

Summary of product characteristics for a biocidal product

Product name: BACTY SP Isopropyl alcohol 70% Wipes P

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

Authorisation number: FR-2018-0100

R4BP 3 asset reference number: FR-0015032-0005

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Administrative information

1.1. Trade names of the product

BACTY SP Isopropyl alcohol 70% Wipes P
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1.2. Authorisation holder

Name and address of the authorisation holder

Name	Conformat
Address	10-12, avenue de Verdun 1916 92257 LA GARENNE COLOMBES CEDEX France
Authorisation number	FR-2018-0100 1-3

R4BP 3 asset reference number

FR-0015032-0005

Date of the authorisation

03/10/2018

Expiry date of the authorisation

02/10/2028

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Conformat

Address of the manufacturer

140 avenue Paul Doumer 92500 Rueil Malmaison France

Location of manufacturing sites

SIMAGEC 54 Avenue de la Plaine 13106 Rousset France

ARDEPHARM Les iles ferays 07300 Tournon 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) 4999 Baton Rouge, Louisiana 70897 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	70.6

2.2. Type of formulation

wipes

3. Hazard and precautionary statements

Hazard statements	Causes serious eye irritation. Highly flammable liquid and vapour. May cause drowsiness or dizziness.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Avoid breathing . Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.

Wear .

Call a 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 .

4. Authorised use(s)

4.1 Use description

Use 1 - Wiping

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

Target organism(s) (including development stage)

bacteria-Bacteria-
yeast-Yeasts-

Field(s) of use

Indoor

Indoor use
Industries

Application method(s)

wiping -
The product is applied uniformly with a ready to use impregnated wipe on the surfaces to disinfect.

Application rate(s) and frequencies

Ready-to-use - 0 -
Ready-to-use
Application rate: depending on the size of the wipe. A 23*23 cm wipe is sufficient to disinfect 1-2 m²
Contact time 5 minutes
Temperature: 20°C

Category(ies) of users

Professional

Pack sizes and packaging material

Multi-layer bags (film layer = PET + VMPET + metallocene-LLDPE).

4.1.1 Use-specific instructions for use

Apply the product with a wipe uniformly on the surface to be treated in sufficient quantity (one 23*23 cm wipe for 1-2m²) so that the surface remains wet during at least 5 minutes.

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

- Always read the label or leaflet before use and respect all the instructions provided.
- Let the surface dry.
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- Inform the authorization holder if the treatment is ineffective.
- Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C).

5.2. Risk mitigation measures

- In a room with a ventilation rate 21 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 \geq 21 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:
 - 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.
- For people not applying the product, do not enter the room with a ventilation rate 21 vol/h during the application of the product.
- Avoid direct or indirect contact with food and feed.
- 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.
- Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed.

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

Do not store at temperatures above 40°C.
Shelf-life : 2 years

6. Other information

- The authorization holder should report any observed incidents related to efficacy to the Competent Authorities (CA).
- Shelf-life studies are on-going and should be provided in post-authorisation within 2 years.