

Summary of product characteristics for a biocidal product

Product name: Product

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

Authorisation number: IE/BPA 70793

R4BP 3 asset reference number: IE-0023582-0002

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Administrative information

1.1. Trade names of the product

InSpec IPA Wipes

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Enviresearch PT
Address	Rua Fernando Pessoa 319 2 C Carcevelso Portugal
Authorisation number	IE/BPA 70793 1-2

R4BP 3 asset reference number

IE-0023582-0002

Date of the authorisation

26/03/2020

Expiry date of the authorisation

27/03/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Redditch Medical

Address of the manufacturer

Discovery 2, William Armstrong Way, NET Park, Sedgefield, County Durham TS21 3FD Sedgefield United Kingdom

Location of manufacturing sites

Discovery 2, William Armstrong Way, NET Park, Sedgefield, County Durham TS21 3FD Sedgefield United Kingdom

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Stinnes Platz 1 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Haven 3222, Vondelingenweg 601 3196 KK Vondelingenplaat Netherlands

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Stinnes Platz 1 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Baton Rouge Chemical Plant (BRCP), Exxon Mobil Chemical Plant, 4999 Scenic Highway, 70897 Baton Rouge, Louisiana United States

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	64

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	<p>Highly flammable liquid and vapour.</p> <p>Causes serious eye irritation.</p> <p>May cause drowsiness or dizziness.</p>
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Precautionary statements

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

Avoid breathing vapours.

Wash hands thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Wear eye protection.

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 doctor if you feel unwell.

If eye irritation persists:Get medical advice.

In case of fire:Use foam to extinguish.

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

Store locked up.

Dispose of container to refuse site.

4. Authorised use(s)

4.1 Use description

Use 1 - Wipes

Product type

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

Where relevant, an exact description of the authorised use

Disinfectant for use against bacteria, fungi and yeast on non-porous hard surfaces in biopharmaceutical, medical device and laboratory cleanrooms on cleanroom floors, walls, ceilings, equipment surfaces and gloved hands.

Target organism(s) (including development stage)

Scientific name: Gram negative bacteria
Common name: Bacteria, aerobic Gram-negative
Development stage: all

Scientific name: Gram positive bacteria
Common name: Bacteria, aerobic Gram-positive
Development stage: all

Scientific name: Fungi (yeast)
Common name: Fungi/yeasts

	Development stage: All
Field(s) of use	Indoor Indoor
Application method(s)	wiping - 6 wipes per m2 of surface.
Application rate(s) and frequencies	As required. - 0 - 6 wipes per m2 of surface. Ensuring the following contact times: Bacteria – 5 minutes in clean conditions Yeast – 5 minutes in clean conditions
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated 55 % cellulose / 45 % polyester wipes in: EVOH PE laminated to PET packet – 50 wipes

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

5.1. Instructions for use

For the wipe product, surfaces or instruments should be visibly clean prior to using the product to disinfect them. For heavily soiled surfaces, cleaning prior to disinfection is required.

Use recommended cleanroom wiping procedure.

Wipes should be folded so that the entire surface of the wipe can be used.

Typically wipes are quarter folded, and then refolded after every wipe of the surface, to contain and remove the contamination.

In this manner, there are eight different surfaces of the wipe exposed and able to be used for wiping.

Wiping should be done in overlapping linear strokes from clean to dirty or dry to wet. After all eight surfaces have been used, the wipe (and its captured contamination) should be discarded in an appropriate container.

Ensure complete wetting of the surfaces, leave for appropriate contact time. Reseal after use.

For use at room temperature (20±2 °C).

5.2. Risk mitigation measures

FOR PROFESSIONAL USE ONLY.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

The use of eye protection during handling of the product is recommended

Used wipes must be disposed in a closed container

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

Likely direct or indirect adverse effects:

Irritation of skin, eyes, mucous membranes, gastrointestinal and respiratory tract.

Headaches, vertigo, functional CNS disturbances and respiratory depression.

Pulmonary aspiration hazard may induce chemical pneumonia, hypotension and hypoglycemia.

First aid instructions:

Inhalation - Call a doctor or physician if you feel unwell.

Skin contact - Wash skin with plenty of lukewarm, gently flowing water. Take off immediately all contaminated clothing and wash it before re-use.

If skin irritation occurs: get medical advice or attention.

Eye contact - Immediately rinse eyes cautiously with lukewarm water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If irritation occurs and persists, get medical attention.

Ingestion - Rinse mouth. Immediately drink 1 glass of water. Get medical attention.

Medical professionals should contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), for further advice.

In case of fire:

Extinguishing media - Carbon dioxide, Dry powder, Water spray jet.

Fight larger fires with water spray jet or alcohol-resistant foam.

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

Dispose of contents/container in accordance with local regulations.

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 away from sources of ignition.

Keep away from direct sunlight.

Keep container tightly closed.

Shelf-life: 2 years

6. Other information

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 this product.