

Summary of product characteristics for a biocidal product

Product name: Sterigene IPA

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

Authorisation number: FR-2018-0023

R4BP 3 asset reference number: FR-0015033-0000

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	5
5.1. Instructions for use	5
5.2. Risk mitigation measures	6
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	6
5.4. Instructions for safe disposal of the product and its packaging	6
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	7
6. Other information	7

Administrative information

1.1. Trade names of the product

Sterigene IPA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sterigene
	Address	2 rue André Citroën 95130 Franconville France
Authorisation number	FR-2018-0023	
R4BP 3 asset reference number	FR-0015033-0000	
Date of the authorisation	12/04/2018	
Expiry date of the authorisation	11/04/2028	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	ECP - Entegris Cleaning Process
Address of the manufacturer	395 rue Louis Lépine 34000 Montpellier France
Location of manufacturing sites	395 rue Louis Lépine 34000 Montpellier France

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Ineos Solvents Germany GmbH
Address of the manufacturer	Römerstraße 733 474433 Moers Germany
Location of manufacturing sites	Ineos Solvents Grangemouth PO Box 21 FK3 9XH Grangemouth Stirlingshire United Kingdom
	Ineos Solvents Germany GmbH, Werk Herne Shamrockstraße 88 44623 Herne Germany
	Ineos Solvents Germany GmbH, Werk Moers Römerstraße 733 474433 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	64,7

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	<p>Causes serious eye irritation.</p> <p>May cause drowsiness or dizziness.</p> <p>Highly flammable liquid and vapour.</p>
Precautionary statements	<p>Avoid breathing .</p> <p>Wash thoroughly after handling.</p> <p>Use only outdoors or in a well-ventilated area.</p>

Wear

Call a POISON CENTER/ doctor if you feel unwell.

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.

If eye irritation persists:Get medical

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

Store locked up.

Dispose of ... to .

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

Keep container tightly closed.

Ground and bond container and receiving equipment.

Use explosion-proof electrical/ventilating/lighting/.../ equipment.

Use non-sparking tools.

Take action to prevent static discharges.

Wear .

4. Authorised use(s)

4.1 Use description

Use 1 - Surface disinfection in clean rooms

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

The product Sterigene IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) to disinfect hard surfaces. It can be used on walls, grounds, benches and equipments.

Target organism(s) (including development stage)

Scientific name: bacteria
Common name: Bacteria
Development stage: -

Scientific name: yeast
Common name: Yeasts
Development stage: -

Scientific name: fungi
Common name: Fungi
Development stage: -

Field(s) of use	Indoor Indoor use Industries
Application method(s)	Method: Spraying Detailed description: Mopping (damp mopping)
Application rate(s) and frequencies	Application Rate: - Dilution (%): - Number and timing of application: Ready-to-use Contact time: 5 minutes Temperature: 20°C Use in clean rooms only (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C)
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Primary packaging :</p> <p>Bottle, Plastic: PET , 500.0 mL</p> <p>Diameter – height: 78 mm – 172 mm</p> <p>Transparent PETE (polyethylene terephthalate) bottle fitted with trigger spray The nominal volume of the content is 500 mL.</p> <p>Bottle, Plastic: PET , 750.0 mL</p> <p>Transparent PETE (polyethylene terephthalate) bottle fitted with trigger spray The nominal volume of the content is 750 mL.</p> <p>Bottle, Plastic: PET , 1.0 L</p> <p>Diameter – height: 93 mm – 228 mm</p> <p>Transparent PETE (polyethylene terephthalate) oblong bottle fitted with trigger spray. The nominal volume of the content is 1 L</p> <p>Can, Plastic: HDPE, 5L</p>

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4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

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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

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

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

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5. General directions for use

5.1. Instructions for use

- Use only in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C).
- Always read the label or leaflet before use and respect all the instructions provided.
- Remove the first packaging before entering the controlled atmosphere area.
- Then remove the 2nd package on first use.-
- For spraying application, hold bottle upright and spray directly from a distance of 10 to 20 cm.
- Apply the product uniformly on the surface to be treated in sufficient quantity so that the surfaces remain wet during the indicated contact time.
- Let the surfaces dry.
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. The users should inform if the treatment is ineffective and report straightforward to the registration holder.

5.2. Risk mitigation measures

- Avoid direct or indirect contact with food and feed.
 - In a room with a ventilation rate 17 vol/h, during the application of the product, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and RPE (with APF of 10).
 - In a room with a ventilation rate ≥ 17 vol/h, during the application of the product, wear protective chemical resistant gloves only (glove material to be specified by the authorisation holder within the product information).
- During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
- Minimisation of splashes and spills;
 - Minimise number of staff exposed;
 - Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed;
 - Training for staff on good practice;
 - Good standard of personal hygiene.
- PPE for the spraying phase are as following:
- Eye protection.
 - For people not applying the product, do not enter the room with a ventilation rate 17 vol/h during the application of the product.

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

- Impaired consciousness: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.
- Keep the container or label available.
- Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Mouth contact/Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.

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

- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Dispose of the product in accordance with local requirements.

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

- Shelf life 2 years.
- Do not store at a temperature above 35°C.

6. Other information

- Final report of long term storage study has to be provided within 2 year.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.