

Summary of product characteristics for a biocidal product family

Family name: BACTY SP IPA

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-0015032-0000

Table Of Contents

Part I.- First information level	1
1. Administrative information	1
1.1. Family name	1
1.2. Product type(s)	1
1.3. Authorisation holder	1
1.4. Manufacturer(s) of the biocidal products	1
1.5. Manufacturer(s) of the active substance(s)	2
2. Product family composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the family	2
2.2. Type of formulation	2
Part II.- Second information level - meta SPC(s)	3
1. Meta SPC administrative information	3
1.1. Meta SPC identifier - Meta SPC 1	3
1.2. Suffix to the authorisation number	3
1.3 Product type(s)	3
2. Meta SPC composition	3
2.1. Qualitative and quantitative information on the composition of the meta SPC	3
2.2. Type(s) of formulation of the meta SPC	3
3. Hazard and precautionary statements of the meta SPC	3
4. Authorised use(s) of the meta SPC	4
4.1.1 Use-specific instructions for use	5
4.1.2 Use-specific risk mitigation measures	5
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	5
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its	5
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under	5
4.2.1 Use-specific instructions for use	6
4.2.2 Use-specific risk mitigation measures	6
4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	6

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its	7
4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under	7
4.3.1 Use-specific instructions for use	8
4.3.2 Use-specific risk mitigation measures	8
4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	8
4.3.4 Where specific to the use, the instructions for safe disposal of the product and its	8
4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under	8
5. General directions for use of the meta SPC	8
5.1. Instructions for use	8
5.2. Risk mitigation measures	9
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to	9
5.4. Instructions for safe disposal of the product and its packaging	9
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	9
6. Other information	9
7. Third information level: individual products in the meta SPC	9
7.1 Trade name(s), authorisation number and specific composition of each individual product	10
1. Meta SPC administrative information	11
1.1. Meta SPC identifier - Meta SPC 2	11
1.2. Suffix to the authorisation number	11
1.3 Product type(s)	11
2. Meta SPC composition	11
2.1. Qualitative and quantitative information on the composition of the meta SPC	11
2.2. Type(s) of formulation of the meta SPC	12
3. Hazard and precautionary statements of the meta SPC	12
4. Authorised use(s) of the meta SPC	13
4.1.1 Use-specific instructions for use	13
4.1.2 Use-specific risk mitigation measures	14
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	14
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its	14
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under	14

5. General directions for use of the meta SPC	14
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	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	15
7. Third information level: individual products in the meta SPC	15
7.1 Trade name(s), authorisation number and specific composition of each individual product	15
1.Meta SPC administrative information	16
1.1. Meta SPC identifier - Meta SPC 3	16
1.2. Suffix to the authorisation number	16
1.3 Product type(s)	16
2. Meta SPC composition	16
2.1. Qualitative and quantitative information on the composition of the meta SPC	16
2.2. Type(s) of formulation of the meta SPC	17
3. Hazard and precautionary statements of the meta SPC	17
4. Authorised use(s) of the meta SPC	17
4.1.1 Use-specific instructions for use	18
4.1.2 Use-specific risk mitigation measures	18
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	19
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its	19
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under	19
5. General directions for use of the meta SPC	19
5.1. Instructions for use	19
5.2. Risk mitigation measures	19
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to	20
5.4. Instructions for safe disposal of the product and its packaging	20
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	20
6. Other information	20

7. Third information level: individual products in the meta SPC	20
7.1 Trade name(s), authorisation number and specific composition of each individual product	20

Part I.- First information level

1. Administrative information

1.1. Family name

BACTY SP IPA

1.2. Product type(s)

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

1.3. 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

R4BP 3 asset reference number

FR-0015032-0000

Date of the authorisation

03/10/2018

Expiry date of the authorisation

02/10/2028

1.4. 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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.6 - 70.8

2.2. Type(s) of formulation

AE - Aerosol dispenser
AL - Any other liquid
wipes

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7 - 70.7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.

Precautionary statements

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) of the meta SPC**4.1 Use description****Use 1 - Spraying****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 for the disinfection of industrial process equipment's work plan (upper surface) and soil in clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) of industrial process (except in veterinary and food industry).

Target organism(s) (including development stage)

bacteria-Bacteria-
yeast-Yeasts-
fungi-Fungi-

Field(s) of use

Indoor
Indoor use

Application method(s)

Spraying -
The product is sprayed (trigger spray) on the surface to disinfect.

Application rate(s) and frequencies

-- 0 --
Ready-to-use
Contact time 5 minutes
Temperature: 20°C

Category(ies) of users

Professional

Pack sizes and packaging material

Bottle with trigger spray in HDPE of 750 mL and 1L.

4.1.1 Use-specific instructions for use

Hold the trigger upright and spray from a distance of 10 to 30 cm uniformly on the surface to be treated in sufficient quantity (50 mL/m²) so that surfaces remain wet during at least 5 minutes. If necessary, the product applied can be spread with a cloth.

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 - Mopping

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 equipments.
Target organism(s) (including development stage)	bacteria-Bacteria- yeast-Yeasts- fungi-Fungi-
Field(s) of use	Indoor Indoor use Industries
Application method(s)	mopping - The product is applied by mopping uniformly on the surface to disinfect.
Application rate(s) and frequencies	-- 0 - Ready-to-use Contact time 5 minutes Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Can in HDPE of 5L, 10L, 20L

4.2.1 Use-specific instructions for use

Apply the product by mopping uniformly on the surface to be treated in sufficient quantity so that the surface remains wet during at least 5 minutes.

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 - 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 an 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

Sealed pouch (multi-layer zipper bag, LLDPE + PET + AL + LLDPE). Dry wipes and pouch are contained in a bag (multi-layer bag, PET + VMPET + metallocene-LLDPE) of 200 mL to 2 500 mL.

4.3.1 Use-specific instructions for use

Apply the product with a wipe (impregnated just before use in the case of the product BACTY SP IPA sachets) 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.

4.3.2 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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Always read the label or leaflet before use and respect all the instructions provided.
- Let the surface dry.
- Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C).
- 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.

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.
- 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 30°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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

BACTY SP Isopropyl alcohol 70% Trigger

Authorisation number

FR-0015032-0001 1-1

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7

Trade name(s)

BACTY SP Isopropyl alcohol 70% Bottle

Authorisation number

FR-0015032-0002 1-1

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7

Trade name(s)

BACTY SP Isopropyl alcohol 70% BiB

Authorisation number

FR-0015032-0003 1-1

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7 - 70.7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AE - Aerosol dispenser

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Extremely flammable aerosol.
 Pressurised container: May burst if heated
 Causes serious eye irritation.
 May cause drowsiness or dizziness.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking.
 Do not spray on an open flame or other ignition source.
 Do not pierce or burn, even after use.
 Wear .
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F.
 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 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) of the meta SPC

4.1 Use description

Use 1 - Spraying

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 product BACTY SP IPA is a ready-to-use disinfectant used for the disinfection of industrial process equipment's work plan (upper surface) and soil in clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) of industrial process (except in veterinary and food industry).

Target organism(s) (including development stage)

bacteria-Bacteria-
yeast-Yeasts-
fungi-Fungi-

Field(s) of use

Indoor
Indoor use

Application method(s)

Spraying -
The product is sprayed (aerosol can) on the surface to disinfect.

Application rate(s) and frequencies

-- 0 -
Ready-to-use
Contact time 5 minutes
Temperature: 20°C

Category(ies) of users

Professional

Pack sizes and packaging material

Aerosol in PP bag within an aluminium can of 400 mL.

4.1.1 Use-specific instructions for use

Hold the trigger upright and spray from a distance of 10 to 30 cm uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least 5 minutes.

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Always read the label or leaflet before use and respect all the instructions provided.
- Let the surface dry.
- Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C).
- 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.

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 ≥ 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.
- 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 30°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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

BACTY SP Isopropyl alcohol 70% Spray

Authorisation number

FR-0015032-0004 1-2

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.6 - 70.8

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

wipes

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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 m ² 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

-

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

-

5. General directions for use of the meta SPC

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 ≥ 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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

BACTY SP Isopropyl alcohol 70% Wipes P

Authorisation number

FR-0015032-0005 1-3

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.6

Trade name(s)

BACTY SP Isopropyl alcohol 70% Wipes C

Authorisation number

FR-0015032-0006 1-3

(R4BP 3 asset reference number - National
Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70.8
