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)

 $\mathsf{PT02}$ - $\mathsf{Disinfectants}$ and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: IE/BPA 70793

R4BP 3 asset reference number: IE-0023582-0001

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	2
3. Hazard and precautionary statements	2
4. Authorised use(s)	3
5. General directions for use	7
5.1. Instructions for use	
5.2. Risk mitigation measures	7
	7
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	7
5.4. Instructions for safe disposal of the product and its packaging	8
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	8
6. Other information	8

Administrative information

1.1. Trade names of the product

InSpec IPA Bottle		
InSpec IPA Spray		

1.2. Authorisation holder

Name and address of the	Name	Enviresearch PT
authorisation holder	Address	Rua Fernando Pessoa 319 2 C Carcevelso Portugal
Authorisation number	IE/BPA 70793 1-1	
R4BP 3 asset reference number	IE-0023582-0001	
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 Mülhelm 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 Mülhelm 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	
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3. Hazard and precautionary statements

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 spray.
	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 - Screw Top Bottle

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	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: Fungi (yeasts) Common name: Yeasts Development stage: all
	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 (mould) Common name: Fungi Development stage: All

Indoor
Indoor
Spraying - Spraying, pouring and mopping 50 ml product per m2 of surface. Ensuring the following contact times:
Bacteria – 5 minutes in clean conditions – 15 minutes in dirty conditions
Yeast – 5 minutes in clean conditions – 15 minutes in dirty conditions
Fungi – 15 minutes in clean conditions
50ml per m2 - 0 - Daily clean of floors Daily clean of benches and equipment surfaces to a maximum of 16 times per day depending on usage (twice per hour maximum likely to be conducted in an eight hour shift). Regular cleaning of gloved hands to a maximum of 16 times per day (twice per hour of an eight hour shift). Monthly top-down 'super clean' to include walls and ceilings.
Professional
Bottle, Plastic: HDPE , 5 L

4.1.1 Use-specific instructions for use

Unscrew the bottle and dispense the contents into a suitable containers. Ensure complete wetting of the surfaces, leave for appropriate wet contact time.

The product is intended to be sprayed on to a surface and wiped over the surface using a tissue or applied with a wipe, cloth or mop. For walls and ceiling applicator will be thoroughly soaked but with no excess to prevent dripping. Disinfection of equipment will only be by wiping of exterior surfaces and liquid will not be used as a disinfectant bath. 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

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

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

4.2 Use description

Use 2 - Spray

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	Ensure complete wetting of the surfaces, leave for appropriate wet contact time. The product is intended to be sprayed on to a surface and wiped over the surface using a tissue or applied with a wipe, cloth or mop. For walls and ceiling applicator will be thoroughly soaked but with no excess to prevent dripping. Disinfection of equipment will only be by wiping of exterior surfaces and liquid will not be used as a disinfectant bath.
Target organism(s) (including development stage)	Scientific name: Fungi (mould) Common name: Fungi Development stage: all Scientific name: Gram positive bacteria Common name: Bacteria, aerobic Gram-positive Development stage: all Scientific name: Gram negative bacteria Common name: Bacteria, aerobic Gram-negative Development stage: all Scientific name: Fungi (mould) Common name: Fungi (mould) Common name: Fungi

Field(s) of use	Indoor
	For use on cleanroom floors, walls, ceilings, equipment surfaces and the gloved hand. Designed for use in Biopharmaceutical, Medical Device and Laboratory Cleanrooms
Application method(s)	Spraying -
	Spraying, pouring and mopping
Application rate(s) and frequencies	50ml per m2 - 0 -
	50 ml product per m2 of surface. Ensuring the following contact times:
	Bacteria – 5 minutes in clean conditions – 15 minutes in dirty conditions
	Yeast – 5 minutes in clean conditions – 15 minutes in dirty conditions
	Fungi – 15 minutes in clean conditions
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE screw top bottle – 5 L HDPE trigger spray bottle – 0.5 L, 1 L

4.2.1 Use-specific instructions for use

See section 5.1

4.2.2 Use-specific risk mitigation measures

See section 5.2

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

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

See section 5.4

4.2.5 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

Ready to use do not dilute.

Spray the product approximately 15cm-20cm from the surface to be treated, pour directly onto surfaces, or apply with a cloth or mop. Ensure complete wetting of the surfaces, leave for appropriate contact time. Not to be used as a disinfectant bath.

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

If using a 5-minute contact time against bacteria and yeast only, ensure the surface is clean before using the product to disinfect the surface.

For fungicidal efficacy, cleaning prior to disinfection is required.

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

Application of technical/engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) before operatives are permitted to enter into treated areas after large surface disinfection. Where necessary, setting a waiting restriction of sufficient duration to allow time for the removal of airborne residues.

For use during disinfection of large surfaces (e.g. floors) and top-down 'super clean' in cleanrooms/controlled environments, application of technical/engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV)."

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.