



COMMISSION IMPLEMENTING REGULATION (EU) 2023/364
of 16 February 2023
granting a Union authorisation for the biocidal product family ‘IPA Family 1’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

Article 1

A Union authorisation with authorisation number EU-0028425-0000 is hereby granted to Ecolab Deutschland GmbH for the making available on the market and use of the biocidal product family ‘IPA Family 1’ subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 9 March 2023 to 28 February 2033.

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.

*ANNEX I***Terms and conditions (EU-0028425-0000)**

The authorisation holder shall conduct a long-term ambient storage stability test of 'Klercide 70/30 IPA Aerosol' of meta-SPC 1.3 in the commercial packaging in which the product will be made available on the market. The long-term ambient storage stability test shall address the relevant physical, chemical and technical properties of that product both prior to and after storage in accordance with section 2.6.4 of the Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment (ECHA, March 2022) ⁽¹⁾, in order to confirm a shelf life of 24 months. The authorisation holder shall include in the study report information about the packaging stability, the spray characteristics and internal pressure before and after storage.

By 9 January 2024 the authorisation holder shall submit the results of the study to the Agency.

⁽¹⁾ https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b

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ANNEX II

Summary of product characteristics for a biocidal product family

IPA Family 1

Product type(s)

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

PT04: Food and feed area

Authorisation number EU-0028425-0000**R4BP asset number** EU-0028425-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	IPA Family 1
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1.2. Product type(s)

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

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1 40789 Monheim am Rhein Germany
Authorisation number	EU-0028425-0000	
<i>R4BP asset number</i>	EU-0028425-0000	
Date of the authorisation	9.3.2023	
Expiry date of the authorisation	28.2.2033	

1.4. Manufacturer(s) of the product

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtstrasse, 7 8304 Walliselen Switzerland
Location of manufacturing sites	Ecolab Europe GmbH site 1 Richtstrasse, 7 8304 Walliselen Switzerland

Name of manufacturer	Ecolab Limited
Address of manufacturer	Brunel Way, Baglan Energy Park, SA11 2GA Neath United Kingdom of Great Britain and Northern Ireland (the)

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Location of manufacturing sites	Ecolab Limited site 1 Brunel Way, Baglan Energy Park, SA11 2GA Neath United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Ecolab Leeds
Address of manufacturer	Lotherton Way, Garforth, LS25 2JY Leeds United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Ecolab Leeds site 1 Lotherton Way, Garforth, LS25 2JY Leeds United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Esoform S.p.A.
Address of manufacturer	Viale del Lavoro 10, 45100 Rovigo Italy
Location of manufacturing sites	Esoform S.p.A. site 1 Viale del Lavoro 10, 45100 Rovigo Italy
Name of manufacturer	Nalco Deutschland Manufacturing GmbH und Co.KG
Address of manufacturer	Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany
Location of manufacturing sites	Nalco Deutschland Manufacturing GmbH und Co.KG site 1 Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany
Name of manufacturer	Ecolab NETHERLANDS BV
Address of manufacturer	Brugwal 11, 3432NZ Nieuwegein Netherlands (the)
Location of manufacturing sites	Ecolab NETHERLANDS BV site 1 Brugwal 11, 3432NZ Nieuwegein Netherlands (the)
Name of manufacturer	Ecolab Weavergate
Address of manufacturer	Winnington Avenue CW8 3AA Northwich Cheshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Ecolab Weavergate site 1 Winnington Avenue CW8 3AA Northwich Cheshire United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Ecolab Mullingar, Ireland
Address of manufacturer	Forest Park, Zone C Mullingar Ind. Estate, - Mullingar, Co. Westmeath, Ireland
Location of manufacturing sites	Ecolab Mullingar, Ireland site 1 Forest Park, Zone C Mullingar Ind. Estate, - Mullingar, Co. Westmeath, Ireland

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Name of manufacturer	Ecolab d.o.o.
Address of manufacturer	Vajngerlova 4 2000 Maribor Slovenia
Location of manufacturing sites	Ecolab d.o.o. site 1 Vajngerlova 4 2000 Maribor Slovenia
Name of manufacturer	Ecolab Rozzano, Italy
Address of manufacturer	Via A. Grandi 9/11, 20089 Rozzano (MI) Italy
Location of manufacturing sites	Ecolab Rozzano, Italy site 1 Via A. Grandi 9/11, 20089 Rozzano (MI) Italy
Name of manufacturer	Ecolab B.V.B.A
Address of manufacturer	Havenlaan 4 3980 Tessenderlo Belgium
Location of manufacturing sites	Ecolab B.V.B.A site 1 Havenlaan 4 3980 Tessenderlo Belgium
Name of manufacturer	Nalco Española Manufacturing, SLU
Address of manufacturer	C/Tramuntana s/n Polígono Industrial de Celrà 17460 Celrà Spain
Location of manufacturing sites	Nalco Española Manufacturing, SLU site 1 C/ Tramuntana s/n Polígono Industrial de Celrà 17460 Celrà Spain
Name of manufacturer	Ecolab production France SAS
Address of manufacturer	BP509, Avenue de Général Patton 51006 Châlons-en-Champagne France
Location of manufacturing sites	Ecolab production France SAS site 1 BP509, Avenue de Général Patton 51006 Châlons-en-Champagne France
Name of manufacturer	Ecolab Mandra, Greece
Address of manufacturer	25km Old National Road Athens- Theve, - Mandra Attica Greece
Location of manufacturing sites	Ecolab Mandra, Greece site 1 25km Old National Road Athens- Theve, - Mandra Attica Greece
Name of manufacturer	NALCO FINLAND MANUFACTURING OY
Address of manufacturer	Kivikumuntie 1, FIN-07955 Tesjoki Finland
Location of manufacturing sites	NALCO FINLAND MANUFACTURING OY site 1 Kivikumuntie 1, FIN-07955 Tesjoki Finland

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Name of manufacturer	Manufacturing Plant Cisterna Nalco
Address of manufacturer	Via Ninfina II 4012 Cisterna Di Latina, Italy
Location of manufacturing sites	Manufacturing Plant Cisterna Nalco site 1 Via Ninfina II 4012 Cisterna Di Latina Italy
Name of manufacturer	Manufacturing Plant Fawley Nalco
Address of manufacturer	One buisness center 1180 SO45 3NP Hardley Hants United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Manufacturing Plant Fawley Nalco site 1 One buisness center 1180 SO45 3NP Hardley Hants United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Nalco Champion Plant, Tooling Plant, Aberdeen Nalco
Address of manufacturer	Minto Avenue, Alten Industrial Estate AB12 3JZ Aberdeen United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Nalco Champion Plant, Tooling Plant, Aberdeen Nalco site 1 Minto Avenue, Alten Industrial Estate AB12 3JZ Aberdeen United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Microtek Medical B.V.
Address of manufacturer	Hekkehorst, 24 7207 BN Zutphen Netherlands (the)
Location of manufacturing sites	Microtek Medical B.V. site 1 Hekkehorst, 24 7207 BN Zutphen Netherlands (the)
Name of manufacturer	Microtek Medical Malta Ltd.
Address of manufacturer	Sorbonne Centre F20 Mosta Technopark MST 3000 Mosta Malta
Location of manufacturing sites	Microtek Medical Malta Ltd. site 1 Sorbonne Centre F20 Mosta Technopark MST 3000 Mosta Malta
Name of manufacturer	Innovate GmbH
Address of manufacturer	Am Hohen Stein, 11 06618 Naumburg Germany
Location of manufacturing sites	Innovate GmbH site 1 Am Hohen Stein, 11 06618 Naumburg Germany

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Name of manufacturer	CHRISTEYNS FRANCE S.A.
Address of manufacturer	31 rue de la Maladrie 44120 Vertou France
Location of manufacturing sites	CHRISTEYNS FRANCE S.A. site 1 54 avenue de la Plaine - ZI 13106 Rousset France
Name of manufacturer	Techtex
Address of manufacturer	Units 7 & 8, Rhodes Business Park, Silburn Way M24 4NE Middleton, Manchester United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Techtex site 1 Units 7 & 8, Rhodes Business Park, Silburn Way M24 4NE Middleton, Manchester United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Technical Textile Services Ltd
Address of manufacturer	Unit 4, Rhodes Business Park, Silburn Way M24 4NE Middleton, Manchester United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Technical Textile Services Ltd Unit 4, Rhodes Business Park, Silburn Way M24 4NE Middleton, Manchester United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	Pal International Limited
Address of manufacturer	Unit 3 Mountpark, Victoria Road LE67 1FA Ellistown, Coalville United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Pal International Limited Unit 3 Mountpark, Victoria Road LE67 1FA Ellistown, Coalville United Kingdom of Great Britain and Northern Ireland (the)
Name of manufacturer	CID LINES NV
Address of manufacturer	Waterpoortstraat 2 8900 Ieper Belgium
Location of manufacturing sites	CID LINES NV Waterpoortstraat 2 8900 Ieper Belgium
Name of manufacturer	LABORATOIRES ANIOS
Address of manufacturer	3330 Rue de Lille 59262 Sainghin-en-Mélantois France
Location of manufacturing sites	LABORATOIRES ANIOS 3330 Rue de Lille 59262 Sainghin-en-Mélantois France

▼ **M1**1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733, D-47443 Moers Germany
Location of manufacturing sites	Ineos Solvents Germany GmbH site 1 Shamrockstrasse 88 D-44623 Herne Germany Ineos Solvents Germany GmbH site 2 Romestrasse, 733, D-47443 Moers Germany

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

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil Chemical Europe
Address of manufacturer	Hermeslaan 2 1831 Machelen Belgium
Location of manufacturing sites	ExxonMobil Chemical Europe site 1 Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom of Great Britain and Northern Ireland (the) ExxonMobil Chemical Europe site 2 Baton Rouge Chemical Plant 4999 Scenic Highway 70805-3359 LA United States (the)

Active substance	Propan-2-ol
Name of manufacturer	Brenntag N.V.
Address of manufacturer	Nijverheidslaan, 38 8540 Deerlijk Belgium
Location of manufacturing sites	Shell Energy and Chemicals Park Rotterdam Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands (the) ExxonMobil Baton Rouge Refinery 4045 Scenic Highway Baton Rouge 70805 LA United States (the)

Active substance	Propan-2-ol
Name of manufacturer	UNIVAR
Address of manufacturer	Steuber Drive M44 5AL Manchester United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	ExxonMobil Chemicals Fawley Refinery and Petrochemical Plant, Fawley SO45 1TX Southampton United Kingdom of Great Britain and Northern Ireland (the)

▼ M1**2. PRODUCT FAMILY COMPOSITION AND FORMULATION****2.1. Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	30,3 - 65,66 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AE Aerosol dispenser AL Any other liquid XX – Ready to use wipe impregnated with water based liquid
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PART II

SECOND INFORMATION LEVEL META SPC(S)**1. META SPC 1 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 1 identifier**

Identifier	Meta SPC: Meta-SPC 1.1
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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)	PT02: Disinfectants and algacides not intended for direct application to humans or animals
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2. META SPC 1 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	60,61 - 65,66 % (w/w)

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

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

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
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Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280: Wear eye protection. P280: Wear face protection.
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

Use # 1.1 – Disinfection of surfaces in cleanrooms by spraying or mopping.

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use Disinfection of cleanroom hard non-porous surfaces in life sciences industry.
Application method(s)	Method: Trigger spraying or mopping Detailed description: Direct application onto surfaces by trigger spraying followed by wiping with a dry wipe for distribution or mopping.
Application rate(s) and frequency	Application Rate: c.a. 18 ml/m ² ready to use product Number and timing of application: As required
Category(ies) of users	professional
Pack sizes and packaging material	0,5 liter - 10 liters Polyvinylpyrrolidone (PVP) or (High density polyethylene (HDPE) bottle / container (with and without trigger spray)

4.1.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection.

Application by trigger spraying directly onto the surface: Open the nozzle before use. For optimum results hold bottle upright and apply from a distance of 10 cm to 20 cm. Ensure complete wetting of the surfaces (18 ml/m², corresponding to 20 strokes/m²) followed by wiping with a dry wipe for distribution. Allow to take effect for 5 minutes for bacteria, yeast and enveloped viruses and 15 minutes for fungi. Always close the nozzle after use. Do not transfer the product to a trigger sprayer, but apply from a package delivered with trigger sprayer.

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Application on surfaces by Mopping: Impregnate the clean mop with the liquid using a mop bucket and apply to the surface to be disinfected. Ensure complete wetting of the surface (18 mL/m²). Allow to take effect for 5 minutes for bacteria, yeast and enveloped viruses and 15 minutes for fungi. No additional wiping necessary.

Do not mix product with other products. Do not pour any unused product back into the original container.

4.1.2. Use-specific risk mitigation measures

Avoid contact with eyes.

Gloves, eye protection and respiratory protection equipment (RPE) of protection factor of 10 should be worn during mopping. Unprotected personnel should not be present in the room during disinfection by mopping.

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**Potential Health Effects**

Eyes – Causes serious eye irritation.

Skin – Health injuries are not known or expected under normal use.

Ingestion – Health injuries are not known or expected under normal use.

Inhalation – Inhalation may cause central nervous system effects.

Chronic Exposure - Health injuries are not known or expected under normal use.

First Aid Measures

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

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

IF SWALLOWED : Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

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

See general directions for use (5.4).

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- 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 (5.5).

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

5.1. **Instructions for use**

Please refer to specific instructions for use for meta-SPC 1

5.2. **Risk mitigation measures**

Please refer to specific Risk mitigation measures for meta-SPC 1

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

Please refer to specific information for meta-SPC 1

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

Product

Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, regional, national, and/or international regulations.

Product residues

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Store away from direct sunlight and at temperature between 0°C to 25°C

Shelf life: 24 months

6. **OTHER INFORMATION**

Safety data sheet and technical sheet available for professional users on request.

AEL acute/medium-term/long-term 17,9 mg/kg body weight (bw)/day for professional workers and AEL acute/medium-term/long-term 10,7 mg/kg bw/day were used for the risk assessment in the Assessment Report on Propan-2-ol in PT2 – Germany – (January 2015).

▼M1**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)		Klercide 70/30 IPA	Market area: EU			
		Klercide non-sterile 70/30 IPA	Market area: EU			
		Klercide 70/30 IPA non-sterile	Market area: EU			
Authorisation number		EU-0028425-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	63,27 % (w/w)	

1. META SPC 2 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 2 identifier**

Identifier	Meta SPC: Meta-SPC 1.2
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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)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
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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 (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	60,61 - 65,66 % (w/w)

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

Formulation type(s)	XX – Ready to use wipe impregnated with water based liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
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▼ **M1**

Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

Use # 2.1 – Disinfection of surfaces in cleanroom by wiping

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use Disinfection of cleanroom hard non-porous surfaces in life sciences industry by wiping.
Application method(s)	Method: Wiping Detailed description: Direct application onto surfaces by wiping with pre-wetted wipes.
Application rate(s) and frequency	Application Rate: c.a. 10 ml/m ² ready to use product Number and timing of application: Tub (200 wipes/pack, 230×200, Synthetic/cellulose blend): c.a. 0,13 m ² can be disinfected with 1 wipe Tub (100 wipes/pack, 200×230, Synthetic/cellulose blend): c.a. 0,23 m ² can be disinfected with 1 wipe Mop (10 wipes/pack, 420×250, Polyester/cellulose): c.a. 1,1 m ² can be disinfected with 1 wipe Pouch (15 wipes/pack, 200×200, Polyester/cellulose): c.a. 0,33 m ² can be disinfected with 1 wipe Pouch (10 wipes/pack, 200×200, 100% polyester): c.a. 0,51 m ² can be disinfected with 1 wipe Pouch (15 wipes/pack, 300×300, Polyester/cellulose): c.a. 0,47 m ² can be disinfected with 1 wipe Pouch (10 wipes/pack, 300×300, 100% polyester): c.a. 0,73 m ² can be disinfected with 1 wipe
Category(ies) of users	professional

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Pack sizes and packaging material	Tub (HDPE) (100-200 wipes/pack, 200×230, Synthetic/cellulose blend) Pouch (10-30 wipes/pack, 200×200, Polyester/cellulose, 100% polyester) Pouch (10-30 wipes/pack, 300×300, Polyester/cellulose, 100% polyester) Mop wipe (10-30 wipes/pack, 420×250, Polyester/cellulose)
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4.1.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection.

Wiping: Wipe surface to be disinfected. Use wipe once. Ensure complete wetting of the surface (10 ml/m²).

About 0,13-1,1 m² can be disinfected with 1 wipe depending on the wipe.

Allow to take effect for 5 minutes for bacteria, yeast and enveloped viruses and 15 minutes for fungi. Dispose of the wipes in the appropriate closed waste bin immediately after use. No additional wiping necessary.

For multipack wipes, close the package after opening.

Do not mix with other products.

4.1.2. *Use-specific risk mitigation measures*

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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***Potential Health Effects**

Eyes – Causes serious eye irritation.

Skin – Health injuries are not known or expected under normal use.

Ingestion – Health injuries are not known or expected under normal use.

Inhalation – Inhalation may cause central nervous system effects.

Chronic Exposure – Health injuries are not known or expected under normal use.

First Aid Measures

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

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

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IF SWALLOWED : Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

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

See general directions for use (5.4).

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 (5.5).

5. **GENERAL DIRECTIONS FOR USE OF THE META SPC 2**

5.1. **Instructions for use**

Please refer to specific instructions for use for meta-SPC 2

5.2. **Risk mitigation measures**

Please refer to specific risk mitigation measures for meta-SPC 2

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

Please refer to specific information for meta-SPC 2

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

Product

Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, regional, national and/or international regulations.

Product residues

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Store away from direct sunlight and at temperature between 0°C to 25°C

Shelf life: 24 months

▼ M1**6. OTHER INFORMATION**

Safety data sheet and technical sheet available for professional users on request.

AEL acute/medium-term/long-term 17,9 mg/kg bw/day for professional workers and AEL acute/medium-term/long-term 10,7 mg/kg bw/day were used for the risk assessment in the Assessment Report of Propan-2-ol in PT2 Germany – (January 2015).

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)		Klerwipe 70/30 IPA	Market area: EU			
		Klerwipe non-sterile 70/30 IPA	Market area: EU			
		Klerwipe 70/30 IPA non-sterile	Market area: EU			
Authorisation number		EU-0028425-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	63,27 % (w/w)	

1. META SPC 3 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 3 identifier**

Identifier	Meta SPC: Meta-SPC 1.3
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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)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
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2. META SPC 3 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	60,61 - 65,66 % (w/w)

▼ M1**2.2. Type(s) of formulation of the meta SPC 3**

Formulation type(s)	AE Aerosol dispenser
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	H222 : Extremely flammable aerosol. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. H229: Pressurised container: May burst if heated EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280: Wear eye protection. P280: Wear face protection. P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after use. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C/ 122°F.

4. AUTHORISED USE(S) OF THE META SPC**4.1. Use description***Table 1***Use # 3.1 – Disinfection of surfaces in cleanroom by aerosols**

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use Disinfection of cleanroom hard non-porous surfaces in life sciences industry.
Application method(s)	Method: Aerosol spraying Detailed description: Direct application onto surfaces by aerosol spraying followed by wiping with a dry wipe for distribution.

▼ **M1**

Application rate(s) and frequency	Application Rate: c.a. 18 ml/m ² ready to use product Number and timing of application: As required
Category(ies) of users	professional
Pack sizes and packaging material	0,2 liter – 0,5 liter aluminium can

4.1.1. *Use-specific instructions for use*

Clean and dry surfaces prior to disinfection.

Application by aerosol spraying: For optimum results hold can upright and apply from a distance of 10 cm to 20 cm. Ensure complete wetting of the surfaces (18 ml/m², corresponding to 7,2 seconds/m² spraying) followed by wiping with a dry wipe for distribution. Allow to take effect for 5 minutes for bacteria, yeast and enveloped viruses and 15 minutes for fungi.

Do not mix product with other products.

4.1.2. *Use-specific risk mitigation measures*

Avoid contact with eyes.

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***Potential Health Effects**

Eyes – Causes serious eye irritation.

Skin – Health injuries are not known or expected under normal use.

Ingestion – Health injuries are not known or expected under normal use.

Inhalation – Inhalation may cause central nervous system effects. Intentional misuse by deliberate inhalation may be harmful or fatal.

Chronic Exposure – Health injuries are not known or expected under normal use.

First Aid Measures

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

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

IF SWALLOWED : Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

▼ M1

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

See general directions for use (5.4).

- 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 (5.5).

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

5.1. **Instructions for use**

Please refer to specific instructions of use for meta-SPC 3

5.2. **Risk mitigation measures**

Please refer to specific risk mitigation measures for meta-SPC 3

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

Please refer to specific information for meta-SPC 3

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

Product

Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, regional, national and/or international regulations.

Product residues

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Store away from direct sunlight and at temperature between 0°C to 25°C

Shelf life: 24 months

6. **OTHER INFORMATION**

Safety data sheet and technical sheet available for professional users on request.

AEL acute/medium-term/long-term 17,9 mg/kg bw/day for professional workers and AEL acute/medium-term/long-term 10,7 mg/kg bw/day were used for the risk assessment in the Assessment Report of Propan-2-ol in PT2 – Germany – (January 2015).

▼ **M1****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)		Klercide 70/30 IPA Aerosol	Market area: EU		
Authorisation number		EU-0028425-0003 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	63,269 % (w/w)

1. META SPC 4 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 4 identifier**

Identifier	Meta SPC: Meta-SPC 1.4
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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)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
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2. META SPC 4 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	30,3 - 30,3 % (w/w)

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

Formulation type(s)	XX - Ready to use wipe impregnated with water based liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

▼ **M1**4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

Use # 4.1 – Disinfection of non-food and food contact surfaces by pre-wetted wipes

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Disinfection of food contact and non-food contact hard non-porous surfaces in: Commercial kitchens, Catering, Food processing and Food Retail, Canteen, Bathrooms and Restrooms in hotels, restaurants, stores, schools, offices.
Application method(s)	Method: Wiping Detailed description: Direct application onto hard non-porous surfaces by wiping.
Application rate(s) and frequency	Application Rate: c.a. 10 ml/m ² at room temperature ready to use product Number and timing of application: Wiping with two superposed wipes. About 0,074-0,222 m ² can be disinfected with two superposed wipes depending on the size of wipe used.
Category(ies) of users	professional
Pack sizes and packaging material	Container (PP) (100 wipes 130×210) Container (HDPE) (150 wipes 180×300) Bucket (PP) (1500 wipes 150×210) Pouch (PET/PE) (200 wipes 130×210) Wipe material (all packagings): blend of Pulp, Polyester, Binder

4.1.1. *Use-specific instructions for use*

Wiping: Clean and dry surfaces prior to disinfection.

Wipe surface to be disinfected with two superposed wipes. Use the wipes once. For optimum results ensure complete wetting of the surface (10 ml/m²), about 0,074-0,222 m² can be disinfected with two superposed wipes depending on the size of wipe used. Allow to take effect for 15 minutes for bacteria and yeast. Dispose the wipes in the appropriate closed waste bin immediately after use. No additional wiping necessary.

▼ M1

For multipack wipes, close the package after opening.

Do not mix product with other products.

4.1.2. *Use-specific risk mitigation measures*

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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*

Potential Health Effects

Eyes – Causes serious eye irritation.

Skin – Health injuries are not known or expected under normal use.

Ingestion – Health injuries are not known or expected under normal use.

Inhalation – Inhalation may cause central nervous system effects.

Chronic Exposure – Health injuries are not known or expected under normal use.

First Aid Measures

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

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

IF SWALLOWED : Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

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

See general directions for use (5.4).

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 (5.5).

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

5.1. **Instructions for use**

Please refer to specific instructions of use for meta-SPC 4

5.2. **Risk mitigation measures**

Please refer to specific risk mitigation measures for meta-SPC 4

▼ M1**5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Please refer to specific information for meta-SPC 4

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

Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, regional, national and/or international regulations.

Product residues

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Store away from direct sunlight and at temperature between 0°C to 25°C

Shelf life: 24 months

6. OTHER INFORMATION

Safety data sheet and technical sheet available for professional users on request.

AEL acute/medium-term/long-term 17,9 mg/kg bw/day for professional workers and AEL acute/medium-term/long-term 10,7 mg/kg bw/day were used for the risk assessment in the Assessment Report of Propan-2-ol in PT2 – Germany – (January 2015).

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)		Eco-Bac Wipes	Market area: EU		
		Sirafan Bac Wipes	Market area: EU		
Authorisation number		EU-0028425-0004 1-4			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	30,3 % (w/w)

▼ M1**1. META SPC 5 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 5 identifier**

Identifier	Meta SPC: Meta-SPC 1.5
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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)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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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 (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	30,3 - 30,3 % (w/w)

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

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

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280: Wear eye protection. P280: Wear face protection.

4. AUTHORISED USE(S) OF THE META SPC**4.1. Use description**

Table 1

Use # 5.1 – Disinfection of non-food and food contact surfaces by trigger spray

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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▼ **M1**

Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Disinfection of food contact and non-food contact hard non-porous surfaces in: Commercial kitchens, Catering, Food processing and Food Retail, Canteen, Bathrooms and Restrooms in hotels, restaurants, stores, schools, offices.
Application method(s)	Method: Trigger spraying Detailed description: Direct application onto hard non-porous surfaces by trigger spraying.
Application rate(s) and frequency	Application Rate: c.a. 18 ml/m ² at room temperature ready to use product Number and timing of application: As required
Category(ies) of users	professional
Pack sizes and packaging material	0,5 liter – 10 liter HDPE container (with trigger spray)

4.1.1. *Use-specific instructions for use*

Application by trigger spraying: Open the nozzle before use. For optimum results hold bottle upright and apply from a distance of 10 cm to 20 cm. Ensure complete wetting of the surfaces (18 ml/m², corresponding to 29 strokes/m²). Allow to take effect for 30 seconds for bacteria and yeast. Always close the nozzle after use.

Do not mix product with other products. Do not pour any unused product back into the original container.

4.1.2. *Use-specific risk mitigation measures*

Avoid contact with eyes.

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***Potential Health Effects**

Eyes – Causes serious eye irritation.

Skin – Health injuries are not known or expected under normal use.

Ingestion – Health injuries are not known or expected under normal use.

Inhalation – Inhalation may cause central nervous system effects.

Chronic Exposure – Health injuries are not known or expected under normal use.

▼ M1***First Aid Measures***

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

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

IF SWALLOWED : Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

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

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

See general directions for use (5.4).

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 (5.5).

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

5.1. **Instructions for use**

Please refer to specific instructions of use for meta-SPC 5

5.2. **Risk mitigation measures**

Please refer to specific risk mitigation measures for meta-SPC 5

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

Please refer to specific information for meta-SPC 5

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

Product

Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, regional, national and/or international regulations.

Product residues

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

▼ M1**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

Store away from direct sunlight and at temperature between 0°C to 25°C

Shelf life: 24 months

6. OTHER INFORMATION

Safety data sheet and technical sheet available for professional users on request.

AEL acute/medium-term/long-term 17,9 mg/kg bw/day for professional workers and AEL acute/medium-term/long-term 10,7 mg/kg bw/day were used for the risk assessment in the Assessment Report of Propan-2-ol in PT2 – Germany – (January 2015).

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)		Sirafan Speed-FR	Market area: EU		
Authorisation number		EU-0028425-0005 1-5			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	30,3 % (w/w)