#### **COMMISSION IMPLEMENTING REGULATION (EU) 2023/2087**

#### of 28 September 2023

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

#### Whereas:

- (1) On 25 November 2022, Lysoform Dr Hans Rosemann GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 (²) for authorisation of a same biocidal product family, as referred to in Article 1 of that Regulation, named 'Lysoform IPA Surface', for product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-DP082158-26 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Lyso IPA Surface Disinfection', recorded in the Register under case number BC-GX025200-35.
- (2) The same biocidal product family 'Lysoform IPA Surface' contains propan-2-ol as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 31 March 2023, the Agency submitted to the Commission its opinion (3) and the draft summary of the biocidal product characteristics ('SPC') of 'Lysoform IPA Surface' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same biocidal product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Lyso IPA Surface Disinfection' and subject to compliance with the draft SPC, the same biocidal product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.
- (5) On 31 March 2023, 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.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same biocidal product family 'Lysoform IPA Surface'.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

<sup>(3)</sup> ECHA opinion for 'Lysoform IPA Surface', 31 March 2023, https://echa.europa.eu/opinions-on-union-authorisation.

<sup>(4)</sup> Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

- (7) The expiry date of this authorisation is aligned to the expiry date of the reference biocidal product family 'Lyso IPA Surface Disinfection'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

#### Article 1

A Union authorisation with authorisation number EU-0030790-0000 is hereby granted to Lysoform Dr Hans Rosemann GmbH for the making available on the market and use of the same biocidal product family 'Lysoform IPA Surface' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 19 October 2023 until 30 November 2030.

#### 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, 28 September 2023.

For the Commission The President Ursula VON DER LEYEN

#### ANNEX

## Summary of product characteristics for a biocidal product family

## **Lysoform IPA Surface**

# Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0030790-0000

R4BP asset number: EU-0030790-0000

#### PART I

#### FIRST INFORMATION LEVEL

#### 1. ADMINISTRATIVE INFORMATION

## 1.1. Family name

Name	Lysoform IPA Surface

## 1.2. **Product type(s)**

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

## 1.3. Authorisation holder

Name and address of the authorisation holder	Name Lysoform Dr Hans Rosemann GmbH		
	Address	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany	
Authorisation number	EU-0030790-0000		
R4BP asset number	EU-0030790-0000		
Date of the authorisation	19 October 2023		
Expiry date of the authorisation	30 November 20	030	

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

Name of manufacturer	Lysoform Dr Hans Rosemann GmbH	
Address of manufacturer	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany	
Location of manufacturing sites	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany	
Name of manufacturer	Imeco	
Address of manufacturer	Boschstr. 5, 63768 Hösbach Germany	

Location of manufacturing sites	Boschstr. 5, 63768 Hösbach Germany
	Neue Straße 2-4, 09471 Köningswalde Germany
Name of manufacturer	A.F.P. GmbH
Address of manufacturer	Otto Brenner Straße 16, 21337 Lüneburg Germany
Location of manufacturing sites	Otto Brenner Straße 16, 21337 Lüneburg Germany
Name of manufacturer	Sterisol AB
Address of manufacturer	Kronoängsgatan 3, 592 23 Vadstena Sweden
Location of manufacturing sites	Kronoängsgatan 3, 592 23 Vadstena Sweden
Name of manufacturer	WHR GmbH
Address of manufacturer	Am Galgenturm 2, 97638 Mellrichstadt Germany
Location of manufacturing sites	Am Galgenturm 2, 97638 Mellrichstadt Germany
Name of manufacturer	Hygan GmbH   Srl
Address of manufacturer	Meucci-Str. 5, 39055 Leifers   Laives (BZ) Italy
Location of manufacturing sites	Meucci-Str. 5, 39055 Leifers   Laives (BZ) Italy
Name of manufacturer	Laboratoire Sarbec SA
Address of manufacturer	10 rue du Vertuquet, 59960 Neuville-en-Ferrain France
Location of manufacturing sites	10 rue du Vertuquet, 59960 Neuville-en-Ferrain France
Name of manufacturer	Dr Schumacher GmbH
Address of manufacturer	Am Roggenfeld 3, 34323 Malsfeld Germany
Location of manufacturing sites	Am Roggenfeld 3, 34323 Malsfeld Germany Jeleniogórska 12, 59-800 Lubań Poland

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

Active substance	Propan-2-ol	
Name of manufacturer	Ineos Solvents Germany GmbH (formerly Sasol)	
Address of manufacturer	Römerstraße 733, 47443 Moers Germany	
Location of manufacturing sites	Römerstraße 733, 47443 Moers Germany Shamrockstr. 88, 44643 Herne Germany	
Active substance	Propan-2-ol	
Name of manufacturer	Shell Chemicals Europe B.V.	
Address of manufacturer	Postbus 2334, 3000 CH Rotterdam Netherlands	
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam-Pernis Netherlands	

### 2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name IUPAC name	HIDAC	Function	CAS number	EC number	Content (%)	
	TOPAC name				Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

## 2.2. Type(s) of formulation

Formulation(s)	Any other liquid (AL), ready-to-use
	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

#### PART II

### SECOND INFORMATION LEVEL – META SPC(S)

### **META SPC 1**

#### 1. META SPC 1 ADMINISTRATIVE INFORMATION

#### 1.1. Meta SPC 1 identifier

Identifier	Superficid®
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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)	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 1 COMPOSITION

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

Common name IUPAC name	H IDA C	Function	CAS number	EC number	Content (%)	
	TOPAC name				Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

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

Hazard statements	Highly flammable liquid and vapour.
	Causes serious eye irritation.
	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.
	Ground and bond container and receiving equipment.
	Use explosion-proof electrical/ventilating/lighting equipment.
	Use non-sparking tools.
	Take action to prevent static discharges.
	Avoid breathing vapours.
	Avoid breathing spray.
	Use only outdoors or in a well-ventilated area.
	Wear eye protection.
	IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.
	Call a POISON CENTER or doctor if you feel unwell.
	If eye irritation persists:Get medical advice.
	If eye irritation persists:Get medical attention.
	In case of fire:Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	Store in a well-ventilated place. Keep cool.
	Store locked up.
	Dispose of contents to/container to an approved waste disposal plant.

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

## 4.1. Use description

Table 1

## Use # 1 disinfection of surfaces – spraying

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

Target organism(s) (including development stage)	Scientific name: Bacteria		
development stage)	Common name: -		
	Development stage: -		
	Scientific name: Yeast		
	Common name: -		
	Development stage: -		
Field(s) of use	Indoor		
	Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)		
Application method(s)	Method: Spraying		
	Detailed description:		
	Product will be sprayed directly on the surface.		
Application rate(s) and frequency	Application Rate: Ready-to-use. Do not apply more than 25 ml/m².		
	Dilution (%): -		
	Number and timing of application:		
	-		
Category(ies) of users	Industrial		
	Professional		
Pack sizes and packaging material	Bottle: 125-1 000 ml		
	packaging material: HDPE		
	Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)		

### 4.1.1. Use-specific instructions for use

Spray ready-to-use product onto the surfaces and allow to take effect for at least 1 minute at room temperature (20 ± 2 °C).

## 4.1.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

- 4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging
- $4.1.5. \ \ Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage$

See general directions for use.

## 4.2. Use description

Table 2

## Use # 2 – disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: -		
	Scientific name: Yeast Common name: - Development stage: -		
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)		
Application method(s)	Method: Wiping  Detailed description:  Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).		
Application rate(s) and frequency	Application Rate: Ready-to-use. Do not apply more than 25 ml/m².  Dilution (%): -  Number and timing of application: -		
Category(ies) of users	Industrial Professional		

Pack sizes and packaging material	Bottle: 125-1 000 ml
	packaging material: HDPE
	Clack cap material: PP
	Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel);
	Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)
	Canister: 5-30 L
	packaging material: HDPE
	closure material: HDPE

#### 4.2.1. Use-specific instructions for use

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature ( $20 \pm 2$  °C).

### 4.2.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

#### 4.3. Use description

Table 3

Use # 3 – disinfection of surfaces with food and feed contact – spraying

Product type	PT04 - Food and feed area (Disinfectants)		
Where relevant, an exact description of the authorised use	-		

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -			
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)			
Application method(s)	Method: Spraying  Detailed description: Product will be sprayed directly on the surface.			
Application rate(s) and frequency	Application Rate: Ready-to-use. Do not apply more than 25 ml/m².  Dilution (%): -  Number and timing of application: -			
Category(ies) of users	Industrial Professional			
Pack sizes and packaging material	Bottle: 125-1 000 ml  packaging material: HDPE  Clack cap material: PP  Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel)  Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)			

#### 4.3.1. Use-specific instructions for use

Spray ready-to-use product onto the surface and allow to take effect at room temperature ( $20 \pm 2$  °C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

### 4.3.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

### 4.4. Use description

Use # 4 – disinfection of surfaces with food and feed contact – wiping

Table 4

Product type	PT04 – Food and feed area (Disinfectants)			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including	Scientific name: Bacteria			
development stage)	Common name: -			
	Development stage: -			
	Scientific name: Yeast			
	Common name: -			
	Development stage: -			
	Scientific name: Viruses			
	Common name: -			
	Development stage: -			
Field(s) of use	Indoor			
(-)	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)			
Application method(s)	Method: Wiping			
	Detailed description:			
	Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).			
Application rate(s) and frequency	Application Rate: Ready-to-use. Do not apply more than 25 ml/m².			
	Dilution (%): -			
	Number and timing of application:			
	-			
Category(ies) of users	Industrial			
	Professional			

Pack sizes and packaging material	Bottle: 125-1 000 ml			
	packaging material: HDPE			
	Clack cap material: PP			
	Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel);			
	Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)			
	Canister: 5-30 L			
	packaging material: HDPE			
	closure material: HDPE			

#### 4.4.1. Use-specific instructions for use

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature ( $20 \pm 2$  °C).

#### 4.4.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

- 4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging
- 4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 5. GENERAL DIRECTIONS FOR USE (1) OF THE META SPC 1

#### 5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m<sup>2</sup>.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

<sup>(1)</sup> 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.

#### 5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

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

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

#### 6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

#### 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)	Superficid®	Market area: EU
	Desocid rapid	Market area: EU
	Neoseptin rapid	Market area: EU
	Novosept rapid	Market area: EU
	Novoseptin rapid	Market area: EU

	Lyorthol rapid		Market area: EU		
	Cosmo rapid Fordesin rapid Saltero rapid Prop70 rapid Aldovet rapid Vetfarm rapid MDI rapid Antiseptica rapid Sterisol Surface		Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
			Market area: EU		
	MENNO® I-QUICK plus		Market area: EU		
Authorisation number	EU-0030790-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

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

Trade name(s)	Superficid® pure	Market area: EU
	Desocid rapid pure	Market area: EU
	Neoseptin rapid pure	Market area: EU
	Novosept rapid pure	Market area: EU
	Novoseptin rapid pure	Market area: EU
	Lyorthol rapid pure	Market area: EU
	Cosmo rapid pure	Market area: EU
	Fordesin rapid pure	Market area: EU
	Saltero rapid pure	Market area: EU
	Prop70 rapid pure	Market area: EU
	Aldovet rapid pure	Market area: EU
	Vetfarm rapid pure	Market area: EU
	MDI rapid pure	Market area: EU
	Antiseptica rapid pure	Market area: EU
	Sterisol Surface pure	Market area: EU
	BTS 6000	Market area: EU
	MENNO® I-QUICK	Market area: EU
	EWA® DES ready	Market area: EU
	Kiehl-Rapinol	Market area: EU
	Des A	Market area: EU

Authorisation number	EU-0030790-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

### META SPC 2

#### 1. META SPC 2 ADMINISTRATIVE INFORMATION

### 1.1. Meta SPC 2 identifier

#### 1.2. Suffix to the authorisation number

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

<b>7.</b>	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
	PT04 – Food and feed area (Disinfectants)

## 2. META SPC 2 COMPOSITION

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

Common name	II IDAC mama	Function CAS number EC number	EC mumb on	Content (%)		
	IUPAC name		CAS number	EC number	Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Highly flammable liquid and vapour.	
	Causes serious eye irritation.	
	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.
	Ground and bond container and receiving equipment.
	Use explosion-proof electrical/ventilating/lighting equipment.
	Use non-sparking tools.
	Take action to prevent static discharges.
	Avoid breathing vapours.
	Avoid breathing spray.
	Use only outdoors or in a well-ventilated area.
	Wear eye protection.
	IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.
	Call a POISON CENTER or doctor if you feel unwell.
	If eye irritation persists:Get medical advice.
	If eye irritation persists:Get medical attention.
	In case of fire:Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.
	Store in a well-ventilated place.Keep cool.
	Store locked up.
	Dispose of contents to/container to an approved waste disposal plant.

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

## 4.1. Use description

Table 5

## Use # 1 – disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: -  Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)	Method: Wiping Detailed description: Product will be wiped directly on the surface.
	,
Application rate(s) and frequency	Application Rate: Ready-to-use wipes
	Dilution (%): -
	Number and timing of application:
	-
Category(ies) of users	Industrial
	Professional
Pack sizes and packaging material	Can: 100-150 wipes
	Packaging: HDPE
	Closure material: HDPE
	Pack: 100-150 wipes
	Packaging: PET/PE

### 4.1.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

## 4.1.2. Use-specific risk mitigation measures

See general directions for use.

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.

- 4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging
- 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.2. Use description

Table 6

Use # 2 - disinfection of surfaces with food and feed contact - wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-



Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Method: Wiping  Detailed description:  Product will be wiped directly on the surface.
Application rate(s) and frequency	Application Rate: Ready-to-use wipes  Dilution (%): -  Number and timing of application: -
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

## 4.2.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20  $\pm$  2 °C).

## 4.2.2. Use-specific risk mitigation measures

See general directions for use.

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.

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

See general directions for use.

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

#### 5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

#### Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

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

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

<sup>(2)</sup> 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.

### 6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No: 67-63-0), for which a European reference value of  $129,28 \text{ mg/m}^3$  for the professional user was agreed and used for the risk assessment of the product.

### 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)	Descorapid® Tücher	Market area: EU		
	Desocid Tücher	Market area: EU		
	Neoseptin Tücher	Market area: EU		
	Novosept Tücher	Market area: EU		
	Novoseptin Tücher	Market area: EU		
	Lyorthol Tücher	Market area: EU		
	Cosmo Tücher	Market area: EU		
	Fordesin Tücher	Market area: EU		
	Saltero Tücher	Market area: EU		
	Prop70 Tücher	Market area: EU		
	Manosafe Tücher	Market area: EU		
	Dermoguard Tücher	Market area: EU		
	Dermosafe Tücher	Market area: EU		
	Aldovet Tücher	Market area: EU		
	Vetfarm Tücher	Market area: EU		
	MDI Tücher	Market area: EU		
	Antiseptica Tücher	Market area: EU		
	Antiseptica wipes	Market area: EU		
	MENNO@WIP	Market area: EU		
	Descorapid® wipes	Market area: EU		
	Desocid wipes	Market area: EU		
	Neoseptin wipes	Market area: EU		
	Novosept wipes	Market area: EU		
	Novoseptin wipes	Market area: EU		
	Lyorthol wipes	Market area: EU		
	Cosmo wipes	Market area: EU		
	Fordesin wipes	Market area: EU		
	Saltero wipes	Market area: EU		
	Prop70 wipes	Market area: EU		
	Manosafe wipes	Market area: EU		
	Dermoguard wipes	Market area: EU		
	Dermosafe wipes	Market area: EU		
	Aldovet wipes	Market area: EU		

	Vetfarm wipes		Market area: EU				
	MDI wipes Antiseptica wipes		Market area: EU				
			Market area: EU				
Authorisation number	EU-0030790-0003 1-2						
Common name	IUPAC name	Function	CAS number	EC number	Content (%)		
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1		

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

Trade name(s)	Superficid® pure wipes		Market area: EU				
	Desocid rapid pure wipes		Market area: EU				
	Neoseptin rapid 1	Neoseptin rapid pure wipes					
	Novosept rapid p	Novosept rapid pure wipes		Market area: EU			
	Novoseptin rapid pure wipes		Market area: EU				
	Lyorthol rapid pure wipes		Market area: EU				
	Cosmo rapid pure wipes		Market area: EU				
	Fordesin rapid pure wipes		Market area: EU				
	Saltero rapid pure wipes		Market area: EU				
	Prop70 rapid pui	Prop70 rapid pure wipes		Market area: EU			
	Aldovet rapid pure wipes		Market area: EU				
	Vetfarm rapid pure wipes		Market area: EU				
	MDI rapid pure wipes		Market area: EU				
	Antiseptica rapid pure wipes		Market area: EU				
Authorisation number	EU-0030790-0004 1-2						
Common name	IUPAC name	Function	CAS number	EC number	Content (%)		
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1		