2025/2074

20.10.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2074

of 16 October 2025

granting a Union authorisation for the biocidal product family 'B. Braun Medical Propanol Family' 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 12 April 2019, B. Braun Medical AG 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 'B. Braun Medical Propanol Family' of product-types 1, 2 and 4 as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-CP050930-37 in the Register for Biocidal Products.

(2) 'B. Braun Medical Propanol Family' 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 7 June 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 13 December 2024, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'B. Braun Medical Propanol Family' 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 'B. Braun Medical Propanol Family' 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 January 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 'B. Braun Medical Propanol Family'.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 28 November 2024 on the Union authorisation of the biocidal product family 'B. Braun Medical Propanol Family' (ECHA/BPC/453/2024), https://echa.europa.eu/opinions-on-union-authorisation.

(8) In its opinion, the Agency recommends that the authorisation holder conducts a long-term storage stability test as a condition in the authorisation to confirm the storage stability. The Commission agrees with that recommendation and considers that the submission of the results of that test should be a condition relating to the making available on the market and use of the biocidal product family pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of that Regulation based on existing data.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0033840-0000 is granted to B. Braun Medical AG for the making available on the market and use of the biocidal product family 'B. Braun Medical Propanol Family' subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 9 November 2025 until 31 October 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 October 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Terms and conditions (EU-0033840-0000)

The authorisation holder shall conduct a long-term storage stability test of products representative for all meta-SPCs within the biocidal product family 'B. Braun Medical Propanol Family'. The tests shall be performed at ambient temperature in commercial packaging in which the products in the family will be made available on the market. All relevant properties should be determined prior and after storage.

By 9 September 2026 the authorisation holder shall submit the results of the test to the Agency.

ANNEX

Summary of product characteristics for a biocidal product family

B. Braun Medical Propanol Family

Product type(s)

PT01: Human hygiene

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

PT04: Food and feed area

Authorisation number EU-0033840-0000

R4BP asset number EU-0033840-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	B. Braun Medical Propanol Family

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	B. Braun Medical AG
	Address	Seesatz 17 6204 Sempach CH
Authorisation number	EU-0033840-0000	
R4BP asset number	EU-0033840-0000	
Date of the authorisation	9 November 2025	
Expiry date of the authorisation	31 October 2035	

1.4. **Manufacturer(s) of the product**

Name of manufacturer	B. Braun Medical AG
Address of manufacturer	Seesatz 17 6204 Sempach Switzerland
Location of manufacturing sites	B. Braun Medical AG site 1 B. Braun Medical AG, Seesatz 17 6204 Sempach Switzerland

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

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

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals GmbH (formerly Oxea GmbH) site 1 OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX 77414 Bay City United States (the)

Active substance	Propan-1-ol
Name of manufacturer	Oxea GmbH
Address of manufacturer	Rheinpromenade 4a 40789 Monheim am Rhein Germany
Location of manufacturing sites	Oxea GmbH site 1 Oxea Corporation, 2001 FM 3057 TX 77414 Bay City United States (the)

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 INEOS Solvents Germany GmbH, Römerstr. 733 47443 Moers Germany INEOS Solvents Germany GmbH site 2 INEOS Solvents Germany GmbH, Shamrockstrasse 88 44623 Herne Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334 3000 CH Rotterdam Netherlands (the)
Location of manufacturing sites	Shell Chemicals Europe B.V. site 1 Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands (the)

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	20 - 30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	10 - 45 % (w/w)

2.2. **Type(s) of formulation**

Formulation type(s)	AL Any other liquid Impregnated wipes

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

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT01: Human hygiene

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)

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

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	H225: Highly flammable liquid and vapour. H318: Causes serious eye damage. H336: May cause drowsiness or dizziness. EUH208: Contains (2R)-6-methyl-2-[(1R)-4-methyl-1-cyclohex-3-enyl]hept-5-en-2-ol. May produce an allergic reaction. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	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. 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. P312: Call a POISON CENTER if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to a hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to a hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Hygienic handrub

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: yeasts Common name: bacteria Common name: Mycobacteria Common name: enveloped viruses Common name: viruses (limited spectrum virucidal activity)
Field(s) of use	indoor use The product can be applied for hygienic handrub in all situations necessary, e.g. — hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories.
Application method(s)	Method: Handrub Detailed description: It is a ready-to-use product which shall be rubbed undiluted into visibly clean and dry hands only.
Application rate(s) and frequency	Undiluted; ready-to-use product Number and timing of application: Application rate: 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strikes per 3 ml). Frequency: Professional user: Up to 25 applications per day General public (home-dialysis): Once per day General public (entering/leaving hospitals): Adults: Up to 11 applications per day Children: Up to 3 applications per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented high-density polyethylene (HDPE) bottles with screwed flip top caps of pigmented polypropylene (PP). Sizes: 100/500/1 000 ml pigmented HDPE folding bottle with integrated Pump. Sizes: 500/1 000 ml pigmented HDPE canister with screwed caps of pigmented HDPE. Size: 5 000 ml

4.1.1. *Use-specific instructions for use*

The ready-to-use product shall be rubbed undiluted into visibly clean and dry hands only.

Rub sufficient amount (at least 3 ml) into hands and keep moist during the indicated minimum exposure time:

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 30 seconds

— limited spectrum virucidal activity: 2 minutes

The product can be applied directly, or the product can be used in a dispenser or with a pump (use integrated pump: 2 strokes for 3 ml; use dispensers: e.g. set to 1,5 ml per stroke, 2 strokes for 3 ml).

4.1.2. *Use-specific risk mitigation measures*

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

Use by children only under adult supervision when visiting hospitals.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Keep out of reach of children and pets.

The following personal protective equipment (PPE) is stipulated 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:

During refilling: The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

The product information (i.e. label and/or leaflet) shall clearly state that: for the following specific uses the product can be exceptionally used by the general public:

— Hygienic hand rub during home dialysis.

— Hygienic hand rub when entering/leaving hospitals.

Application by a non-professional is always carried out after professional instruction or under professional supervision.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 1.

4.2. **Use description**

Table 2

Surgical handrub

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
Field(s) of use	indoor use The products can be applied for surgical handrub in hospitals and other health care institutions.
Application method(s)	Method: Handrub Detailed description: It is a ready-to-use product which shall be rubbed undiluted in portions into the visibly clean hands and forearms only.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: 2 or 3 portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strikes per 3 ml). Frequency professional user: Typically up to 25 applications per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented HDPE bottles with screwed flip top caps of pigmented PP. Sizes: 100/500/1 000 ml pigmented HDPE folding bottle with integrated PP pump. Sizes: 500/1 000 ml pigmented HDPE canister with screwed caps of pigmented HDPE. Size: 5 000 ml

4.2.1. *Use-specific instructions for use*

The ready-to-use product shall be rubbed undiluted in portions into the visibly clean and dry hands and forearms only.

Rub sufficient amount in portions of 3 ml (2 or 3 times) into hands and forearms and keep moist during the indicated minimum contact time:

— for the control of bacteria, mycobacteria and yeasts: 90 seconds

The product can be applied directly, or the product can be used in a dispenser or with a pump (use integrated pump: 2 strokes for 3 ml; use dispensers: e.g. set to 1,5 ml per stroke, 2 strokes for 3 ml).

Refilling/decanting of the product should only be done under aseptic conditions.

All materials must be fully compatible with the product. The dispenser or container, which is refilled, must have the following minimum labelling information: The authorisation number; The trade name of the biocidal product; The identity and content of each active ingredient; The instructions for use, including the incorporation time required for the biocidal action. The information according to CLP.

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

In case of skin dryness, use appropriate skin care lotion

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Keep out of reach of children and pets.

The following personal protective equipment (PPE) is stipulated 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:

During refilling: The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 1.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 1**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months).

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store at temperatures not exceeding 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value of 129,28 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)	Softalind Pro	Market area: EU
	Softa-Man	Market area: EU
Authorisation number	EU-0033840-0001 1-1	

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

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

Trade name(s)	Softalind Pro pure	Market area: EU
Authorisation number	EU-0033840-0002 1-1	

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

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

Trade name(s)	Softalind Pro acute	Market area: EU
Authorisation number	EU-0033840-0003 1-1	

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

1.3. **Product type(s)**

Product type(s)	PT01: Human hygiene

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

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	H225: Highly flammable liquid and vapour. H318: Causes serious eye damage. H336: May cause drowsiness or dizziness. EUH208: Contains (2R)-6-methyl-2-[(1R)-4-methyl-1-cyclohex-3-enyl]hept-5-en-2-ol. May produce an allergic reaction. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	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. 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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Hygienic handrub

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: enveloped viruses

Field(s) of use	indoor use The product can be applied for hygienic handrub in all situations necessary, e.g. — hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories.
Application method(s)	Method: Handrub Detailed description: It is a ready-to-use product which shall be rubbed undiluted into visibly clean and dry hands only.
Application rate(s) and frequency	Undiluted; ready-to-use product Number and timing of application: Application rate: 3 ml. Frequency: Professional user: Typically up to 25 applications per day General public (home-dialysis): Once per day General public (entering/leaving hospitals): Adults: Typically up to 11 applications per day Children: Typically up to 3 applications per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented HDPE bottles with screwed flip top caps of pigmented PP. Sizes: 100/500/1 000 ml pigmented HDPE canister with screwed caps of pigmented HDPE. Size: 5 000 ml

4.1.1. *Use-specific instructions for use*

The ready-to-use product shall be rubbed undiluted into visibly clean and dry hands only.

Rub sufficient amount (at least 3 ml) into hands and keep moist during the indicated minimum exposure time:

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 30 seconds

The product can be applied directly, or the product can be used in a dispenser or with a pump (use dispensers: e.g. set to 1,5 ml per stroke, 2 strokes for 3 ml).

4.1.2. *Use-specific risk mitigation measures*

In case of skin dryness, use appropriate skin care lotion

Use by children only under adult supervision when visiting hospitals.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Keep out of reach of children and pets.

The following personal protective equipment (PPE) is stipulated 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

During refilling: The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

The product information (i.e. label and/or leaflet) shall clearly state that: for the following specific uses the product can be exceptionally used by the general public:

— Hygienic hand rub during home dialysis.

— Hygienic hand rub when entering/leaving hospitals.

Application by a non-professional is always carried out after professional instruction or under professional supervision..

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 2.

4.2. **Use description**

Table 2

Surgical handrub

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
Field(s) of use	indoor use The product can be applied for surgical handrub in hospitals and other health care institutions.
Application method(s)	Method: Handrub Detailed description: It is a ready-to-use product which shall be rubbed undiluted in portions into the visibly clean hands and forearms only.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: 2 or 3 portions of 3 ml. Frequency professional user: Typically up to 25 applications per day.
Category(ies) of users	professional
Pack sizes and packaging material	pigmented HDPE bottles with screwed flip top caps of pigmented PP. Sizes: 100/500/1 000 ml pigmented HDPE canister with screwed caps of pigmented HDPE. Size: 5 000 ml

4.2.1. *Use-specific instructions for use*

The ready-to-use product shall be rubbed undiluted in portions into the visibly clean and dry hands and forearms only.

Rub sufficient amount in portions of 3 ml (2 or 3 times) into hands and forearms and keep moist during the indicated minimum exposure time:

— for the control of bacteria, mycobacteria and yeasts: 90 seconds

The product can be applied directly, or the product can be used in a dispenser or with a pump (use dispensers: e.g. set to 1,5 ml per stroke, 2 strokes for 3 ml).

Refilling/decanting of the product should only be done under aseptic conditions.

All materials must be fully compatible with the product. The dispenser or container, which is refilled, must have the following minimum labelling information: The authorisation number; The trade name of the biocidal product; The identity and content of each active ingredient; The instructions for use, including the incorporation time required for the biocidal action. The information according to CLP.

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

In case of skin dryness, use appropriate skin care lotion

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Keep out of reach of children and pets.

The following personal protective equipment (PPE) is stipulated 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

During refilling: The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 2.

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**

See use-specific risk mitigation measures.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)		Softalind Pro gel	Market area: EU		
Authorisation number		EU-0033840-0004 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance	67-63-0	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

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

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	H225: Highly 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	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. 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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Hygienic handrub

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: enveloped viruses
Field(s) of use	indoor use The product can be applied for hygienic handrub in all situations necessary, e.g. — hospitals and other health care institutions such as in ambulances, surgeries and nursing homes (incl. home-care of patients)

	— hospital canteens, large kitchens, pharmaceutical industries, production sites and laboratories.
Application method(s)	Method: Handrub Detailed description: It is a ready-to-use product which shall be rubbed undiluted into visibly clean and dry hands only.
Application rate(s) and frequency	Undiluted; ready-to-use product Number and timing of application: Application rate: 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strikes per 3 ml). Frequency: Professional user: Typically up to 25 applications per day General public (home-dialysis): Once per day General public (entering/leaving hospitals): Adults: Typically up to 11 applications per day Children: Typically up to 3 applications per day
Category(ies) of users	professional
Pack sizes and packaging material	500 ml pigmented HDPE bottles with screwed foam head of pigmented PP

4.1.1. *Use-specific instructions for use*

The ready-to-use product shall be rubbed undiluted into visibly clean and dry hands only.

Rub sufficient amount (at least 3 ml) into hands and keep moist during the indicated minimum exposure time:

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 30 seconds

The product is applied with a screwed foam head (1,5 ml per stroke, 2 strokes for 3 ml).

4.1.2. *Use-specific risk mitigation measures*

In case of skin dryness, use appropriate skin care lotion

Use by children only under adult supervision when visiting hospitals.

Avoid contact with eyes.

Avoid unnecessary contact to skin.

Keep out of reach of children and pets.The following personal protective equipment (PPE) is stipulated 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

During refilling: The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

The product information (i.e. label and/or leaflet) shall clearly state that: for the following specific uses the product can be exceptionally used by the general public:

— Hygienic hand rub during home dialysis.

— Hygienic hand rub when entering/leaving hospitals.

Application by a non-professional is always carried out after professional instruction or under professional supervision.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 3.

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**

See use-specific risk mitigation measures.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)			Softalind Pro foam	Market area: EU	
Authorisation number			EU-0033840-0005 1-3		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 % (w/w)

1. **META SPC 4 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC: meta SPC 4

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

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

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4**

Hazard statements	H225: Highly 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	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. 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/face 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. P312: Call a POISON CENTER/doctor if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU liquid

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: Mycobacteria Common name: enveloped viruses
Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).

Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a patient room: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.1.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

Do not apply more than: 21 ml per m^2.

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 4.

4.2. **Use description**

Table 2

Surface disinfection RTU liquid

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
Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).

Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a kitchen: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.2.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (4°C, 10°C and 20°C):

— for the control of bacteria and yeasts: 2 minutes

Do not apply more than 21 ml per m^2.

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes

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

Only for treatment of small surfaces (up to 1 m^2).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 4.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 4**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)	Meliseptol Pro pure 88319	Market area: EU
Authorisation number	EU-0033840-0006 1-4	

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

1. **META SPC 5 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 5 identifier**

Identifier	Meta SPC: meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

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 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	20 - 20 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	10 - 10 % (w/w)

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

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5**

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	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. 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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell.

	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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam to extinguish. P403+P235: Store in a well-ventilated place. Keep cool. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU foam

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: Mycobacteria Common name: enveloped viruses Common name: viruses (limited spectrum virucidal activity)
Field(s) of use	indoor use The product is applied by foaming followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).
Application method(s)	Method: foaming followed by wiping Detailed description: The ready-to-use product is applied by foaming followed by wiping.

Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18 -21 ml per m^2 of surface. For foam spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a patient room: 1-2 times per day.
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottle with screwed foam head of pigmented PP Sizes: 750 ml pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.1.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection. For limited spectrum virucidal activity the surfaces should be cleaned before using the product and excessive amount of water should be removed prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by spraying from short distance with a pump spray head and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

— limited spectrum virucidal activity: 5 minutes

Do not apply more than 21 ml per m^2.

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 5.

4.2. **Use description**

Table 2

Surface disinfection RTU foam

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
Field(s) of use	indoor use The product is applied by foaming followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces in food contact (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).
Application method(s)	Method: foaming followed by wiping Detailed description: The ready-to-use product is applied by foaming followed by wiping.

Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For foam spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a kitchen: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottle with screwed foam head of pigmented PP Sizes: 750 ml pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.2.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by spraying from short distance with a pump spray head and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (20°C):

— for the control of bacteria and yeasts: 1 minute

Do not apply more than 21 ml per m^2.

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces (up to 1 m^2).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 5.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 5**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicalst.

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)		Meliseptol Pro foam		Market area: EU	
Authorisation number		EU-0033840-0007 1-5			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	20 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	10 % (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)**

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	20 - 20 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	10 - 10 % (w/w)

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

Formulation type(s)	Impregnated wipes

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	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. 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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P403+P233: Store in a well-ventilated place. Keep container tightly closed.

	P310: Immediately call a POISON CENTER/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam to extinguish. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of contents to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU wipes

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: Mycobacteria Common name: enveloped viruses Common name: viruses (limited spectrum virucidal activity)
Field(s) of use	indoor use The product is applied by wipe disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).
Application method(s)	Method: wiping Detailed description: The ready-to-use product is applied by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18,0 × 20,0 cm wipe – 2-4 wipes per m^2 24,0 × 30,0 cm wipe – 1-2 wipe per m^2 Frequency: reasonable application frequency in a patient room: 1-2 times per day.
Category(ies) of users	professional

Pack sizes and packaging material	HDPE Dispenser box with PP closure including a polyethylene terephthalate/ polyethylene (PET/PE) flow pack with 60 PET wipes (with refill pack) PET/PE Flow-pack with 100 PET wipes and PP flap cover PET/PE Flow-pack XL with 42 PET wipes and PP flap cover

4.1.1. *Use-specific instructions for use*

It is a ready-to-use pre-soaked disinfectant wipe. Surfaces should be visibly clean prior to disinfection. For limited spectrum virucidal activity the surfaces should be cleaned before using the product and excessive amount of water should be removed prior to disinfection.

The surface to be disinfected is wetted with a sufficient amount of wipes to completely wet the surface during the indicated exposure time. Only wet wipes shall be used.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

— limited spectrum virucidal activity: 5 minutes

18,0 × 20,0 cm wipe – 2-4 wipes per m^2

24,0 × 30,0 cm wipe – 1-2 wipe per m^2

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 6.

4.2. **Use description**

Table 2

Surface disinfection RTU wipes

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
Field(s) of use	indoor use The product is intended to be used for the control of bacteria and yeasts. The product is applied for wipe disinfection of alcohol-resistant small hard non-porous surfaces in food contact (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).
Application method(s)	Method: wiping Detailed description: The ready-to-use product is applied by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18,0 × 20,0 cm wipe – 2-4 wipes per m^2 24,0 × 30,0 cm wipe – 1-4 wipe per m^2 Frequency: Typical application frequency in a kitchen: 1-2 times per day.
Category(ies) of users	professional

Pack sizes and packaging material	HDPE Dispenser box with PP closure including a PET/PE flow pack with 60 PET wipes (with refill pack) PET/PE Flow-pack with 100 PET wipes and PP flap cover PET/PE Flow-pack XL with 42 PET wipes and PP flap cover

4.2.1. *Use-specific instructions for use*

It is a ready-to-use pre-soaked disinfectant wipe. Surfaces should be visibly clean prior to disinfection. The surface to be disinfected is wetted with a sufficient amount of wipes to completely wet the surface during the indicated exposure time. Only wet wipes shall be used.

Minimum exposure time (20°C):

— for the control of bacteria and yeasts: 1 minute

18,0 × 20,0 cm wipe – 2-4 wipes per m^2

24,0 × 30,0 cm wipe – 1-2 wipes per m^2

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces (up to $1m^2$).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 6.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 6**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value of 129,28 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)			Meliseptol Pro wipes	Market area: EU	
Authorisation number			EU-0033840-0008 1-6		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	20 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	10 % (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

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 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	25 - 25 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	20 - 20 % (w/w)

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

Formulation type(s)	AL Any other liquid

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	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. 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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU liquid

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: Mycobacteria Common name: enveloped viruses Common name: viruses (limited spectrum virucidal activity)
Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).
Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a patient room: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.1.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant. Surfaces should be visibly clean prior to disinfection. For limited spectrum virucidal activity the surfaces should be cleaned before using the product and excessive amount of water should be removed prior to disinfection. The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

— limited spectrum virucidal activity: 2 minutes

Do not apply more than 21 ml per m^2.

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 7.

4.2. **Use description**

Table 2

Surface disinfection RTU liquid

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
Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).
Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a kitchen: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.2.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant. Surfaces should be visibly clean prior to disinfection. The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (4°C, 10°C, 20°C):

— for the control of bacteria and yeasts: 1 minute

Do not apply more than 21 ml per m^2.

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces (up to 1 m^2).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 7.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 7**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value of 129,28 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)			Meliseptol Pro rapid		Market area: EU
Authorisation number			EU-0033840-0009 1-7		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	25 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	20 % (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**

Number	1-8

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	25 - 25 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	20 - 20 % (w/w)

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

Formulation type(s)	impregnated wipes

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

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU wipes

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: Mycobacteria Common name: enveloped viruses Common name: viruses (limited spectrum virucidal activity)
Field(s) of use	indoor use The product is applied by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).
Application method(s)	Method: wiping Detailed description: The ready-to-use product is applied by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18,0 × 20,0 cm wipe – 2-4 wipes per m^2 24,0 × 30,0 cm wipe – 1-2 wipe per m^2 Frequency: Typical application frequency in a patient room: 1-2 times per day.
Category(ies) of users	professional
Pack sizes and packaging material	HDPE Dispenser box with PP closure including a PET/PE flow pack with 60 PET wipes (with refill pack) PET/PE Flow-pack with 100 PET wipes and PP flap cover PET/PE Flow-pack XL with 42 PET wipes and PP flap cover

4.1.1. *Use-specific instructions for use*

It is a ready-to-use pre-soaked disinfectant wipe. Surfaces should be visibly clean prior to disinfection. For limited spectrum virucidal activity the surfaces should be cleaned before using the product and excessive amount of water should be removed prior to disinfection.The surface to be disinfected is wetted with a sufficient amount of wipes to completely wet the surface during the indicated exposure time. Only wet wipes shall be used.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

— limited spectrum virucidal activity: 2 minutes

18,0 × 20,0 cm – 2-4 wipes per m^2

24,0 × 30,0 cm wipe – 1-2 wipe per m^2

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 8.

4.2. **Use description**

Table 2

Surface disinfection RTU wipes

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
Field(s) of use	indoor use The product is applied by wiping for disinfection of alcohol-resistant small hard non-porous surfaces in food contact (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).
Application method(s)	Method: wiping Detailed description: The ready-to-use product is applied by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18,0 × 20,0 cm – 2-4 wipes per m^2 24,0 × 30,0 cm wipe – 1-2 wipe per m^2 Frequency: Typical application frequency in a kitchen: 1-2 times per day.
Category(ies) of users	professional
Pack sizes and packaging material	HDPE Dispenser box with PP closure including a PET/PE flow pack with 60 PET wipes (with refill pack) PET/PE Flow-pack with 100 PET wipes and PP flap cover PET/PE Flow-pack XL with 42 PET wipes and PP flap cover

4.2.1. *Use-specific instructions for use*

It is a ready-to-use pre-soaked disinfectant wipe. Surfaces should be visibly clean prior to disinfection.The surface to be disinfected is wetted with a sufficient amount of wipes to completely wet the surface during the indicated exposure time. Only wet wipes shall be used.

Minimum exposure time (4°C, 10°C, 20°C):

— for the control of bacteria and yeasts: 1 minute

18,0 × 20,0 cm – 2-4 wipes per m^2

24,0 × 30,0 cm wipe – 1-2 wipe per m^2

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces (up to 1 m^2).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 8.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 8**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)			Meliseptol Pro wipes rapid		Market area: EU
Authorisation number			EU-0033840-0010 1-8		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	25 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	20 % (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

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	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 9**

Formulation type(s)	AL Any other liquid

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	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.

	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/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. 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/doctor. P370+P378: In case of fire: Use water spray/dry powder/carbon dioxide/alcohol resistant foam 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 to hazardous waste disposal service in accordance with the statutory regulations. P501: Dispose of container to hazardous waste disposal service in accordance with the statutory regulations.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Surface disinfection RTU liquid

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: Mycobacteria Common name: enveloped viruses

Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other health care institutions such as in patient-near surrounding, ambulances, surgeries and nursing homes, e.g. incl. home-care of patients (excluding food contact surfaces).
Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a patient room: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.1.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (20°C):

— for the control of bacteria, mycobacteria, yeasts and enveloped viruses: 1 minute

Do not apply more than 21 ml per m^2

4.1.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

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

Only for treatment of small surfaces.

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 9.

4.2. **Use description**

Table 2

Surface disinfection RTU liquid

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: yeasts Common name: bacteria

Field(s) of use	indoor use The product is applied by spraying or pouring followed by wiping for disinfection of alcohol-resistant small hard non-porous surfaces (disinfection in the presence of soiling) in hospitals and other healthcare institutions, incl. hospital canteens and large kitchens (e.g. food processing, preparation and handling).
Application method(s)	Method: spraying or pouring followed by wiping Detailed description: The ready-to-use product is applied by pouring or trigger spraying followed by wiping.
Application rate(s) and frequency	undiluted; ready-to-use product Number and timing of application: Application rate: Use sufficient product to ensure complete coverage. 18-21 ml per m^2 of surface. For trigger spraying this corresponds to approximately 23 - 26 sprays per m^2 or 12 - 13 sprays per 0,5 m^2. Frequency: Typical application frequency in a kitchen: 1-2 times per day
Category(ies) of users	professional
Pack sizes and packaging material	pigmented/transparent HDPE bottles, closed with screwed flip top caps of pigmented PP. Sizes: 250/500/1 000ml (accessory: PP spray head) pigmented/transparent HDPE canister with screwed caps of pigmented HDPE. Sizes: 5 000 ml

4.2.1. *Use-specific instructions for use*

It is a ready-to-use surface disinfectant.

Surfaces should be visibly clean prior to disinfection.

The entire surface to be disinfected is wetted with a sufficient amount of the product by pouring or spraying from short distance with a pump spray head as a possible application aid and subsequently thoroughly wiped with a cloth.

Make sure that the surface to be disinfected is completely wetted.

Minimum exposure time (4°C, 10°C and 20°C):

— for the control of bacteria and yeasts: 2 minutes

Do not apply more than:

— 21 ml per m^2

4.2.2. *Use-specific risk mitigation measures*

For professional use only.

Avoid contact with eyes.

Only for treatment of small surfaces (up to 1 m^2).

The following personal protective equipment (PPE) is stipulated 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

The use of eye protection (goggles) [consistent with the European standard EN 166] during handling of the product is mandatory.

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*

Likely direct or indirect effects: May cause drowsiness or dizziness. Causes serious eye damage

General information: Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible show this sheet.

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 ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Contaminated packaging: Re-using the polluted packaging materials is not allowed.

Packaging that cannot be cleaned should be disposed of like the product.

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 directions for use of meta SPC 9.

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 9**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

See use-specific instructions and measures.

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

See use-specific instructions.

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

Shelf-life: 24 months.

Requirements for storage rooms and vessels:

Keep container tightly closed in a dry, cool and well-ventilated place.

Further information on storage conditions: Keep away from food, drink and animal feeding stuffs.

Store below 40°C.

6. **OTHER INFORMATION**

Please be aware of the European reference value 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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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

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

EN 166 – Eye protection against chemicals

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)			Meliseptol Pro pure 88321	Market area: EU	
Authorisation number			EU-0033840-0011 1-9		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	30 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	45 % (w/w)