

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)**

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 10 June 2016, Ecolab Deutschland GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'IPA Family 1' of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-HN024859-20 in the Register for Biocidal Products.
- (2) 'IPA Family 1' 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 25 August 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 Agency.
- (4) On 23 March 2022, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'IPA Family 1' 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 'IPA Family 1' 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 12 April 2022, 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 'IPA Family 1'.
- (8) In its opinion, the Agency recommends that the authorisation holder conducts 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 is to be made available on the market, as a condition in the authorisation. The test should address the relevant physical, chemical and technical properties of that product both prior to and after storage to confirm a shelf life of 24 months. The authorisation holder should include in the test report information about the packaging stability, the spray characteristics and internal pressure before and after storage. The Commission agrees with that recommendation

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 1 March 2022 on the Union authorisation of "IPA Family 1" (ECHA/BPC/316/2022), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

and considers that the submission of the results of that test should be a condition relating to the making available on the market and use of the biocidal product family 'IPA Family 1' pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of that Regulation based on the existing data.

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

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-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.

Done at Brussels, 16 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

ANNEX II

Summary of product characteristics for a biocidal product family

IPA Family 1

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-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 (Disinfectants) PT04 – Food and feed area (Disinfectants)
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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	
R4BP asset number	EU-0028425-0000	
Date of the authorisation	9 March 2023	
Expiry date of the authorisation	28 February 2033	

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

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse, 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	Richtistrasse, 7, 8304 Wallisellen Switzerland

Name of manufacturer	Ecolab Limited
Address of manufacturer	Brunel Way, Baglan Energy Park, SA11 2GA Neath United Kingdom
Location of manufacturing sites	Brunel Way, Baglan Energy Park, SA11 2GA Neath United Kingdom

Name of manufacturer	Laboratoires Prodene Klint
Address of manufacturer	Rue Denis Papin, 2 Z.I. Mitry Compans, F-77290 Mitry Mory France
Location of manufacturing sites	Rue Denis Papin, 2 Z.I. Mitry Compans, F-77290 Mitry Mory France

Name of manufacturer	Ecolab Leeds
Address of manufacturer	Lotherton Way, Garforth, LS25 2JY Leeds United Kingdom
Location of manufacturing sites	Lotherton Way, Garforth, LS25 2JY Leeds United Kingdom

Name of manufacturer	Esoform S.p.A.
Address of manufacturer	Viale del Lavoro 10, 45100 Rovigo Italy
Location of manufacturing sites	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	Justus-von-Liebig-Str. 11, D-64584 Biebesheim Germany

Name of manufacturer	Ecolab NETHERLANDS BV
Address of manufacturer	Brugwal 11, 3432NZ Nieuwegein Netherlands
Location of manufacturing sites	Brugwal 11, 3432NZ Nieuwegein Netherlands

Name of manufacturer	Ecolab Weavergate
Address of manufacturer	Winnington Avenue, CW8 3AA Northwich Cheshire United Kingdom
Location of manufacturing sites	Winnington Avenue, CW8 3AA Northwich Cheshire United Kingdom

Name of manufacturer	Ecolab Mullingar, Ireland
Address of manufacturer	Forest Park, Zone C Mullingar Ind. Estate, – Mullingar, Co. Westmeath, Ireland
Location of manufacturing sites	Forest Park, Zone C Mullingar Ind. Estate, – Mullingar, Co. Westmeath, Ireland

Name of manufacturer	Ecolab d.o.o.
Address of manufacturer	Vajngerlova 4, 2000 Maribor Slovenia
Location of manufacturing sites	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	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	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	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	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	25km Old National Road Athens- Theve, – Mandra Attica Greece

Name of manufacturer	NALCO FINLAND MANUFACTURING OY
Address of manufacturer	Kivikummuntie 1, FIN-07955 Tesjoki Finland
Location of manufacturing sites	Kivikummuntie 1, FIN-07955 Tesjoki Finland
Name of manufacturer	Manufacturing Plant Cisterna Nalco
Address of manufacturer	Via Ninfina II, 4012 Cisterna Di Latina, Italy
Location of manufacturing sites	Via Ninfina II, 4012 Cisterna Di Latina Italy
Name of manufacturer	Manufacturing Plant Fawley Nalco
Address of manufacturer	One business center 1180, SO45 3NP Hardley Hants United Kingdom
Location of manufacturing sites	One business center 1180, SO45 3NP Hardley Hants United Kingdom
Name of manufacturer	Nalco Champion Plant, Tooling Plant, Aberdeen Nalco
Address of manufacturer	Minto Avenue, Alten Industrial Estate, AB12 3JZ Aberdeen United Kingdom
Location of manufacturing sites	Minto Avenue, Alten Industrial Estate, AB12 3JZ Aberdeen United Kingdom
Name of manufacturer	Microtek Medical B.V.
Address of manufacturer	Hekkehorst, 24, 7207 BN Zutphen Netherlands
Location of manufacturing sites	Hekkehorst, 24, 7207 BN Zutphen Netherlands
Name of manufacturer	Microtek Medical Malta Ltd.
Address of manufacturer	Sorbonne Centre F20 Mosta Technopark, MST 3000 Mosta Malta
Location of manufacturing sites	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	Am Hohen Stein, 11, 06618 Naumburg Germany

Name of manufacturer	CHRISTEYNS FRANCE S.A.
Address of manufacturer	31 rue de la Maladrie, 44120 Vertou France
Location of manufacturing sites	54 avenue de la Plaine – ZI, 13106 Rousset France

Name of manufacturer	Techtex
Address of manufacturer	Units 7 & 8, Rhodes Business Park, Silbum Way, M24 4NE Middelton, Manchester United Kingdom
Location of manufacturing sites	Units 7 & 8, Rhodes Business Park, Silbum Way, M24 4NE Middelton, Manchester United Kingdom

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, 47443 Moers Germany
Location of manufacturing sites	Shamrockstrasse 88, D-44623 Herne Germany Romestrasse, 733, D-47443, 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
Location of manufacturing sites	Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam-Pernis, Netherlands

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

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-2-ol		Active Substance	67-63-0	200-661-7	30,3	65,66

2.2. Type(s) of formulation

Formulation(s)	AL – Any other liquid AE – Aerosol dispenser XX – Ready to use wipe impregnated with water based 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 1.1
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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 algaecides not intended for direct application to humans or animals (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-2-ol		Active Substance	67-63-0	200-661-7	60,61	65,66

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	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. Wear eye protection. Wear face protection.

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

4.1. **Use description****Table 1. Use # 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 (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor 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 Dilution (%): 0 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 (max. 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.

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 (max. 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).

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 ⁽¹⁾ 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).

⁽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.

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		
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

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	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 (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-2-ol		Active Substance	67-63-0	200-661-7	60,61	65,66

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

Formulation(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	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.

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

4.1. Use description

Table 2. Use # 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 (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor 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 Dilution (%): 0 Number and timing of application: Tub (200 wipes/pack, 230x200, Synthetic/cellulose blend): c.a. 0,13 m ² can be disinfected with 1 wipe Tub (100 wipes/pack, 200x230, Synthetic/cellulose blend): c.a. 0,23 m ² can be disinfected with 1 wipe Mop (10 wipes/pack, 420x250, Polyester/cellulose): c.a. 1,1 m ² can be disinfected with 1 wipe

	<p>Pouch (15 wipes/pack, 200x200, Polyester/cellulose): c.a. 0,33 m² can be disinfected with 1 wipe</p> <p>Pouch (10 wipes/pack, 200x200, 100 % polyester): c.a. 0,51 m² can be disinfected with 1 wipe</p> <p>Pouch (15 wipes/pack, 300x300, Polyester/cellulose): c.a. 0,47 m² can be disinfected with 1 wipe</p> <p>Pouch (10 wipes/pack, 300x300, 100 % polyester): c.a. 0,73 m² can be disinfected with 1 wipe</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Tub (HDPE) (100-200 wipes/pack, 200x230, Synthetic/cellulose blend)</p> <p>Pouch (10-30 wipes/pack, 200x200, Polyester/cellulose, 100 % polyester)</p> <p>Pouch (10-30 wipes/pack, 300x300, Polyester/cellulose, 100 % polyester)</p> <p>Mop wipe (10-30 wipes/pack, 420x250, Polyester/cellulose)</p>

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 (max. 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

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 ^(²) 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

6. OTHER INFORMATION

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

^(²) 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.

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		
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

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	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 algacides not intended for direct application to humans or animals (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-2-ol		Active Substance	67-63-0	200-661-7	60,61	65,66

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

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

Hazard statements	Extremely flammable aerosol. Causes serious eye irritation. May cause drowsiness or dizziness. Pressurised container: May burst if heated 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. Wear eye protection. Wear face protection. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 3. Use # 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 (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor 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.

Application rate(s) and frequency	Application Rate: c.a. 18 ml/m ² Dilution (%): 0 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 (max. 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

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 ⁽³⁾ 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).

⁽³⁾ 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.

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

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	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 (Disinfectants) PT04 – Food and feed area (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-2-ol		Active Substance	67-63-0	200-661-7	30,3	30,3

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

Formulation(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	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.

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

4.1. Use description

Table 4. Use # 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 (Disinfectants) PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor 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 Dilution (%): 0 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 130x210) Container (HDPE) (150 wipes 180x300) Bucket (PP) (1 500 wipes 150x210) Pouch (PET/PE) (200 wipes 130x210) Wipe material (all packagings): blend of Pulp, Polyester, Binder
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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 (max. 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.

For multipack wipes, close the package after opening.

Do not mix product with other products.

4.1.2. Use-specific risk mitigation measures

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

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).

(*) 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)	Eco-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

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	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 algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (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-2-ol		Active Substance	67-63-0	200-661-7	30,3	30,3

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	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. Wear eye protection. Wear face protection.

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

4.1. Use description

Table 5. Use # 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 (Disinfectants) PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor 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 Dilution (%): 0 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 (max. 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.

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

(*) 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.

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.

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