

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1282
of 8 July 2022
granting a Union authorisation for the biocidal product family 'Knieler & Team Propanol Family'
(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 17 April 2019, Knieler & Team GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Knieler & Team 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 Switzerland had agreed to evaluate the application. The application was recorded under case number BC-AQ050985-22 in the Register for Biocidal Products.
- (2) 'Knieler & Team Propanol Family' contains propan-1-ol and propan-2-ol, as the active substances, which are 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 29 March 2021, 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 European Chemicals Agency ('the Agency').
- (4) On 4 November 2021, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics ('SPC') of 'Knieler & Team 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 'Knieler & Team 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(1) and (6) of that Regulation.
- (6) On 22 November 2021, 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 'Knieler & Team Propanol Family'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on biocidal products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 7 October 2021 on the Union authorisation of 'Knieler & Team Propanol Family' (ECHA/BPC/292/2021), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027467-0000 is granted to Knieler & team GmbH for the making available on the market and use of the biocidal product family 'Knieler & Team Propanol Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 11 August 2022 to 31 July 2032.

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, 8 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Knieler & Team Propanol Family

Product type 1 - Human hygiene (Disinfectants)

Product type 2 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0027467-0000

R4BP asset number: EU-0027467-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Knieler & Team Propanol Family
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1.2. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Knieler & Team GmbH
	Address	Kattrepelsbrücke 1, 20095 Hamburg Germany
Authorisation number	EU-0027467-0000	
R4BP asset number	EU-0027467-0000	
Date of the authorisation	11 August 2022	
Expiry date of the authorisation	31 July 2032	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Knieler & Team GmbH
Address of manufacturer	Kattrepelsbrücke 1, 20095 Hamburg Germany
Location of manufacturing sites	Knieler & Team GmbH, Kattrepelsbrücke 1, 20095 Hamburg Germany

	A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto-Brenner-Straße 16-18, 21337 Lüneburg Germany
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1.5. Manufacturer(s) of the active substance(s)

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 Corporation (formerly Oxea Corporation), 2001 FM 3057 TX, 77414 Bay City United States

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

Active substance	Propan-1-ol
Name of manufacturer	SASOL Chemie GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	Stockmeier Chemie GmbH & Co. KG
Address of manufacturer	Am Stadtholz 37, 33609 Bielefeld Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1, 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., 3196 KK Rotterdam-Pernis Netherlands Exxon Mobil, LA 70805 Baton Rouge United States

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvent Germany GmbH

Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	63,14

2.2. Type(s) of formulation

Formulation(s)	AL - Any other liquid
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PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta SPC 1
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT01 - Human hygiene (Disinfectants)
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2. META SPC 1 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0	45,0

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

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

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Mycobacteria Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <ul style="list-style-type: none"> — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands — for professional use only
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml) Contact time: 30 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	<p>Industrial Professional</p>
Pack sizes and packaging material	<p>100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap.</p> <p>In addition, exclusively for E-HDL (product 1.2): 500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.</p>

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 1

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

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

Use # 2 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Mycobacteria Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.</p>
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	Professional

Pack sizes and packaging material	<p>100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps;</p> <p>5 000 ml transparent/white HDPE canister with HDPE screwed cap.</p> <p>In addition, exclusively for E-HDL (product 1.2):</p> <p>500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.</p>
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4.2.1. *Use-specific instructions for use*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

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*

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

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 ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	A-HDL		Market area: EU		
Authorisation number	EU-0027467-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

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

Trade name(s)	E-HDL		Market area: EU		
Authorisation number	EU-0027467-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

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

Trade name(s)	H-HDL		Market area: EU		
Authorisation number	EU-0027467-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT01 - Human hygiene (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	20,0	20,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0	60,0

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

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

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 3

Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	<p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <ul style="list-style-type: none"> — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands — for professional use only.
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	<p>Industrial Professional</p>
Pack sizes and packaging material	<p>1 50, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps;</p> <p>5 000 ml HDPE canister with transparent/white HDPE screwed cap;</p> <p>700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.</p>

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 2

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 2

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

See general directions for use of meta SPC 2

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 4

Use # 2 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.</p>
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml Contact time: 90 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps;

	5 000 ml HDPE canister with transparent/white HDPE screwed cap; 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.
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4.2.1. *Use-specific instructions for use*

The product can be applied directly or the product can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 2

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*

See general directions for use of meta 2

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

See general directions for use of meta 2

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 2

5. GENERAL DIRECTIONS FOR USE ^(?) OF THE META SPC 2

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

^(?) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feeding stuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	C-HDL		Market area: EU		
Authorisation number	EU-0027467-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	20,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3
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1.2. **Suffix to the authorisation number**

Number	1-3
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1.3. **Product type(s)**

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751	63,14

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

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

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

	<p>Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.</p>
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4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 5

Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <ul style="list-style-type: none"> — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands — For professional use only.
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	<p>Industrial Professional</p>

Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for D-HDL (product 3.1): 100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap. In addition, exclusively for B-HDL (product 3.3): 700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.
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4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 3

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

4.2. Use description

Table 6

Use # 2 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: enveloped viruses Development stage:</p>

Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for D-HDL (product 3.1): 100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap. In addition, exclusively for B-HDL (product 3.3): 700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.

4.2.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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 3

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 3

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

6. OTHER INFORMATION

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)	D-HDL		Market area: EU		
Authorisation number	EU-0027467-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751

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

Trade name(s)	G-HDL		Market area: EU		
Authorisation number	EU-0027467-0006 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

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

Trade name(s)	B-HDL		Market area: EU		
Authorisation number	EU-0027467-0007 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4
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1.2. **Suffix to the authorisation number**

Number	1-4
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1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)
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2. META SPC 4 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0	45,0

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

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

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

	<p>Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.</p>
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4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 7

Use # 1 – hygienic handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Mycobacteria Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <ul style="list-style-type: none"> — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. — For professional use only.
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	<p>Industrial Professional</p>

Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for E-HDG (product 4.2): 500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.
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4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 4

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

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 8

Use # 2 – surgical handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Mycobacteria Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: enveloped viruses Development stage:</p>

Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for E-HDG (product 4.2): 500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.

4.2.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

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**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

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)	A-HDG		Market area: EU		
Authorisation number	EU-0027467-0008 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

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

Trade name(s)	E-HDG		Market area: EU		
Authorisation number	EU-0027467-0009 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta SPC 5
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT01 - Human hygiene (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	15,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0	63,14

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

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

Table 9

Use # 1 – hygienic handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	<p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <ul style="list-style-type: none"> — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. — For professional use only.
Application method(s)	<p>Method: Manual application Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	<p>Industrial Professional</p>
Pack sizes and packaging material	<p>125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps;</p> <p>5 000 ml transparent/white HDPE canister with HDPE screwed cap.</p> <p>In addition, exclusively for C-HDG (product 5.1): 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.</p> <p>In addition, exclusively for B-HDG (product 5.2): 700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.</p>

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 5

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

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 10

Use # 2 – surgical handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.</p>
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Rubbing</p>
Application rate(s) and frequency	<p>Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.</p>
Category(ies) of users	Professional

Pack sizes and packaging material	<p>125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps;</p> <p>5 000 ml transparent/white HDPE canister with HDPE screwed cap.</p> <p>In addition, exclusively for C-HDG (product 5.1): 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.</p> <p>In addition, exclusively for B-HDG (product 5.2): 700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.</p>
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4.2.1. *Use-specific instructions for use*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 5

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*

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

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**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	C-HDG		Market area: EU		
Authorisation number	EU-0027467-0010 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	15,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0

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

Trade name(s)	B-HDG		Market area: EU		
Authorisation number	EU-0027467-0011 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	meta SPC 6
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	40,0

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

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. Wear eye protection.. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. **Use description**

Table 11

Use # 1 – hard non-porous small surface disinfection RTU liquid

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: viruses (limited spectrum virucidal activity) Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.

Application method(s)	<p>Method: Manual application</p> <p>Detailed description:</p> <p>Ready-to-use surface disinfectant at room temperature (20±2 °C).</p> <p>The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m² to keep the surface wet during the contact time).</p>
Application rate(s) and frequency	<p>Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec • for the control of viruses (limited spectrum virucidal activity): 5 min</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.</p>
Category(ies) of users	<p>Industrial Professional</p>
Pack sizes and packaging material	<p>100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.</p>

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 6

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 6

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

See general directions for use of meta SPC 6

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 12

Use # 2 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants: disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m ²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 6

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*

See general directions for use of meta SPC 6

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

See general directions for use of meta SPC 6

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 ⁽⁹⁾ OF THE META SPC 6

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

The use of eye protection during handling of the product is mandatory.

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**

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

⁽⁹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	F-FDL		Market area: EU		
Authorisation number	EU-0027467-0012 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0

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

Trade name(s)	A-FDL		Market area: EU		
Authorisation number	EU-0027467-0013 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	35,0

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

Trade name(s)	C-FDL		Market area: EU		
Authorisation number	EU-0027467-0014 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	40,0

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

Trade name(s)	E-FDL	Market area: EU			
Authorisation number	EU-0027467-0015 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	40,0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

Identifier	meta SPC 7
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1.2. Suffix to the authorisation number

Number	1-7
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73	63,14

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

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. Wear eye protection. Immediately call a POISON CENTER/doctor. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. Use description

Table 13

Use # 1 – hard non-porous small surface disinfection RTU liquid

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example in patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C).

	The entire surface to be disinfected is wetted by pouring or spraying from short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m ²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	125, 150, 500, 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.1.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 7

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 7

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

See general directions for use of meta SPC 7

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 14

Use # 2 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m ²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	125, 150, 500, 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 7

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

See general directions for use of meta SPC 7

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

See general directions for use of meta SPC 7

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 ⁽⁷⁾ OF THE META SPC 7

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

The use of eye protection during handling of the product is mandatory.

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**

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

⁽⁷⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

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)	D-FDL		Market area: EU		
Authorisation number	EU-0027467-0016 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73

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

Trade name(s)	B-FDL		Market area: EU		
Authorisation number	EU-0027467-0017 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	meta SPC 8
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1.2. Suffix to the authorisation number

Number	1-8
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	40,0

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

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

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 15

Use # 1 – hard non-porous small surface disinfection RTU wipes

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	<p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: viruses (limited spectrum virucidal activity) Development stage:</p>
Field(s) of use	<p>Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.</p>
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C).</p> <p>The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete coverage.</p>
Application rate(s) and frequency	<p>Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec • for the control of viruses (limited spectrum virucidal activity): 5 min; Make the surface completely wet.</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.</p>
Category(ies) of users	<p>Industrial Professional</p>
Pack sizes and packaging material	<p>Flow-pack of white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% Viscose and 70% Polyethylene Terephthalate (VIS/PET) wipes.</p> <p>Exclusively for C-FDT (product 8.2):</p> <p>Transparent high-density polyethylene (HDPE) Canister with PP screwed cap, containing 30 PET wipes;</p> <p>Dispenser bag of white PE composite foil, containing 30 or 90 PET wipes used with dispenser box.</p>

4.1.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 8.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 8.

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

See general directions for use of meta SPC 8

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 16

Use # 2 – hard non-porous small surface disinfection RTU wipes

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and food industry, for example food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product by wiping, ensuring complete coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet Dilution (%): Ready-to-use product Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% viscose and 70% polyethylene terephthalate (VIS/PET) wipes. Exclusively for C-FDT (product 8.2): Transparent high-density polyethylene (HDPE) Canister with PP screwed cap, containing 30 PET wipes; Dispenser bag of white PE composite foil, containing 30 or 90 PET wipes used with dispenser box.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 8

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

See general directions for use of meta SPC 8

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

See general directions for use of meta SPC 8

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 ⁽⁸⁾ OF THE META SPC 8

5.1. **Instructions for use**

For professional use only.

For wipes reseal the package after opening.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

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**

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.

Information to Healthcare personnel/doctor:

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

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.

⁽⁸⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	F-FDT		Market area: EU		
Authorisation number	EU-0027467-0018 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0

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

Trade name(s)	C-FDT		Market area: EU		
Authorisation number	EU-0027467-0019 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	40,0

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 9 identifier**

Identifier	meta SPC 9
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1.2. **Suffix to the authorisation number**

Number	1-9
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1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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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 (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73	63,14

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

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED:Remove person to fresh air and keep comfortable for breathing.

	<p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to an authorised waste collection point.</p>
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4. AUTHORISED USE(S) OF THE META SPC 9

4.1. Use description

Table 17

Use # 1 – hard non-porous small surface disinfection RTU wipes

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage:</p> <p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces For professional use only.</p>
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete Coverage.</p>
Application rate(s) and frequency	<p>Application Rate: Minimum exposure time: for the control of bacteria, yeasts and enveloped viruses: 60 sec; Make the surface completely wet.</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.</p>

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 9

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 9

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

See general directions for use of meta SPC 9

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 18

Use # 2 – hard non-porous small surface disinfection RTU wipes

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and food industry, for example patient-near surrounding, food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.

Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wetted with a sufficient amount of the product by wiping, ensuring complete coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 9

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

See general directions for use of meta SPC 9

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

See general directions for use of meta SPC 9

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

For professional use only.

For wipes reseal the package after opening.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 9.

5.2. Risk mitigation measures

Avoid contact with eyes.

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

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.

Information to Healthcare personnel/doctor:

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

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.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feeding stuff. Keep away from combustible material.

6. OTHER INFORMATION

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)	D-FDT		Market area: EU		
Authorisation number	EU-0027467-0020 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73

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

Trade name(s)	B-FDT		Market area: EU		
Authorisation number	EU-0027467-0021 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14