b>	Shell Chemicals Europe B.V., Haven 3222, Vondelingenweg 601, Vondelingenplaat 3196 KK Rotterdam 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

Ready to use wipes

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

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 1

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

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

Ready to use wipes

## 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.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

Avoid breathing vapours.

Store in a well-ventilated place.Keep container tightly closed.

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.

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

### 4.1 Use description

#### Use 1 - PT4 Ready to use Wipes

Product type

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

General Disinfection of hard surfaces in industrial and institutional areas including food contact surfaces.

Target organism(s) (including development stage)

Scientific name: Bacteria Gram positive  
Common name: Bacteria  
Development stage: Bacterial cells

Scientific name: Bacteria Gram negative  
Common name: Bacteria  
Development stage: Bacterial cells

Scientific name: Yeast species  
Common name: Yeasts  
Development stage: Cellular yeast

Scientific name: Mycobacteriaceae  
Common name: Mycobacteria  
Development stage: Bacterial cells

Scientific name: Not applicable  
Common name: viruses  
Development stage: Not applicable

**Field(s) of use**

Indoor

Disinfectant of non invasive medical devices and equipment within healthcare environments; disinfectant of hard surfaces in professional environments; disinfectant for use in clean rooms and controlled areas of biotechnology, pharmaceutical, medical device, healthcare and other critical life science applications; disinfectant of food contact surfaces.

**Application method(s)**

Ready to use wipes -

Product is ready to use intended for professional use where training and protocols are already in place or provided for the use of wipes.

1. Follow agreed risk assessment policy guidelines regarding the use of 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. Discard used wipes in the appropriate waste bin following local agreed guidelines. If using a maceratable wipe, discard in the macerator.

**Application rate(s) and frequencies**

6g liquid per wipe (4.2g IPA) - 0 -

As required and according to use instructions. Use one wipe to disinfect the surface. On heavily soiled surfaces, more than one wipe may be required. Typical use frequency is one application every 30 minutes.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

100% Polypropylene wipes:

150 wipes: 0.5L HDPE canister

200 wipes: 2L HDPE canister

500, 1000 and 1500 wipes: 8L PP Bucket

Sterile and non-sterile

#### 4.1.1 Use-specific instructions for use

See general directions.

#### 4.1.2 Use-specific risk mitigation measures

See general directions.

#### 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.

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

See general directions.

#### 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.

### 4.2 Use description

#### Use 2 - PT2 Ready to use Wipes

##### Product type

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

##### Where relevant, an exact description of the authorised use

General Disinfection of hard surfaces in industrial and institutional areas.

##### Target organism(s) (including development stage)

Scientific name: Bacteria Gram positive  
Common name: Bacteria  
Development stage: Bacterial cells

Scientific name: Bacteria Gram negative  
Common name: Bacteria  
Development stage: Bacterial cells

Scientific name: Yeast species  
Common name: Yeasts  
Development stage: Cellular yeast

Scientific name: Mycobacteriaceae  
Common name: Mycobacteria  
Development stage: Bacterial cells

Scientific name: Not applicable  
Common name: Viruses  
Development stage: Not applicable

**Field(s) of use**

Indoor

Disinfectant of non invasive medical devices and equipment within healthcare environments; disinfectant of hard surfaces in professional environments; disinfectant for use in clean rooms and controlled areas of biotechnology, pharmaceutical, medical device, healthcare and other critical life science applications.

**Application method(s)**

Ready to use wipe -  
Product is ready to use intended for professional use where training and protocols are already in place or provided for the use of wipes.  
1. Follow agreed risk assessment policy guidelines regarding the use of 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. Discard used wipes in the appropriate waste bin following local agreed guidelines. If using a maceratable wipe, discard in the macerator.

**Application rate(s) and frequencies**

6g liquid per wipe (4.2g IPA) - 0 -  
As required and according to use instructions. Use one wipe to disinfect the surface. On heavily soiled surfaces, more than one wipe may be required. Typical use frequency is one application every 30 minutes.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

100% Polyester wipes:  
25, 50 wipes: PET/PE laminate flow wrap  
200 wipes: PET/Foil/PE laminate flow wrap  
Sterile and non-sterile

**4.2.1 Use-specific instructions for use**

See general directions.

**4.2.2 Use-specific risk mitigation measures**

See general directions.

#### **4.2.3 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.

#### **4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging**

See general directions.

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

See general directions.

### **5. General directions for use of the meta SPC**

#### **5.1. Instructions for use**

Pal IPA Product Family

Use one wipe to disinfect the surface. On heavily soiled surfaces, more than one wipe may be required. Do not use on surfaces sensitive to alcohol

Product is ready to use intended for professional use where training and protocols are already in place or provided for the use of wipes.

1. Follow agreed risk assessment policy guidelines regarding the use of 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. Discard used wipes in the appropriate waste bin following local agreed guidelines. If using a maceratable wipe, discard in the macerator.

#### **5.2. Risk mitigation measures**

Pal IPA Product Family

Follow agreed risk assessment policy guidelines regarding the use of PPE.

Eyes/Face: Wear chemical goggles; face shield (if splashing is possible).

Skin/hands: Use chemical resistant impervious resistant gloves when handling this product.

Use with adequate ventilation.

The product is highly flammable, and explosive vapour/air mixtures may be formed even at normal room temperatures. Do not handle or store near an open flame, heat or other sources of ignition. Do not smoke. Use only in well-ventilated areas. Avoid prolonged exposure. Wash thoroughly after handling. Handle and open container with care.

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

Pal IPA Product Family 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.
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**5.4. Instructions for safe disposal of the product and its packaging**

Pal IPA Product Family Dispose of contents/container in accordance with local/regional/national/international regulations. Do not flush wipes down the toilet. Residual alcohol should be emptied prior to disposal of container.
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**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

Pal IPA Product Family Must be stored in the original packaging. Keep container tightly closed. Shelf-life (unopened) = 3 years
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**6. Other information**

Protect Iso Propyl Wipes
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**7. Third information level: individual products in the meta SPC**

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

<b>Trade name(s)</b>	Protect Iso Propyl Wipes	Market area: IE
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	IE-0024880-0001 1-1	

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

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