

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2127**of 4 November 2022****granting a Union authorisation for the biocidal product family ‘Ecolab UA BPF 1-Propanol’ 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 26 March 2019, 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 ‘Ecolab UA BPF 1-Propanol’ of product-type 1, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Sweden had agreed to evaluate the application. The application was recorded under case number BC-RS050191-24 in the Register for Biocidal Products.
- (2) ‘Ecolab UA BPF 1-Propanol’ contains propan-1-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-type 1.
- (3) On 9 September 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 24 March 2022, the Agency submitted its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Ecolab UA BPF 1-Propanol’ and the final assessment report on the biocidal product family, to the Commission in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Ecolab UA BPF 1-Propanol’ 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 ‘Ecolab UA BPF 1-Propanol’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on biocidal products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 1 March 2021 on the Union authorisation of ‘Ecolab UA BPF 1-Propanol’ (ECHA/BPC/315/2022), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0028430-0000 is granted to Ecolab Deutschland GmbH for the making available on the market and use of the biocidal product family 'Ecolab UA BPF 1-Propanol' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 November 2022 to 31 October 2032.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab UA BPF 1-Propanol

Product type 1 – Human hygiene (Disinfectants)

Authorisation number: EU-0028430-0000

R4BP asset number: EU-0028430-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Ecolab UA BPF 1-Propanol
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1.2. **Product type(s)**

Product type(s)	PT01 – Human hygiene (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-0028430-0000	
R4BP asset number	EU-0028430-0000	
Date of the authorisation	27 November 2022	
Expiry date of the authorisation	31 October 2032	

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

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtstrasse 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	Richtstrasse 7, 8304 Wallisellen Switzerland AFP GmbH, Otto-Brenner-Straße 16, 21337 Lüneburg Germany Acideka S.A., Edificio FERIA. Capuchinos de Basurto 6. 4a planta, 48013 Bilbao Spain Adiego, Adiego Ctra De Valencia KM 5, 900, 50410 Cuarte de Huerva Zaragoza Spain Allied Products, Allied Hygiene Unit 11, Belvedere Industrial Estate, Fishers Way, Belvedere, Kent, DA17 6BS Belvedere United Kingdom Arkema GmbH, Morschheimer Straße 19, D-67292 Krichbeimbolanden Germany

Azelis Denmark, Lundtoftegårdsvej 95, 2800 Kgs Lyngby Denmark
 Belinka-Ljubljana, Belinka Zasavska Cesta, 95 1001 Ljubljana Slovenia
 Radio street 24 Bld 1, 105005 Moscow Russian Federation
 Bio Productions Ltd inc. Starpro, 72 Victoria Road Victoria Industrial Estate, West Sussex, RH15 9LH Burgess Hill United Kingdom
 Bioxal SA, Route des Varennes – Secteur A, BP 30072 71103 Cedex France
 Bores Srl, Via Pioppa 179, 44030 Pontegradella (FE) Italy
 Brenntag Ardennes, Route de Tournes, CD n 2, 08090 Cliron France
 Brenntag CEE – Guntramsdorf, Blending Bahnstr. 13 A, 2353 Guntramsdorf Austria
 Brenntag GmbH, Humboldttring 15, 45472 Mülheim Germany
 Brenntag Kaiserslautern, Merkurstr. 47, 67663 Kaiserslautern Germany
 Brenntag Nordic – Haslev, Høsten Teglværksvej 47, 4690 Haslev Denmark
 Brenntag Nordic – Vejle, Strandgade 35, 7100 Vejle Denmark
 Brenntag Normandy, 12 Sente des Jumelles, BP 11 76710 Montville France
 Brenntag PL-Zgierz, ul. Kwasowa 5, 95-100 Zgierz Poland
 Brenntag Quimica, Calle Gutemberg n° 22, Poligono Industrial El Lomo, 28906 Getafe Madrid Spain
 Brenntag Schweizerhall, Elsaesserstr. 231, CH-4056 Basel Schweiz Switzerland
 Brenntag SRL, Str. Gării nr 1, 077040 Chiaina, Ilfov Romania
 Budich International GmbH, Dieselstraße 10, 32120 Hiddenhausen Germany
 Caldic Deutschland Chemie B.V, Karlshof 10, D 40231 Düsseldorf Germany
 The Carbon Group, P43 R772, County Cork Ringaskiddy Ireland
 Colep Bad Schmiedeberg, Kemberger Str. 3, 06905 Bad Schmiedeberg Germany
 Comercial Farmaceutica Castel LANA S.A., ‘Cofarcas’ Condado de Trevino 46 P.I Villalonquejar, 09080 Burgos Spain
 Comercial Godo, França 13, 08700 Igaulada Barcelona Spain
 Courtois Sarl, ZA Sous Le Beer, Route de Pacy, 27730 Bueil France
 DAN-MOR (Dr Wipe) Natural products and Chemicals Ltd, Or Akiva Industrial Zone, Hailian street 29, 30600 Akiva Israel
 Denteck BV, Heliumstraat 8, 2718 SL Zoetermeer Netherlands
 Donauchem Kft (Hungary), Bányalég utca 37-43, H-1225 Budapest Hungary
 Detergents Burguera S.L, Joan Ballester 50, 07630 Campos (Illes Balears) Spain
 Champion Technologies Ltd, Minto Avenue, Altens Industrial Estate, AB12 3JZ Aberdeen United Kingdom
 ECL Biebesheim, Justus-von-Liebig-Straße 11, 64584 Biebesheim am Rhein Germany

ECL Chalons, Avenue Du General Patton, 51000 Chalons en
Champagne France

ECL Cisterna, Nalco italiana Manufacturing Srl. Via Ninfina II, 04012
Cisterna di Latina Italy

Champion Technologies Ltd Fawley, Fawley Cadland Road Hythe,
Hampshire, SO45 3NP Southampton United Kingdom

Ecolab Leeds, Lotherton Way, Garforth, LS25 2JY Leeds United
Kingdom

ECL Mandra, 25TH KM Old National Road of Athens To Thiva, 19600
Mandra Greece

ECL Maribor, Vajngerlova Ulica 4, 2000 Maribor Slovenia

ECL Microtek B.V., Gesinkkampstraat 19, 7051 HR Varsseveld
Netherlands

ECL Microtek Mosta, Sorbonne Centre F20 Mosta Technopark, Mst
3000 Mosta Malta

ECL Microtek Zutphen, Hekkehorst 24, 7027 BN Zutphen Netherlands

Ecolab Ltd (IE) and Ecolab Manufacturing IE Ltd (IE), Forest Park, Zone C
Mullingar Ind. Estate N91, Co. Westmeath Mullingar Ireland

ECL Nieuwegein, Brugwal 11A, 3432 NZ Nieuwegein Netherlands

ECL Rovigo Esoform, Esoform SRL Laboratorio Chimico Farmaceutico
Viale del Lavoro 10, 45100 Rovigo Italy

ECL Rozzano, Via A. Grandi, 20089 Milan Italy

ECL Tessengerlo, Havenlaan 4, Ravenshout 4 210, B-3980 Tessengerlo
Belgium

ECL Weavergate/Ecolab Ltd (UK)/Ecolab Manufacturing UK Ltd (UK),
Winnington Avenue, CW8 3AA Northwich United Kingdom

Ecolab LTD Baglan/Swindon, Plot 7a Baglan Energy Park, Baglan,
SA11 2HZ Port Talbot United Kingdom

Ferdinand Eiermacher GmbH & Co. KG, Westring 24, 48356
Nordwalde Germany

F.E.L.T., B.P 64 10 Rue du Vertuquet, 59531 Neuville En Ferrain France

Gallows Green Services Ltd, Cod Beck Mill Industrial Estate Dalton
Lane, YO7 3HR Thirsk United Kingdom

Gerdisa German Rodriguez Drogas IND., Gerdisa Poligono Industrial
Miralcampo C.Pintura n.-4, parc.37, 19200 Azuqueca de Henares
Guadalajara Spain

Girasol Natural Products BV, De Veldoven 12-14, 3342 GR Hendrik-
Ido-Ambacht Netherlands

Henkel Engels, 48 Pr. Stroitelei, 413116 Saratov Russian Federation

IMECO GmbH & Co. KG, Boschstraße 5, D-63768 Hösbach Germany

Innovate GmbH, Am Hohen Stein 11, 06618 Naumberg Germany

Interfill LCC-Tosno, 187000 Moskovskoye shosse 1, 187000
Leningradskaya oblast Russian Federation

Jodel, Jodel Zona Industrial 2050, 2050 Aveiras de Cima Portugal

Kleimann GmbH, Am Trieb 13, 72820 Sonnenbühl Germany

Kompak Nederland BV, 433651 Bavel 0031-161 Bavel Netherlands

La Antigua Lavandera S.L., Ctra. Antigua Sevilla-Alcalá Km.1,5 (SE-410
Apartado de Correos 58, 41500 Alcala De Guadaira Sevilla Spain

Laboratoires Anios, Pavé du moulin, 59260 Lille-Hellemmes France

	<p>Laboratoires Anios, 3330 Rue de Lille, 59262 Sainghin-en-Mélantois France</p> <p>Laboratoires Prodene Klint, Site de Mitry-Mory 2, Rue Denis Papin ZI Mitry-Compans, 77290 Mitry Mory France</p> <p>Lichtenheldt GmbH, Lichtenheldt Industriestraße 7-9, 23812 Wahlstedt Germany</p> <p>Lonza GmbH, Morianstr.32, 42103 Wuppertal Germany</p> <p>Multifill BV, Constructieweg 25-A, 3641 SB Mijdrecht Netherlands</p> <p>NALCO Finland Manufacturing Oy (Teskjoki), Kivikumuntie 1, 07955 Tesjoki Finland</p> <p>NALCO Celra, Celra C/Tramuntana s/n Poligona Industrial, 17460 Celra Spain</p> <p>NOPA Nordisk Parfumerivare, Hvedevej 2-22, DK-8900 Randers Denmark</p> <p>Nuova Farmec Srl, Via Flemming 7, 37026 Settimo di Pescantina (VR) Verona Italy</p> <p>Pal International Ltd, Sandhurst Street, LE17 4JA Leicester United Kingdom</p> <p>Planol GmbH, Maybachstr. 17, 63456 Hanau Germany</p> <p>Plum A/S, Frederik Plums Vej 2, DK 5610 Assens Denmark</p> <p>Productos La Corberana S.L., Ctra Corbera Polinyá, s/n° 4, 46612 Valencia Spain</p> <p>The Proton Group Ltd, Ripley Drive, Normanton Industrial Estate, WF6 1QT Wakefield United Kingdom</p> <p>Quimicas Morales S.L., Misiones, 11 Urb. El Sebadal, 05005 Las Palmas de Gran Canaria Spain</p> <p>RNM Productos Quimicos, Lda Rua da Fabrica 123, Segade, 4765-080 Carreira Vila Nova de Famalicao Portugal</p> <p>RP Adam Ltd (Arpal Group), North Riverside Business Park, Riverside Road,, TD7 5DU Selkirk United Kingdom</p> <p>Roquette & Barentz, Roquette Freres, Route De La Gorgue, F-62136 Lestrem France</p> <p>Rutpen Ltd, Membury Airfield, Lambourn, RG16 7TJ Membury United Kingdom</p> <p>Simagec, Z.I. de Rousset/Peynier, 54 Avenue de la Plaine,, 13790 Rousset France</p> <p>Solimix, Montseny 17-19 Pol. Ind. Sant Pere, Molanta, 08799 Olerdola Barcelona Spain</p> <p>Staub & Co. – Silbermann GmbH, Industriestraße 3, D-86456 Gablingen Germany</p> <p>Stockmeier Chemie, Eilenburg GmbH & Co. Kg, Gustav-Adolf-Ring 5, 04838 Eilenburg Germany</p> <p>Synerlogic BV (IN2FOOD), L.J. Costerstraat 5, 6827 Arnhem Netherlands</p> <p>Techtex (Technical Textile Services Ltd), Units 7 & 8, Rhodes Business Park Silburn Way, Middleton, M24 4NE Manchester United Kingdom</p> <p>Univar Ltd, Argyle House, Epsom Avenue, SK9 3RN Wilmslow United Kingdom</p> <p>Univar SPA, Via Caldera 21, 20-153 Milano Italy</p> <p>Van Dam Bodegraven B.V, Postbus 48 NL, 2410 AA Bodegraven Netherlands</p> <p>McBride, Calle Ramón Esteve, 0 S/N (Pol L'illa), 08650 Botjosa (la) Barcelona Spain</p> <p>Extruplast, Avenue de la Repentie, 1700 La Rochelle1 France</p> <p>Brenntag Hungary Kft, Bányalég u. 45, 1225 Budapest Hungary</p>
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	DR. Becher GmbH, Vor den Specken 3,, 30926 Seelze Germany Danlind AS, Lægaardvej 90 – 94, DK-7500 Holstebro Denmark Farmak Moravia a.s, Na Vlčinci 16,, 779 00 Oloumoc Czech Republic Hydrachem LTD, Gillmans Industrial Estate, Natts Lane, RH14 9EZ Billingshurst United Kingdom Julius Hoesch GmbH, Birkesdorfer Str. 5, 52353 Düren Germany Medentech LTD, Whitemill Industrial Estate, Wexford Ireland MKS GmbH & Co. KG, Am Ockenheimer Graben 43, 55411 Bingen am Rhein Germany PDI, Aber Park, Aber Road, CH6 5EX Flint United Kingdom Peenwhite LTD, Midpoint 18 Business Park, Aston Way,, CW10 0HS Middlewich United Kingdom Jago Pro Sp.z.o.o., Szczakowska 35, 43-600 Jaworzno Poland Wesso AG, Martin-Luther-Str. 10, 91217 Hersbruck Germany CID Lines NV, Waterpoorstraat 2, 8900 Leper Belgium
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1.5. Manufacturer(s) of the active substance(s)

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

Active substance	Propan-1-ol
Name of manufacturer	OQ Corporation
Address of manufacturer	2001 FM 3057, TX 77414 Bay City United States
Location of manufacturing sites	2001 FM 3057, TX 77414 Bay City 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-1-ol		Active Substance	71-23-8	200-746-9	70,35	75,38

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

Formulation(s)	AL – Any other liquid
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PART II

SECOND INFORMATION LEVEL – META SPC(S)**META SPC 1**

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	meta SPC 1
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1.2. **Suffix to the authorisation number**

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

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	70,35	75,38

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

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

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
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Precautionary statements	<p>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking.</p> <p>Wear face protection.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Immediately call a POISON CENTER/doctor.</p> <p>Avoid breathing vapours.</p> <p>Call a POISONCENTRE/doctor if you feel unwell.</p>
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4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1.

Use # 1 – Hand disinfection

Product type	PT01 – Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic hand rub
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Tuberculosis bacilli Common name: Tuberculosis bacilli Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p> <p>Scientific name: Viruses (limited spectrum virucidal activity) Common name: Viruses (limited spectrum virucidal activity) Development stage:</p>
Field(s) of use	<p>Indoor Indoor Hand disinfection Food processing areas (industry, institutional and hospital kitchen areas (no contact with patients)) Hygienic hand rub, on visibly clean hands</p>
Application method(s)	<p>Method: Manual or automatic pump</p> <p>Detailed description: Manual (elbow lever or touchless) Automatic (by pump)</p>

Application rate(s) and frequency	Application Rate: 3 ml Dilution (%): Ready to use Number and timing of application: 10 times per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100-20 000 l HEDP bottle, jerry can.

4.1.1. *Use-specific instructions for use*

Refer to general measures (5.1)

4.1.2. *Use-specific risk mitigation measures*

Refer to general measures (5.2))

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

Refer to general measures (5.3)

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

Refer to general measures (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*

Refer to general measures (5.5)

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

5.1. **Instructions for use**

Use 1 – Hand disinfection

Hand Disinfection for food processing areas:

Apply 3 ml product on clean and dry hands for:

- 30 seconds bacteria/yeast/tuberculosis bacilli/enveloped viruses
- 60 seconds viruses (limited spectrum virucidal activity)

Keep hands wet during whole contact time

5.2. **Risk mitigation measures**

Avoid contact with eyes.

If refilling is needed, gloves and eye protection should be used.

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

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

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

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

IF SWALLOWED: Rinse mouth.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions: do not allow contact with soil, surface or ground water.

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

Product and product residues: Do not allow the product to enter drains, water courses or the soil. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of the product in compliance with local regulations. Dispose of wastes in an approved waste disposal facility

Packaging: Bring empty containers to an approved waste handling site for recycling or disposal. Dispose of packaging only if completely empty and closed. Do not re-use empty containers. Dispose of in accordance with local, regional, national regulations.

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

Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labelled containers. Store between 0 °C to 25 °C.

Shelf life: 4 years

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Skinman Sensitive		Market area: EU		
	P3-Manodes LI		Market area: EU		
	Epicare DES		Market area: EU		
	Manodes LI		Market area: EU		
Authorisation number	EU-0028430-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	70,35