

# Summary of product characteristics for a biocidal product

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

**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)

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:** FR-2018-0114

**R4BP 3 asset reference number:** FR-0015013-0002

## 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)	2
2. Product composition and formulation	4
2.1. Qualitative and quantitative information on the composition of the biocidal product	4
2.2. Type of formulation	4
3. Hazard and precautionary statements	4
4. Authorised use(s)	5
5. General directions for use	13
5.1. Instructions for use	14
5.2. Risk mitigation measures	14
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	15
5.4. Instructions for safe disposal of the product and its packaging	15
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	15
6. Other information	16

## Administrative information

### 1.1. Trade names of the product

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

### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	Laboratoires ANIOS
	Address	1 rue de l'Espoir 59260 Lezennes France
<b>Authorisation number</b>	FR-2018-0114 1-1	

<b>R4BP 3 asset reference number</b>	FR-0015013-0002
<b>Date of the authorisation</b>	18/12/2018
<b>Expiry date of the authorisation</b>	17/12/2028

### 1.3. Manufacturer(s) of the biocidal products

<b>Name of the manufacturer</b>	Laboratoire Anios
<b>Address of the manufacturer</b>	Pavé du Moulin 59260 LILLE–HELLEMMES France
<b>Location of manufacturing sites</b>	3330 rue de Lille 59260 SAINGHIN EN MELANTOIS France

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

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

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Univar
<b>Address of the manufacturer</b>	Steuber Drive M44 5AL Manchester United Kingdom
<b>Location of manufacturing sites</b>	N/A – Supplied by Exxon, Shell or Sassol - -

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Univar Belgium
<b>Address of the manufacturer</b>	Rue de Sablieres 1 7522 Biandain (Tournai) Belgium
<b>Location of manufacturing sites</b>	N/A – Supplied by Exxon, Shell or Sassol - -

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Brenntag
<b>Address of the manufacturer</b>	Brenntag Ardennes, Route de Tournes 08090 Cliron France
<b>Location of manufacturing sites</b>	N/A – Supplied by Exxon, Shell or Sassol - -

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

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	STEA SRL
<b>Address of the manufacturer</b>	STEA SRL 30174 Mestre Italy
<b>Location of manufacturing sites</b>	N/A – Supplied by Exxon, Shell or Sassol

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Girelli Alcool SRL
<b>Address of the manufacturer</b>	Girelli Alcool SRL, Via Riva die Trento 20139 Milano Italy
<b>Location of manufacturing sites</b>	N/A – Supplied by Exxon, Shell or Sassol

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Sasol Solvents Germany GmbH
<b>Address of the manufacturer</b>	Sasol Solvents Germany GmbH, Anckelmannsplatz D 20537 Hamburg Germany
<b>Location of manufacturing sites</b>	Sasol Solvents Germany GmbH, Shamrockstrasse 88 D 44623 Herne Germany
	Sasol Solvents Germany GmbH Römerstr. 733 D47443 Moers Germany

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Shell Chemicals Europe B.V
<b>Address of the manufacturer</b>	Shell Chemicals Europe B.V, Postbus 2334 3000 CH Rotterdam Netherlands
<b>Location of manufacturing sites</b>	Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam Pernis Netherlands
<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Exxon Mobil
<b>Address of the manufacturer</b>	ExxonMobil Chemical Europe, Hermeslaan 2 1831 Machelen Belgium
<b>Location of manufacturing sites</b>	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

AL - Any other liquid
-----------------------

## 3. Hazard and precautionary statements

<b>Hazard statements</b>	Causes serious eye irritation. May cause drowsiness or dizziness.
--------------------------	--

## 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 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 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

<b>Field(s) of use</b>	Indoor  Indoor use
<b>Application method(s)</b>	Method: Manual application Detailed description:  The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth.
<b>Application rate(s) and frequencies</b>	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).
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Primary packaging: <ul style="list-style-type: none"> <li>• 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)</li> <li>• 5L (HDPE) with cap (PP)</li> </ul> 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

-

#### 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 - Surface disinfection in sterile conditions in laboratories and hospital pharmacies

<b>Product type</b>	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	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
<b>Target organism(s) (including development stage)</b>	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
<b>Field(s) of use</b>	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 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

-

#### 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

-

#### 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)**

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

**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

#### 4.3.1 Use-specific instructions for use

-

#### 4.3.2 Use-specific risk mitigation measures

-

#### 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

-

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

-

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

-

#### 4.4 Use description

##### Use 4 - Surface disinfection in non-sterile conditions in laboratories and hospital pharmacies

**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 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)**

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

**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**

-

**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**

-

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

-

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

-

**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.