

Summary of product characteristics for a biocidal product

Product name: ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE

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

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Authorisation number: FR-2018-0114

R4BP 3 asset reference number: FR-0015013-0001

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Administrative information

1.1. Trade names of the product

ANIOS ALCOOL ISOPROPYLIQUE 70% V/V IP STERILE
ANIOS ISOPROPYL ALCOHOL 70% V/V IP STERILE
ANIOS IPA 70% V/V IP STERILE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratoires ANIOS
	Address	Pavé du Moulin 59260 Lille-Hellemmes France
Authorisation number	FR-2018-0114 1-1	

R4BP 3 asset reference number	FR-0015013-0001
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	N/A – Supplied by Exxon, Shell or Sassol - -

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	N/A – Supplied by Exxon, Shell or Sassol - -

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	N/A – Supplied by Exxon, Shell or Sassol - -

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Stinnes Platz 1 45477 Mühlheim an der Ruhr Germany
Location of manufacturing sites	N/A – Supplied by Exxon, Shell or Sassol

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	N/A – Supplied by Exxon, Shell or Sassol

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	N/A – Supplied by Exxon, Shell or Sassol

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	Sasol Solvents Germany GmbH, Shamrockstrasse 88 D 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 D47443 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	63

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

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

Highly flammable liquid and vapour. Repeated exposure may cause skin dryness or cracking.
Avoid breathing Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. 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 contents to container in accordance with local/regional/national/international regulation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep cool.

4. Authorised use(s)

4.1 Use description

Use 1 - Surface 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: Yeasts Development stage: - other
Scientific name: - other Common name: Fungi Development stage: - other

Field(s) of use	Indoor Indoor use
Application method(s)	Manual application - The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth.
Application rate(s) and frequencies	- - 0 - 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: <ul style="list-style-type: none"> • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC) • 5L (HDPE) with cap (PP) Secondary material (without contact with product), double bag: Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE

4.1.1 Use-specific instructions for use

Use in clean rooms only (GMP grades A to B)

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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4.2 Use description

Use 2 - Surface 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: Yeasts Development stage: - other Scientific name: - other Common name: Fungi Development stage: - other
Field(s) of use	Indoor Indoor use

Application method(s)

Manual application -

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

Application rate(s) and frequencies

-- 0 -

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 to B).

Category(ies) of users

Professional

Pack sizes and packaging material

Primary packaging:

- 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)

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

- Each 1L bottle is packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE

4.2.1 Use-specific instructions for use

Use in clean rooms only (GMP grades A to B)

4.2.2 Use-specific risk mitigation measures

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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

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4.3 Use description

Use 3 - Surface disinfection in non-sterile conditions in pharmaceutical, medical equipment and cosmetic industries

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 C and D) as well as without controlled atmosphere, in the pharmaceutical, medical (equipment) industries and in 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)	Manual application - The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth
Application rate(s) and frequencies	- - 0 - Ready-to-use Contact time : - 5 minutes for bactericidal and yeasticidal efficacy; - 15 minutes for fungicidal efficacy Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Primary packaging: <ul style="list-style-type: none"> • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC) • 5L (HDPE) with cap (PP) Secondary material (without contact with product), double bag: Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE

4.3.1 Use-specific instructions for use

4.3.2 Use-specific risk mitigation measures

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4.3.3 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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4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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

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4.4 Use description

Use 4 - Surface disinfection in non-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 C and D) as well as without controlled atmosphere 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)	Manual application - The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth.
Application rate(s) and frequencies	- - 0 - Ready-to-use Contact time 5 minutes for bactericidal and yeasticidal efficacy; 15 minutes for fungicidal efficacy Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Primary packaging: 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC) 5L (HDPE) with cap (PP) Secondary material (without contact with product), double bag: Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE

4.4.1 Use-specific instructions for use

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4.4.2 Use-specific risk mitigation measures

-

4.4.3 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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4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.4.5 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

- 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)
- Clean carefully the surfaces before application
- 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.

The product must only be applied for disinfection of small surfaces.

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.
- Towels contaminated with the product / used wipes must be disposed in a closed container.

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.
- Keep container tightly closed.
- Use explosion-proof electrical/ventilating/lighting/.../equipment.
- Use only non-sparking tools.
- Take precautionary measures against static discharge.

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.