

Summary of product characteristics for a biocidal product family

Family name: InSpec IPA

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-0023582-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

InSpec IPA

1.2. Product type(s)

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	Enviresearch PT
Address	Rua Fernando Pessoa 319 2 C Carcevelso Portugal

Authorisation number

IE/BPA 70793

R4BP 3 asset reference number

IE-0023582-0000

Date of the authorisation

26/03/2020

Expiry date of the authorisation

27/03/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Redditch Medical

Address of the manufacturer

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

Location of manufacturing sites

Discovery 2, William Armstrong Way, NET Park, Sedgfield, County Durham TS21 3FD
Sedgfield 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

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 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	64 - 64

2.2. Type(s) of formulation

AL - Any other liquid

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

InSpec IPA SB

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)

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	64 - 64

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

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 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) of the meta SPC

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

Field(s) of use	Indoor Indoor
Application method(s)	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
Application rate(s) and frequencies	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.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle, Plastic: HDPE , 5 L Weight: 245 g Overall dimensions: 242 x 190 x 160 mm Closure type: C51 Sealing method: EPE gasket

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.

4.1.2 Use-specific risk mitigation measures

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 algacides 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

	Development stage: All
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

See section 5.3

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 of the meta SPC

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.

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)

InSpec IPA Bottle	Market area: IE
InSpec IPA Spray	Market area: IE
IE-0023582-0001 1-1	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64

1. Meta SPC administrative information

1.1. Meta SPC identifier

InSpec IPA Wipes

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

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	64 - 64

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

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.
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) of the meta SPC

4.1 Use description

Use 1 - 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	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 of the meta SPC

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.

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)

InSpec IPA Wipes

Market area: IE

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

IE-0023582-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64
