

Summary of product characteristics for a biocidal product

Product name: ANIOS ALCOOL ISOPROPYLIQUE 70% V/V IP STERILE AEROSOL

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

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

Authorisation number: IE/BPA 70474

R4BP 3 asset reference number: IE-0020700-0006

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Administrative information

1.1. Trade names of the product

ANIOS IPA 70% IP STERILE AEROSOL
ANIOS ISOPROPYL ALCOHOL 70% IP STERILE AEROSOL
ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Laboratoires ANIOS
Address	1 rue de l'Espoir 59260 Lezennes France
Authorisation number	IE/BPA 70474 1-2

R4BP 3 asset reference number

IE-0020700-0006

Date of the authorisation

18/12/2018

Expiry date of the authorisation

17/12/2028

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Laboratoire Anios

Address of the manufacturer

Pavé du Moulin 59260 LILLE-HELLEMMES France

Location of manufacturing sites

3330 rue de Lille 59260 SAINGHIN EN MELANTOIS France

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	ExxonMobil Petroleum & Chemical B.V.B.A.
Address of the manufacturer	Polderdijkweg 3B, B-2030 Antwerpen Belgium
Location of manufacturing sites	Baton Rouge Chemical Plant (BRCP) Exxon Mobil Chemical Plant 4999 Scenic Highway, Baton Rouge 70897 Louisiana United States

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Univar
Address of the manufacturer	Steuber Drive M44 5AL Manchester United Kingdom
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, FAWley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Univar Belgium
Address of the manufacturer	Rue de Sablieres 1 7522 Biandain (Tournai) Belgium
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag
Address of the manufacturer	Brenntag Ardennes, Route de Tournes 08090 Cliron France
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Stinnes Platz 1 45477 Mülheim an der Ruhr Germany
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	STEA SRL
Address of the manufacturer	STEA SRL 30174 Mestre Italy
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Girelli Alcool SRL
Address of the manufacturer	Girelli Alcool SRL, Via Riva die Trento 20139 Milano Italy
Location of manufacturing sites	Exxon Mobil Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom
	Exxon Mobil Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 Louisiana United States
	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Permis Netherlands
	Sasol Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Sasol Solvents Germany GmbH
Address of the manufacturer	Sasol Solvents Germany GmbH, Anckelmannsplatz D 20537 Hamburg Germany
Location of manufacturing sites	Shamrockstrasse 88 44623 Herne Germany
	Römerstr. 733 47443 Moers Germany

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Shell Chemicals Europe B.V
Address of the manufacturer	Shell Chemicals Europe B.V, Postbus 2334 3000 CH Rotterdam Netherlands
Location of manufacturing sites	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Pernis Netherlands
Active substance	1355 - Propan-2-ol
Name of the manufacturer	Exxon Mobil
Address of the manufacturer	ExxonMobil Chemical Europe, Hermeslaan 2 1831 Machelen Belgium
Location of manufacturing sites	Fawley Refinery and Petrochemical Plant, Fawley, SO45 1TX Southampton United Kingdom
	Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805 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	70

2.2. Type of formulation

AE - Aerosol dispenser

3. Hazard and precautionary statements

Hazard statements	Causes serious eye irritation. May cause drowsiness or dizziness.
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Precautionary statements

Extremely flammable aerosol. Pressurised container: May burst if heated Repeated exposure may cause skin dryness or cracking.
Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Avoid breathing spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear Call a 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 in accordance with local/regional/national/international regulation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Do not pierce or burn, even after use. Protect from sunlight.Do not expose at temperatures exceeding 50 °C/122 °F.

4. Authorised use(s)

4.1 Use description

Use 1 - Surfaces disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries

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

The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in the pharmaceutical, medical equipment and cosmetic industries.

Target organism(s) (including development stage)

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

Scientific name: - other
Common name: Yeast
Development stage: - other

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

Field(s) of use

Indoor

Indoor use

Application method(s)

Method: Manual application
Detailed description:

The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth.

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:

Ready-to-use
Contact time :

- 5 minutes for bactericidal and yeasticidal efficacy;
- 15 minutes for fungicidal efficacy.

Temperature: 20°C.
Clean rooms (GMP EU in grade A and B).

Category(ies) of users

Professional

Pack sizes and packaging material

Primary packaging:

- Aerosol can 400 mL in aluminum

Secondary material (without contact with product), double bag:

Each aerosol can is packaged in a primary bag, then in a second bag (double bag). Bag Material: LDPE

4.1.1 Use-specific instructions for use

Only use in clean rooms (GMP grades A to B)

4.1.2 Use-specific risk mitigation measures

- Do not apply more than 40 ml/m².

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

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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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4.2 Use description

Use 2 - Surfaces disinfection in sterile conditions in laboratories and hospital pharmacies

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 products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in laboratories and hospital pharmacies.

Target organism(s) (including development stage)

Scientific name: other
Common name: Bacteria
Development stage: other

Scientific name: other

Common name: Yeast
Development stage: other

Scientific name: other
Common name: Fungi
Development stage: other

Field(s) of use

Indoor

Indoor use

Application method(s)

Method: Manual application
Detailed description:

The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth.

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:
Ready-to-use
Contact time :
- 5 minutes for bactericidal and yeasticidal efficacy;
- 15 minutes for fungicidal efficacy.
Temperature: 20°C.
Clean rooms (GMP EU in grade A and B).

Category(ies) of users

Professional

Pack sizes and packaging material

Primary packaging:

- Aerosol can 400 mL in aluminum

Secondary material (without contact with product), double bag:

Each aerosol can is packaged in a primary bag, then in a second bag (double bag). Bag Material: LDPE

4.2.1 Use-specific instructions for use

Only use in clean rooms (GMP grades A to B)

4.2.2 Use-specific risk mitigation measures

- Do not apply more than 40 ml/m².

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

-

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

Please refer to the section "Directions for use" of this Meta SPC.

5. General directions for use

5.1. Instructions for use

- Respect the indicated contact time for the required antimicrobial activity
- Always read the label or leaflet before use and respect all the instructions provided.
- Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and yeasticidal efficacy and for 15 minutes for fungicidal efficacy)
- Only use in clean rooms (grades A to B)
- Let the surface 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.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during loading and the application of the product.

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:

- o Minimisation of splashes and spills;
- o Minimise number of staff exposed;
- o Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed;
- o Training for staff on good practice;
- o Good standard of personal hygiene.

PPE for the spraying phase are as following:

- o Eye protection.

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 40°C.
- Protect from frost.
- Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

6. Other information

- The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- The long term storage stability study (24 months) should be provided within 2 years.