2025/1878

17.9.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1878

of 16 September 2025

granting a Union authorisation for the biocidal product family 'BPF Propanol' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (1), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 29 March 2019, Bode Chemie GmbH submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'BPF Propanol' of product-types 1, 2 and 4 as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-NE050445-47 in the Register for Biocidal Products.
- (2) 'BPF Propanol' contains propan-1-ol and propan-2-ol as the active substances, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 1, 2 and 4.
- (3) On 14 August 2024, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 21 March 2025, the Agency submitted to the Commission its opinion (²), the draft summary of the biocidal product characteristics ('SPC') of 'BPF Propanol' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'BPF Propanol' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(6) of that Regulation.
- (6) On 8 April 2025, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family 'BPF Propanol'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

⁽²⁾ ECHA opinion of 27 February 2025 on the Union authorisation of 'BPF Propanol' (ECHA/BPC/462/2025), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0034602-0000 is hereby granted to Bode Chemie GmbH for the making available on the market and use of the biocidal product family 'BPF Propanol' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 7 October 2025 until 30 September 2035.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 September 2025.

For the Commission The President Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

BPF Propanol

Product type(s)

PT01: Human hygiene

PT04: Food and feed area

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

Authorisation number EU-0034602-0000

R4BP asset number EU-0034602-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. Family name

Name	BPF Propanol

1.2. **Product type(s)**

Product type(s)	PT01: Human hygiene	
	PT04: Food and feed area	
	PT02: Disinfectants and algaecides not intended for direct application to humans or animals	

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	BODE Chemie GmbH	
Name and address of the additionsation holder	Address	Melanchthonstr. 27 22525 Hamburg DE	
Authorisation number	EU-0034602-0000		
R4BP asset number		EU-0034602-0000	
Date of the authorisation		7 October 2025	
Expiry date of the authorisation		30 September 2035	

1.4. Manufacturer(s) of the product

Name of manufacturer	Bode Chemie GmbH	
Address of manufacturer	Melanchthonstrasse 27 22525 Hamburg Germany	
Location of manufacturing sites	BODE Chemie GmbH site 1 Melanchthonstraße 27 22525 Hamburg Germany	

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

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE site 1 Carl-Bosch-Str. 38 67056 Ludwigshafen Germany

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstr. 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvents Germany GmbH site 1 Römerstr. 733 47443 Moers Germany

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-1-ol		Active substance	71-23-8	200-746-9	30 - 45 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	25 - 45 % (w/w)
1-Tetradecanol	-	Non-active substance	112-72-1	204-000-3	0 - 1 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid XX Impregnated wipes
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PART II

SECOND INFORMATION LEVEL META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: meta SPC 1
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. **Product type(s)**

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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 - 45 % (w/w)
1-Tetradecanol	-	Non-active substance	112-72-1	204-000-3	0,25 - 1 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H226: Flammable liquid and vapour.
	H319: Causes serious eye irritation.
	H336: May cause drowsiness or dizziness.
	H412: Harmful to aquatic life with long lasting effects.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.

P271: Use only outdoors or in a well-ventilated area.
P273: Avoid release to the environment.
P280: Wear eye protection.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312: Call a doctor if you feel unwell.
P312: Call a POISON CENTER if you feel unwell.
P337+P313: If eye irritation persists: Get medical advice.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents in accordance with local/regional/national/international regulations.
P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Hygienic handrub, PT1, professional and industrial user - meta SPC 1

Product type	PT01: Human hygiene	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Mycobacteria	
	Common name: Viruses (limited spectrum virucidal activity)	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hygienic handrub for use in industrial, institutional, health care and domestic areas.	
Application method(s)	Method: Hygienic handrub	
	Detailed description:	

Application rate(s) and frequency	Application Rate: 3 ml per application			
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 25 per day)			
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 30 seconds Limited spectrum virucidal activity – 60 seconds			
Category(ies) of users	industrial professional			
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l			

4.1.1. Use-specific instructions for use

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory.

Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.2. Use description

Table 2

Hygienic handrub, PT1, general public - meta SPC 1

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Common name: Yeasts Common name: Mycobacteria
	Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses

Field(s) of use	indoor use
	The product is a ready-to-use hygienic handrub for use in institutional, health care and domestic areas.
Application method(s)	Method: Hygienic handrub
	Detailed description:
Application rate(s) and frequency	Application Rate: 3 ml (the amount of liquid should resemble the size of a large-sized coin)
	Number and timing of application: Product is used as required, for adults and children older than 2 years up to 10 times per day, for toddlers up to 8 times per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 30 seconds Limited spectrum virucidal activity – 60 seconds
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.2.2. Use-specific risk mitigation measures

Do not use more than the specified number of applications per day

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Use for children only under supervision of an adult. Apply the amount for the child/toddler on your own hand first and rub the product on child's/toddler's hand. Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.3. Use description

Table 3

Surgical hand disinfection / residential bacterial skin flora, PT1, professional user - meta SPC 1

Product type	PT01: Human hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development	Common name: Bacteria		
stage)	Common name: Yeasts		
	Common name: Mycobacteria		
	Common name: Viruses (limited spectrum virucidal activity)		
Field(s) of use	indoor use		
	Surgical hand disinfection / resident bacterial skin flora. The product is a ready-to-use alcoholic disinfectant for use in health care areas / hospital sector.		
Application method(s)	Method: Surgical handrub		
	Detailed description:		
Application rate(s) and frequency	Application Rate: 2 times 3 ml per application		
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 4 times per day).		
	Contact time: 90 seconds		
Category(ies) of users	professional		
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l		

4.3.1. Use-specific instructions for use

Rub 2 times 3 ml into dry and visibly clean hands and forearms for 1,5 minutes, keeping the skin moist during the application time.

Any decanting or refilling may only be carried out under aseptic conditions.

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory. Eye protection according to the European Standard EN ISO16321-1 or equivalent.

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

see general section

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. **Instructions for use**

see use-specific instructions

5.2. Risk mitigation measures

Keep out of reach of children and pets or non-target animals.

Ensure adequate ventilation during the application.

Make sure that the applied product is completely dried before entering a room or area where people will stay for a longer period of time.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTER or a doctor.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months.

Store at temperatures not exceeding 40 °C.

Protect from direct light.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)		Sterillium pure		Market area: EU			
Authorisation number			EU-0034602-0001 1-1				
Common name	IUPAC name	Function		CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	45 % (w/w)
1-Tetradecanol	-	Non-active substance		112-7	72-1	204-000-3	0,95 % (w/w)

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

Trade name(s)		Sterillium Market a		Market ar	area: EU		
Authorisation number			EU-0034602-0002 1-1				
Common name	IUPAC name	Function		CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	45 % (w/w)
1-Tetradecanol	-	Non-activ substance	-	112-7	72-1	204-000-3	0,95 % (w/w)

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: meta SPC 2

1.2. Suffix to the authorisation number

Number	1-2
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1.3. **Product type(s)**

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 - 45 % (w/w)

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H226: Flammable liquid and vapour.
	H319: Causes serious eye irritation.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.
	P271: Use only outdoors or in a well-ventilated area.
	P280: Wear eye protection.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312: Call a doctor if you feel unwell.
P312: Call a POISON CENTER if you feel unwell.
P337+P313: If eye irritation persists: Get medical advice.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents in accordance with local/regional/national/international regulations.
P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Hygienic handrub, PT1, professional and industrial user - meta SPC 2

Product type	PT01: Human hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Common name: Bacteria Common name: Yeasts Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses		
Field(s) of use	indoor use The product is a ready-to-use hygienic handrub for use in industrial, institutional, health care and domestic areas.		
Application method(s)	Method: Hygienic handrub Detailed description:		

Application rate(s) and frequency	Application Rate: 3 ml per application			
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 25 per day).			
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 30 seconds Limited spectrum virucidal activity – 60 seconds			
Category(ies) of users	industrial professional			
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l			

4.1.1. Use-specific instructions for use

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory.

Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.2. Use description

Table 2

Hygienic handrub, PT1, general public - meta SPC 2

Product type	PT01: Human hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development	Common name: Bacteria		
stage)	Common name: Yeasts		
	Common name: Mycobacteria		
	Common name: Viruses (limited spectrum virucidal activity)		
	Common name: Enveloped viruses		

Field(s) of use	indoor use		
	The product is a ready-to-use hygienic handrub for use in institutional, health care and domestic areas.		
Application method(s)	Method: Hygienic handrub		
	Detailed description:		
Application rate(s) and frequency	Application Rate: 3 ml (the amount of liquid should resemble the size of a large-sized coin)		
	Number and timing of application: Product is used as required, for adults and children older than 2 years up to 10 times per day, for toddlers up to 8 times per day.		
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 30 seconds Limited spectrum virucidal activity – 60 seconds		
Category(ies) of users	general public (non-professional)		
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml		

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.2.2. Use-specific risk mitigation measures

Do not use more than the specified number of applications per day.

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Use for children only under supervision of an adult. Apply the amount for the child/toddler on your own hand first and rub the product on child's/toddler's hand. Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.3. Use description

Table 3

Surgical hand disinfection / residential bacterial skin flora, PT1, professional user

Product type	PT01: Human hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development	Common name: Bacteria		
stage)	Common name: Yeasts		
	Common name: Mycobacteria		
	Common name: Viruses (limited spectrum virucidal activity)		
Field(s) of use	indoor use		
	Surgical hand disinfection / resident bacterial skin flora. The product is a ready-to-use alcoholic disinfectant for use in health care areas / hospital sector.		
Application method(s)	Method: surgical handrub		
	Detailed description:		
Application rate(s) and frequency	Application Rate: 2 times 3 ml per application		
	Number and timing of application: Product is used as required which may be multiple times per a day (frequency: 4 per day).		
	Contact time: 90 seconds		
Category(ies) of users	professional		
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l		

4.3.1. Use-specific instructions for use

Rub 2 times 3 ml into dry and visibly clean hands and forearms for 1.5 minutes, keeping the skin moist during the application time.

Any decanting or refilling may only be carried out under aseptic conditions.

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1. Instructions for use

see use-specific instructions for use

5.2. Risk mitigation measures

Keep out of reach of children and pets or non-target animals.

Ensure adequate ventilation during the application.

Make sure that the applied product is completely dried before entering a room or area where people will stay for a longer period of time.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Store at temperatures not exceeding 40 °C.

Protect from direct light.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)		Sterillium Market are pure IPM		a: EU			
Authorisation number			EU-0034602-0003 1-2				
Common name	IUPAC name	Function		CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	45 % (w/w)

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC: meta SPC 3

1.2. Suffix to the authorisation number

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT01: Human hygiene
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2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 - 45 % (w/w)

2.2. Type(s) of formulation of the meta SPC 3

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	H226: Flammable liquid and vapour.
	H319: Causes serious eye irritation.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.
	P271: Use only outdoors or in a well-ventilated area.
	P280: Wear eye protection.
	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P312: Call a POISON CENTER if you feel unwell.
	P312: Call a doctor if you feel unwell.
	P337+P313: If eye irritation persists: Get medical advice.
	P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
	P403+P233: Store in a well-ventilated place. Keep container tightly closed.
	P403+P235: Store in a well-ventilated place. Keep cool.
	P405: Store locked up.

P501: Dispose of container in accordance with local/regional/national/international regulations.
P501: Dispose of contents in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Hygienic handrub, PT1, professional and industrial user

Product type	PT01: Human hygiene	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Mycobacteria	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hygienic handrub for use in industrial, institutional, health care and domestic areas.	
Application method(s)	Method: Hygienic handrub	
	Detailed description:	
Application rate(s) and frequency	Application Rate: 3 ml per application	
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 25 per day).	
	Contact time: 30 seconds	
Category(ies) of users	industrial professional	
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE bottle 35 - 100 ml HDPE container 5 l	

4.1.1. Use-specific instructions for use

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.2. Use description

Table 2 **Hygienic handrub, PT1, general public**

Product type	PT01: Human hygiene	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Mycobacteria	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hygienic handrub for use in institutional, health care and domestic areas.	
Application method(s)	Method: Hygienic handrub	
	Detailed description:	
Application rate(s) and frequency	Application Rate: 3 ml (the amount of liquid should resemble the size of a large-sized coin)	
	Number and timing of application: Product is used as required, for adults and children older than 2 years up to 10 times per day, for toddlers up to 8 times per day.	
	Contact time: 30 seconds	
Category(ies) of users	general public (non-professional)	
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE bottle 35 - 100 ml	

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Rub 3 ml into the dry and visibly clean hands and keep moist for the required contact time.

4.2.2. Use-specific risk mitigation measures

Do not use more than the specified number of applications per day.

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Use for children only under supervision of an adult. Apply the amount for the child/toddler on your own hand first and rub the product on child's/toddler's hand. Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

- 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section
- 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.3. Use description

Table 3

Surgical hand disinfection / residential bacterial skin flora, PT1, professional user

Product type	PT01: Human hygiene	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Mycobacteria	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	Surgical hand disinfection / resident bacterial skin flora. The product is a ready-to-use alcoholic disinfectant for use in health care areas / hospital sector.	
Application method(s)	Method: surgical handrub	
	Detailed description:	
Application rate(s) and frequency	Application Rate: At least 3 ml per application	
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 4 per day).	
	Contact time: 90 seconds	
Category(ies) of users	professional	
Pack sizes and packaging material	HDPE bottle 35 - 100 ml HDPE bottle 50 - 1000 ml HDPE container 5 l	

4.3.1. Use-specific instructions for use

Rub at least 3 ml into dry and visibly clean hands and forearms for 1,5 minutes, keeping the skin moist during the application time.

Any decanting or refilling may only be carried out under aseptic conditions.

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3

5.1. **Instructions for use**

see use-specific instructions for use

5.2. Risk mitigation measures

Keep out of reach of children and pets or non-target animals.

Ensure adequate ventilation during the application.

Make sure that product is applied and completely dried before entering the room or area where people will stay for a longer period.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months.

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)		Sterill Gel Pl		Market area: EU			
Authorisation number			EU-0034602-0004 1-3				
Common name	IUPAC name	Functi	on	CAS	Snumber	EC number	Content (%)
Propan-1-ol		Active substance	:	71-2	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance	;	67-63	3-0	200-661-7	45 % (w/w)

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

lentifier Me	Meta SPC: meta SPC 4
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1.2. Suffix to the authorisation number

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
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2. META SPC 4 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 - 45 % (w/w)

2.2. Type(s) of formulation of the meta SPC 4

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	H226: Flammable liquid and vapour.
	H319: Causes serious eye irritation.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.
	P264: Wash hands thoroughly after handling.
	P271: Use only outdoors or in a well-ventilated area.
	P280: Wear eye protection.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312: Call a doctor if you feel unwell.
P312: Call a POISON CENTER if you feel unwell.
P337+P313: If eye irritation persists: Get medical advice.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of container in accordance with local/regional/national/international regulations.
P501: Dispose of contents in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Small surface disinfection, PT2, professional and industrial user - meta SPC 4

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Common name: Bacteria Common name: Yeasts Common name: Fungi Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses		
Field(s) of use	indoor use The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.		
Application method(s)	Method: Spraying or pouring followed by wiping Detailed description:		

Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18 ml/m²; Industrial area: 18 - 50 ml/m².
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l

4.1.1. Use-specific instructions for use

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m^2) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour $(8 - 22 \text{ sec/m}^2)$ on the surface.

Spraying (500 – 1000ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 4

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development	Common name: Bacteria		
stage)	Common name: Yeasts		
	Common name: Fungi		
	Common name: Mycobacteria		
	Common name: Viruses (limited spectrum virucidal activity)		
	Common name: Enveloped viruses		
Field(s) of use	indoor use		
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.		
Application method(s)	Method: Spraying or pouring followed by wiping		
	Detailed description:		
Application rate(s) and frequency	Application Rate: 18 ml/m².		
	Number and timing of application: maximum 5 applications per day.		
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes		
Category(ies) of users	general public (non-professional)		
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml		

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Pouring: Invert the bottle and pour $(8\ sec/m^2)$ on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

- 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section
- 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 4

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional, health care and domestic area.
Application method(s)	Method: Spraying or pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18ml/m²; Industrial area: 18 - 50 ml/m².
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l

4.3.1. Use-specific instructions for use

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour $(8 - 22 \text{ sec/m}^2)$ on the surface.

Spraying (500 – 1000ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

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

see general section

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

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 4

Product type	PT04: Food and feed area		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Common name: Bacteria		
	Common name: Yeasts		
	Common name: Fungi		
	Common name: Mycobacteria		
	Common name: Viruses		
	Common name: Enveloped viruses		
Field(s) of use	indoor use		
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional, health care and domestic area.		

Application method(s)	Method: Spraying or pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 18 ml/m ²
	Number and timing of application: maximum 1 application per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml

4.4.1. Use-specific instructions for use

Comply with the instructions for use.

Pouring: Invert the bottle and pour (8 sec/m^2) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 4

5.1. **Instructions for use**

Spray or pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For use at room temperature.

5.2. Risk mitigation measures

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

Used wipes must be disposed in a closed container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTER or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months.

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

Trade name(s)		Bacillo pure	ol	Market area: EU			
Authorisation number			EU-0034602-0005 1-4				
Common name	IUPAC name	Function		CAS	number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	45 % (w/w)

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

1.2. Suffix to the authorisation number

Number	1-5
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1.3. **Product type(s)**

PT02: Disinfectants and algaecides not intended for direct application to humans or animals
PT04: Food and feed area

2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 - 45 % (w/w)

2.2. Type(s) of formulation of the meta SPC 5

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	H226: Flammable liquid and vapour.
	H319: Causes serious eye irritation.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233: Keep container tightly closed.

P240: Ground and bond container and receiving equipment.

P241: Use explosion-proof electrical equipment.

P241: Use explosion-proof lighting equipment.

P242: Use non-sparking tools.

P243: Take actions to prevent static discharges.

P261: Avoid breathing vapours.

P264: Wash hands thoroughly after handling.

P271: Use only outdoors or in a well-ventilated area.

P280: Wear eye protection.

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312: Call a doctor if you feel unwell.

P312: Call a POISON CENTER if you feel unwell.

P337+P313: If eye irritation persists: Get medical advice.

P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P403+P235: Store in a well-ventilated place. Keep cool.

P405: Store locked up.

P501: Dispose of contents in accordance with local/regional/national/international regulations.

P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Small surface disinfection, PT2, professional and industrial user - meta SPC 5

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses (limited spectrum virucidal activity)
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.
Application method(s)	Method: Wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	PET tissues/wipes in a PET/PE flowpack or PET/PE sachet.

4.1.1. Use-specific instructions for use

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.1.2. Use-specific risk mitigation measures

see general section

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 5

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria
	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses (limited spectrum virucidal activity)
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.
Application method(s)	Method: Wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: maximum 5 applications per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	PET tissues/wipes in a PET/PE flowpack or PET/PE sachet.

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Provide adequate ventilation (e.g. by opening windows or by mechanical ventilation) for 15 min before re-entry.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section

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

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 5

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional, health care and domestic area.
Application method(s)	Method: Wiping
	Detailed description:

Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	PET tissues/wipes in a PET/PE flowpack or PET/PE sachet.

4.3.1. Use-specific instructions for use

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.3.2. Use-specific risk mitigation measures

see general section

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

see general section

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

see general section

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

see general section

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 5

PT04: Food and feed area
-
Common name: Bacteria
Common name: Yeasts
Common name: Fungi
Common name: Mycobacteria
Common name: Viruses
Common name: Enveloped viruses

Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional, health care and domestic area.
Application method(s)	Method: Wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: maximum 1 application per day
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	PET tissues/wipes in a PET/PE flowpack or PET/PE sachet.

4.4.1. Use-specific instructions for use

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 5

5.1. **Instructions for use**

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product and allow to act for the required contact time. Dispose tissue after use.

Only use wet wipes.

For use at room temperature.

Close the package after opening.

5.2. Risk mitigation measures

Used wipes must be disposed in a closed container.

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)		pure	Bacillol Market area: EU pure Tissues				
Authorisation number			EU-0034602-0006 1-5				
Common name	IUPAC name	Functi	on	CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-2	3-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance	:	67-6	3-0	200-661-7	45 % (w/w)

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	Meta SPC: meta SPC 6

1.2. Suffix to the authorisation number

Number	1-6

1.3. **Product type(s)**

PT02: Disinfectants and algaecides not intended for direct application to humans or animals	
PT04: Food and feed area	

2. META SPC 6 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	45 - 45 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	25 - 25 % (w/w)

2.2. Type(s) of formulation of the meta SPC 6

Formulation type(s)	AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	H226: Flammable liquid and vapour.
	H318: Causes serious eye damage.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.
	P271: Use only outdoors or in a well-ventilated area.
	P280: Wear eye protection.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310: Immediately call a POISON CENTER.
	P310: Immediately call a doctor.
	P312: Call a doctor if you feel unwell.
	P312: Call a POISON CENTER if you feel unwell.
	P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
	1

P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of container in accordance with local/regional/national/international regulations.
P501: Dispose of contents in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1
Small surface disinfection, PT2, professional and industrial user - meta SPC 6

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses (limited spectrum virucidal activity)
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.
Application method(s)	Method: Spraying or pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18 ml/m²; Industrial area: 18 - 50 ml/m².
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l

4.1.1. Use-specific instructions for use

Spray or pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour (8 - 22 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles and handling of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 6

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development	Common name: Bacteria		
stage)	Common name: Yeasts		
	Common name: Fungi		
	Common name: Mycobacteria		
	Common name: Viruses (limited spectrum virucidal activity)		
	Common name: Enveloped viruses		

Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.
Application method(s)	Method: Pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 18 ml/m².
	Number and timing of application: maximum 5 applications per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml
	L

4.2.1. Use-specific instructions for use

Pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

Comply with the instructions for use.

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Avoid splashes.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 6

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional, health care and domestic area.
Application method(s)	Method: Spraying or pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18ml/m²; Industrial area: 18 - 50 ml/m².
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l

4.3.1. Use-specific instructions for use

Spray or pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour $(8 - 22 \text{ sec/m}^2)$ on the surface.

Spraying (500 - 1000 ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles and handling of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

- 4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section
- 4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 6

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional, health care and domestic area.
Application method(s)	Method: Pouring followed by wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 18 ml/m²
	Number and timing of application: maximum 1 application per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml

4.4.1. Use-specific instructions for use

Pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

Comply with the instructions for use.

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Avoid splashes.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 6

5.1. **Instructions for use**

For use at room temperature.

5.2. Risk mitigation measures

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

Used wipes must be disposed in a closed container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor..

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance. Information to Healthcare personnel or doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

Trade name(s)		Bacillol AF Market are pro		ea: EU			
Authorisation number				EU-0034602-0007 1-6			
Common name	IUPAC name	Functi	on	CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	45 % (w/w)
Propan-2-ol		Active substance	:	67-63	3-0	200-661-7	25 % (w/w)

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

Identifier	Meta SPC: meta SPC 7

1.2. Suffix to the authorisation number

Number	1-7
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1.3. **Product type(s)**

PT02: Disinfectants and algaecides not intended for direct application to humans or animals
PT04: Food and feed area

2. META SPC 7 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	45 - 45 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	25 - 25 % (w/w)

2.2. Type(s) of formulation of the meta SPC 7

Formulation type(s)	XX Impregnated wipes
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	H226: Flammable liquid and vapour.		
	H318: Causes serious eye damage.		
	H336: May cause drowsiness or dizziness.		
	EUH066: Repeated exposure may cause skin dryness or cracking.		
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.		
	P102: Keep out of reach of children.		
	P103: Read carefully and follow all instructions.		
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.		
	P233: Keep container tightly closed.		

P240: Ground and bond container and receiving equipment.
P241: Use explosion-proof electrical equipment.
P241: Use explosion-proof lighting equipment.
P242: Use non-sparking tools.
P243: Take actions to prevent static discharges.
P261: Avoid breathing vapours.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear eye protection.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a doctor.
P312: Call a doctor if you feel unwell.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents in accordance with local/regional/national/international regulations.
P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

 $\label{eq:Table 1}$ Small surface disinfection, PT2, professional and industrial user - meta SPC 7

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-

Common momos Postorio
Common name: Bacteria
Common name: Yeasts
Common name: Fungi
Common name: Mycobacteria
Common name: Viruses (limited spectrum virucidal activity)
Common name: Enveloped viruses
indoor use
The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.
Method: Wiping
Detailed description:
Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes
industrial professional
PET tissues/wipes in PET/PE flowpack or PET/PE sachet

4.1.1. Use-specific instructions for use

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.1.2. Use-specific risk mitigation measures

see general section

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 7

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Fungi	
	Common name: Mycobacteria	
	Common name: Viruses (limited spectrum virucidal activity)	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.	
Application method(s)	Method: Wiping	
	Detailed description:	
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.	
	Number and timing of application: maximum 5 applications per day.	
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes	
Category(ies) of users	general public (non-professional)	
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet	

4.2.1. Use-specific instructions for use

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

- 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section
- 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 7

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional, health care and domestic area.
Application method(s)	Method: Wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet

4.3.1. Use-specific instructions for use

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.3.2. Use-specific risk mitigation measures

see general section

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

see general section

4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging see general section

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

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 7

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Common name: Bacteria
stage)	Common name: Yeasts
	Common name: Fungi
	Common name: Mycobacteria
	Common name: Viruses
	Common name: Enveloped viruses
Field(s) of use	indoor use
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional, health care and domestic area.
Application method(s)	Method: Wiping
	Detailed description:
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.
	Number and timing of application: maximum 1 application per day.
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet

4.4.1. Use-specific instructions for use

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Use 2 - 3 wipes per m².

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 7

5.1. **Instructions for use**

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product and allow to act for the required contact time. Dispose tissue after use.

Only use wet wipes.

For use at room temperature.

Close the package after opening.

5.2. Risk mitigation measures

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

Used wipes must be disposed in a closed container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

Information to Healthcare personnel or doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months.

Store at temperatures not exceeding 40 °C.

6. OTHER INFORMATION

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

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

Trade name(s)		Bacille pro Ti		Market ar	ea: EU		
Authorisation nun	ıber			EU-0034602-0008 1-7			
Common name	IUPAC name	Functi	on	CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-2	3-8	200-746-9	45 % (w/w)
Propan-2-ol		Active substance	;	67-63	3-0	200-661-7	25 % (w/w)

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	Meta SPC: meta SPC 8

1.2. Suffix to the authorisation number

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1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
	PT04: Food and feed area

2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	45 - 45 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	25 - 25 % (w/w)

2.2. Type(s) of formulation of the meta SPC 8

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	H226: Flammable liquid and vapour.
	H318: Causes serious eye damage.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.

P271: Use only outdoors or in a well-ventilated area.
P280: Wear eye protection.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a doctor.
P312: Call a doctor if you feel unwell.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents in accordance with local/regional/national/international regulations.
P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Small surface disinfection, PT2, professional and industrial user - meta SPC 8

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Common name: Yeasts Common name: Fungi Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses

Field(s) of use	indoor use	
	The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.	
Application method(s)	Method: Spraying or pouring followed by wiping	
	Detailed description:	
Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18 ml/m²; Industrial area: 18 - 50 ml/m².	
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).	
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes	
Category(ies) of users	industrial professional	
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l	

4.1.1. Use-specific instructions for use

Spray or pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For use at room temperature.

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m^2) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour (8 - 22 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.1.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles and handling of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 8

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Fungi	
	Common name: Mycobacteria	
	Common name: Viruses (limited spectrum virucidal activity)	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.	
Application method(s)	Method: Pouring followed by wiping	
	Detailed description:	
Application rate(s) and frequency	Application Rate: 18 ml/m²	
	Number and timing of application: maximum 5 applications per day.	
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes	
Category(ies) of users	general public (non-professional)	
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml	

4.2.1. Use-specific instructions for use

Pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

For use at room temperature.

Comply with the instructions for use.

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Avoid splashes.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 8

Product type	PT04: Food and feed area	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Fungi	
	Common name: Mycobacteria	
	Common name: Viruses	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hard non-porous surface disinfectant for use in industrial, institutional, health care and domestic area.	
Application method(s)	Method: Spraying or pouring followed by wiping	
	Detailed description:	

Application rate(s) and frequency	Application Rate: Institutional, health care and domestic area: 18ml/m²; Industrial area: 18 - 50 ml/m²
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes
Category(ies) of users	industrial professional
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml HDPE container 5 l

4.3.1. Use-specific instructions for use

Spray or pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For bactericidal and yeasticidal efficacy: For use at 4°C up to room temperature.

For efficacy against other target organisms: For use at room temperature.

For institutional, health care and domestic area:

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

Spraying (500 – 1000ml bottle): 15 pump strokes per m².

Spraying (50ml bottle): 12 pump strokes per 0,1m².

For industrial area:

Pouring: Invert the bottle and pour $(8 - 22 \text{ sec/m}^2)$ on the surface.

Spraying (500 – 1000ml bottle): 15 - 41 pump strokes per m².

Spraying (50ml bottle): at least 12 pump strokes per 0,1m².

4.3.2. Use-specific risk mitigation measures

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied:

The use of eye protection during refilling of the application bottles and handling of the product is mandatory. Eye protection according to the European Standard EN ISO 16321 or equivalent.

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

see general section

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

see general section

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

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 8

Product type	PT04: Food and feed area	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development	Common name: Bacteria	
stage)	Common name: Yeasts	
	Common name: Fungi	
	Common name: Mycobacteria	
	Common name: Viruses	
	Common name: Enveloped viruses	
Field(s) of use	indoor use	
	The product is a ready-to-use hard non-porous surface disinfectant for use in institutional, health care and domestic area.	
Application method(s)	Method: Pouring followed by wiping	
	Detailed description:	
Application rate(s) and frequency	Application Rate: 18 ml/m².	
	Number and timing of application: maximum 1 application per day.	
	Contact times: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes	
Category(ies) of users	general public (non-professional)	
Pack sizes and packaging material	HDPE bottle 50 - 1000 ml	

4.4.1. Use-specific instructions for use

Pour a sufficient amount of the product on the surface to be disinfected, if needed wipe to ensure complete coverage and allow to act for the required contact time.

For bactericidal and yeasticidal efficacy: For use at 4°C up to room temperature.

For efficacy against other target organisms: For use at room temperature.

Comply with the instructions for use.

Pouring: Invert the bottle and pour (8 sec/m²) on the surface.

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Avoid splashes.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 8

5.1. **Instructions for use**

5.2. Risk mitigation measures

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

Used wipes must be disposed in a closed container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance. Information to Healthcare personnel or doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of 129,28 mg/m³ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

The full title of the EN standard referenced in the Risk mitigation measures are:

the European Standard EN ISO 16321 - Eye and face protection for occupational use.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade name(s)		Bacillo classio		Market area: EU			
Authorisation number		EU-0034602-0009 1-8					
Common name	IUPAC name	Function		CAS	S number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	45 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	25 % (w/w)

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 9 identifier

Identifier	Meta SPC: meta SPC 9

1.2. Suffix to the authorisation number

Number	1-9
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1.3. Product type(s)

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
	PT04: Food and feed area

2. META SPC 9 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 9

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	45 - 45 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	25 - 25 % (w/w)

2.2. Type(s) of formulation of the meta SPC 9

Formulation type(s)	XX Impregnated wipes

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

Hazard statements	H226: Flammable liquid and vapour.
	H318: Causes serious eye damage.
	H336: May cause drowsiness or dizziness.
	EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233: Keep container tightly closed.
	P240: Ground and bond container and receiving equipment.
	P241: Use explosion-proof electrical equipment.
	P241: Use explosion-proof lighting equipment.
	P242: Use non-sparking tools.
	P243: Take actions to prevent static discharges.
	P261: Avoid breathing vapours.
	P271: Use only outdoors or in a well-ventilated area.
	P280: Wear eye protection.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a doctor.
P310: Immediately call a POISON CENTER.
P312: Call a doctor if you feel unwell.
P312: Call a POISON CENTER if you feel unwell.
P370+P378: In case of fire: Use water mist, foam, carbon dioxide or powder extinguishing agent to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents in accordance with local/regional/national/international regulations.
P501: Dispose of container in accordance with local/regional/national/international regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Small surface disinfection, PT2, professional and industrial user - meta SPC 9

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals				
Where relevant, an exact description of the authorised use	-				
Target organism(s) (including development	Common name: Bacteria				
stage)	Common name: Yeasts				
	Common name: Fungi				
	Common name: Mycobacteria				
	Common name: Viruses (limited spectrum virucidal activity)				
	Common name: Enveloped viruses				
Field(s) of use	indoor use				
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.				

Application method(s)	Method: Wiping			
	Detailed description:			
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.			
	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).			
	Contact times: 1) For Bacillol AF classic Tissues and Bacillol classic Wipes: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes 2) For Bacillol classic Tissues: 5 minutes, with 2 tissues one above the other			
Category(ies) of users	industrial professional			
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet PET/Cellulose tissues/wipes in HDPE dispenser or PET/PE sachet			

4.1.1. Use-specific instructions for use

For use at room temperature.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Bacillol classic Tissues: Use 5 - 8 wipes per m².

Bacillol AF classic Tissues: Use 2 - 3 wipes per m².

Bacillol classic Wipes: Use ca. 1 wipe per m².

4.1.2. Use-specific risk mitigation measures

see general section

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

see general section

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.2. Use description

Table 2

Small surface disinfection, PT2, general public - meta SPC 9

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including development	Common name: Bacteria			
stage)	Common name: Yeasts			
	Common name: Fungi			
	Common name: Mycobacteria			
	Common name: Viruses (limited spectrum virucidal activity)			
	Common name: Enveloped viruses			
Field(s) of use	indoor use			
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional (e.g. hotels), health care (e.g. hospitals, medical practices) and domestic area.			
Application method(s)	Method: Wiping			
	Detailed description:			
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.			
	Number and timing of application: maximum 5 applications per day.			
	Contact times: 1) For Bacillol AF classic Tissues and Bacillol classic Wipes: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and limited spectrum virucidal activity – 5 minutes 2) For Bacillol classic Tissues: 5 minutes, with 2 tissues one above the other			
Category(ies) of users	general public (non-professional)			
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet PET/Cellulose tissues/wipes in HDPE dispenser or PET/PE sachet			

$4.2.1. \ \ Use-specific instructions for use$

For use at room temperature.

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Bacillol classic Tissues: Use 5 - 8 wipe per m².

Bacillol AF classic Tissues: Use 2 - 3 wipes per m².

Bacillol classic Wipes: Use ca. 1 wipe per m².

4.2.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

see general section

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

see general section

4.3. Use description

Table 3

Small surface disinfection, PT4, professional and industrial user - meta SPC 9

PT04: Food and feed area			
-			
Common name: Bacteria			
Common name: Yeasts			
Common name: Fungi			
Common name: Mycobacteria			
Common name: Viruses			
Common name: Enveloped viruses			
indoor use			
The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in industrial, institutional, health care and domestic area.			
Method: Wiping			
Detailed description:			
Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.			

	Number and timing of application: Product is used as required which may be multiple times per day (frequency: 8 per day).			
	Contact times: 1) For Bacillol AF classic Tissues and Bacillol classic Wipes: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes 2) For Bacillol classic Tissues: 5 minutes, with 2 tissues one above the other			
Category(ies) of users	industrial professional			
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet PET/Cellulose tissues/wipes in HDPE dispenser or PET/PE sachet			

4.3.1. Use-specific instructions for use

For bactericidal and yeasticidal efficacy: For use at 4°C up to room temperature.

For efficacy against other target organisms: For use at room temperature.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Bacillol classic Tissues: Use 5 - 8 wipes per m².

Bacillol AF classic Tissues: Use 2 - 3 wipes per m².

Bacillol classic Wipes: Use ca. 1 wipe per m².

4.3.2. Use-specific risk mitigation measures

see general section

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

see general section

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

see general section

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

see general section

4.4. Use description

Table 4

Small surface disinfection, PT4, general public - meta SPC 9

Product type	PT04: Food and feed area			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including development	Common name: Bacteria			
stage)	Common name: Yeasts			
	Common name: Fungi			
	Common name: Mycobacteria			
	Common name: Viruses			
	Common name: Enveloped viruses			
Field(s) of use	indoor use			
	The product is a ready-to-use hard non-porous surface disinfectant tissue/wipe for use in institutional, health care and domestic area.			
Application method(s)	Method: Wiping			
	Detailed description:			
Application rate(s) and frequency	Application Rate: 0,2 - 0,5 m²/wipe. The wipe should be replaced as frequently as needed to ensure complete wetting of the surface.			
	Number and timing of application: maximum 1 application per day.			
	Contact times: 1) For Bacillol AF classic Tissues and Bacillol classic Wipes: Bacteria, yeasts, mycobacteria and enveloped viruses – 1 minute Fungi and viruses – 5 minutes 2) For Bacillol classic Tissues: 5 minutes, with 2 tissues one above the other			
Category(ies) of users	general public (non-professional)			
Pack sizes and packaging material	PET tissues/wipes in PET/PE flowpack or PET/PE sachet PET/Cellulose tissues/wipes in HDPE dispenser or PET/PE sachet			

4.4.1. Use-specific instructions for use

For bactericidal and yeasticidal efficacy: For use at $4\,^\circ\text{C}$ up to room temperature.

For efficacy against other target organisms: For use at room temperature.

Comply with the instructions for use.

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product.

Bacillol classic Tissues: Use 5 - 8 wipes per m².

Bacillol AF classic Tissues: Use 2 - 3 wipes per m².

Bacillol classic Wipes: Use ca. 1 wipe per m^2 .

4.4.2. Use-specific risk mitigation measures

The authorisation holder shall specify the application rate in a simple, easily understandable form on the label.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

In case of skin dryness, use appropriate skin care lotion.

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

If medical advice is needed, have product container or label at hand.

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

see general section

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

see general section

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 9

5.1. **Instructions for use**

Wipe the surface with a tissue/wipe ensuring the complete coverage with the product and allow to act for the required contact time.

Only use wet wipes.

Close the package after opening.

5.2. Risk mitigation measures

Ensure adequate ventilation (e. g. by opening windows or by mechanical ventilation) during application. In small rooms avoid presence of toddlers and pets for 15 min before re-entry.

Keep out of reach of children and non-target animals or pets.

Used wipes must be disposed in a closed container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel or doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance. Information to Healthcare personnel or doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

5.4. Instructions for safe disposal of the product and its packaging

Avoid release to the environment.

Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Store at temperatures not exceeding 40 °C.

6. **OTHER INFORMATION**

Please be aware of the European reference values of $129,28 \text{ mg/m}^3$ for the active substance Propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product.

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

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

Trade name(s)			Bacillo classic Tissue	2	F Market area: EU		
Authorisation number			EU-0034602-0010 1-9				
Common name	IUPAC name	Function	Function C		Snumber	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	45 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	25 % (w/w)

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

Trade name(s)			Bacillo classic Tissue	ic			
Authorisation number				EU-0034602-0011 1-9			
Common name	IUPAC name	Function		CAS	number	EC number	Content (%)
Propan-1-ol		Active substance		71-23	3-8	200-746-9	45 % (w/w)
Propan-2-ol		Active substance		67-63	3-0	200-661-7	25 % (w/w)

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

Trade name(s)			Bacillol classic Wipes		Market area: EU			
Authorisation number				EU-0034602-0012 1-9				
Common name	IUPAC name	Function		CAS	S number	EC number	Content (%)	
Propan-1-ol		Active substance		71-2	3-8	200-746-9	45 % (w/w)	
Propan-2-ol		Active substance		67-6	3-0	200-661-7	25 % (w/w)	