

# Summary of product characteristics for a biocidal product

**Product name:** Sterile IPA 70% in WFI Alcohol Wipes

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

**Authorisation number:** IE/BPA 70468

**R4BP 3 asset reference number:** IE-0026188-0001

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## Administrative information

### 1.1. Trade names of the product

Sterile IPA 70% in WFI Alcohol Wipes
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### 1.2. Authorisation holder

**Name and address of the authorisation holder**

Name	Agma Europe Limited
Address	Number 2 Geraldu Farrugia Street ZBG 4351 Zebbug Malta
Authorisation number	IE/BPA 70468 1-1

**R4BP 3 asset reference number**

IE-0026188-0001
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**Date of the authorisation**

18/05/2021
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**Expiry date of the authorisation**

18/05/2031
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### 1.3. Manufacturer(s) of the biocidal products

**Name of the manufacturer**

AGMA Ltd
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**Address of the manufacturer**

Gemini Works, Haltwhistle NE49 9HA Northumberland United Kingdom
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**Location of manufacturing sites**

Gemini Works, Haltwhistle NE49 9HA Northumberland United Kingdom
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### 1.4. Manufacturer(s) of the active substance(s)

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

## 2. Product composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70

### 2.2. Type of formulation

impregnated wipes
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## 3. Hazard and precautionary statements

<b>Hazard statements</b>	<p>Highly flammable liquid and vapour.</p> <p>Causes serious eye irritation.</p> <p>May cause drowsiness or dizziness.</p> <p>Repeated exposure may cause skin dryness or cracking.</p>
<b>Precautionary statements</b>	<p>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.</p> <p>Keep container tightly closed.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves/protective clothing/eye protection/face protection..</p>

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.

If eye irritation persists: Get medical attention.

Avoid breathing dust.

Avoid breathing fume.

Avoid breathing gas.

Avoid breathing mist.

Avoid breathing vapours.

Avoid breathing spray.

Use only outdoors or in a well-ventilated area.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Call a POISON CENTER or doctor/physician if you feel unwell.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of container to .

Dispose of contents to .

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - Ready-to-use wipe for hard surface disinfection in cleanrooms

<b>Product type</b>	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Disinfectants and algaecides not intended for direct application to humans or animals.
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: fungi Common name: fungi Development stage:</p>

<b>Field(s) of use</b>	Indoor  Disinfection of clean non-porous hard surfaces in cleanrooms - for transfer disinfection - as part of the rotational disinfectant regime - as part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures
<b>Application method(s)</b>	Method: wiping Detailed description: -
<b>Application rate(s) and frequencies</b>	Application Rate: 1 wipe for up to 0.1 m <sup>2</sup> . The wipe should be replaced as frequently as needed to ensure complete wetting of the surface and to avoid transferring contaminants to other parts of the surface. Dilution (%): 0 Number and timing of application:  Disinfection should be performed as and when required in accordance with cleanroom protocols. contact times: - 5 min for bacteria and yeast - 15 min for fungi
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	White laminate pouch Packaging material: PET/PE

#### 4.1.1 Use-specific instructions for use

Refer to general directions for use.

#### 4.1.2 Use-specific risk mitigation measures

Refer to 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**

Refer to general directions for use.

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

Refer to 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**

Refer to general directions for use.

**5. General directions for use**

**5.1. Instructions for use**

Only use on clean surfaces.

Make sure to wet surfaces completely.

Wipe the surface to be disinfected using unidirectional, overlapping strokes. Use a different, unused wipe surface area for each stroke (maximum of eight strokes). This can be done by unfolding and refolding the wipe.

Used wipes must be disposed in a closed container.

**5.2. Risk mitigation measures**

Avoid contact with eyes.  
The product must only be applied for disinfection of small surfaces.  
A ventilation rate of at least 20/h has to be ensured.

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

#### FIRST AID

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 The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference. if you feel unwell.

If eye irritation persists: Get medical advice/attention.

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

None

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

Shelf life: 24 months.

Storage requirement: Keep cool and away from heat. Keep away from frost.

#### 6. Other information

1. Please be aware of the European reference value of 129.28 mg/m<sup>3</sup> for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.
2. All information on the content is given in volume percent (% v/v). The product contains 70% v/v propan-2-ol, which corresponds to 62.7% w/w propan-2-ol.