

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1186
of 8 July 2022
granting a Union authorisation for the biocidal product family ‘L+R Propanol PT1 Family’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 25 April 2019, Lohmann & Rauscher International GmbH&Co.KG submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘L+R Propanol PT1 Family’ of product-type 1, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Switzerland had agreed to evaluate the application. The application was recorded under case number BC-MU051242-25 in the Register for Biocidal Products.
- (2) ‘L+R Propanol PT1 Family’ contains propan-1-ol and propan-2-ol, as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for PT 1.
- (3) On 29 March 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 4 November 2021, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘L+R Propanol PT1 Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘L+R Propanol PT1 Family’ is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 22 November 2021, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘L+R Propanol PT1 Family’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 7 October 2021 on the Union authorisation of ‘L+R Propanol PT1 Family’ (ECHA/BPC/291/2021), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027466-0000 is granted to Lohmann & Rauscher International GmbH&Co.KG for the making available on the market and use of the biocidal product family 'L+R Propanol PT1 Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 31 July 2022 until 30 June 2032.

Article 2

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

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

Done at Brussels, 8 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

L+R Propanol PT1 Family

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027466-0000

R4BP asset number: EU-0027466-0000

PART I

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

Name	L+R Propanol PT1 Family
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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	Lohmann & Rauscher International GmbH & Co. KG
	Address	Westerwaldstrasse 4, 56579 Rengsdorf Germany
Authorisation number	EU-0027466-0000	
R4BP asset number	EU-0027466-0000	
Date of the authorisation	31 July 2022	
Expiry date of the authorisation	30 June 2032	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Lohmann & Rauscher International GmbH & Co. KG
Address of manufacturer	Westerwaldstrasse 4, 56579 Rengsdorf Germany
Location of manufacturing sites	A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto-Brenner-Straße 16-18, 21337 Lüneburg Germany

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

Active substance	Propan-2-ol
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Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly OXEA)
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals Corporation, 2001 FM 3057 (formerly OXEA Corporation), TX 77414-2968 Bay City United States

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

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

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	45,0	45,0
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	30,0
Tetradecanol	Myristil alcohol	Non-active substance	112-72-1	204-000-3	0,0	0,95

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-2-ol		Active Substance	67-63-0	200-661-7	45,0	45,0
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	30,0
Tetradecanol	Myristil alcohol	Non-active substance	112-72-1	204-000-3	0,95	0,95

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. Harmful to aquatic life with long lasting effects. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. Avoid release to the environment. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER / doctor. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an approved waste disposal plant.

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

4.1. Use description

Table 1. Use # 1 – Hygienic handrub

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: viruses (limited spectrum of virucidal activity) Development stage:
Field(s) of use	Indoor — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients), — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. — for professional use only.

Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum contact time: 30 sec Dilution (%): ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100ml, 500ml and 1000ml in transparent HDPE bottles with PP flip top cap.

4.1.1. Use-specific instructions for use

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

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

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of meta SPC 1

4.2. Use description

Table 2. Use # 2 – Surgical handrub

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

	Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: viruses (limited spectrum of virucidal activity) Development stage:
Field(s) of use	Indoor hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: in portions of 3 ml (use dispensers: for example set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum exposure time: 90s Dilution (%): ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100ml, 500ml and 1 000ml in transparent HDPE bottles with PP flip top cap.

4.2.1. Use-specific instructions for use

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

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

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of meta SPC 1

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

5.1. Instructions for use

For professional use only.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water. for 15 minutes. Call a POISON CENTRE or a doctor.

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

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

Information to healthcare personnel/doctor:

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

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

After spilling: Take up with absorbent material (for example sand, kieselgur, universal binder). When picked up, treat material as prescribed under "Disposal considerations".

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

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal.

Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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

Technical measures and storage conditions:

Shelf-life: 36 months

Keep container tightly closed and dry in a cool, well-ventilated place. Protect from direct sunlight.

Recommended storage temperature: 0-30°C

Requirements for storage rooms and vessels:

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original one.

Advice on storage assembly:

Do not store together with: oxidizing substances; spontaneously combusting substances.

⁽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.

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)	L+R handdisinfect blue		Market area: EU		
Authorisation number	EU-0027466-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Tetradecanol	Myristil alcohol	Non-active substance	112-72-1	204-000-3	0,95

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

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

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

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

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

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

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

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

4.1. Use description

Table 3. Use # 1 – Hygienic handrub

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: viruses (limited spectrum of virucidal activity) Development stage:
Field(s) of use	Indoor — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients),

	<ul style="list-style-type: none"> — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. — for professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1.5 ml per stroke, 2 strokes per= 3 ml). Minimum exposure time: 30s Dilution (%): ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100ml, 500ml and 1 000ml in transparent HDPE bottles with PP flip top cap.

4.1.1. Use-specific instructions for use

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

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

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 2

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

See general directions for use of meta SPC 2

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

See general directions for use of meta SPC 2

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of meta SPC 2

4.2. Use description

Table 4. Use # 2 – Surgical handrub

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

	Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: viruses (limited spectrum of virucidal activity) Development stage:
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: in portions of 3 ml (use dispensers: for example set to 1.5 ml per stroke, 2 strokes per 3 ml). Minimum exposure time: 90s Dilution (%): ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100ml, 500ml and 1 000ml in transparent HDPE bottles with PP flip top cap.

4.2.1. Use-specific instructions for use

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

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

4.2.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 2.

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

See general directions for use of meta SPC 2.

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

See general directions for use of meta SPC 2.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 2.

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

5.1. Instructions for use

For professional use only

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water. for 15 minutes. Call a POISON CENTRE or a doctor.

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

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

Information to healthcare personnel/doctor:

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

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

After spilling: Take up with absorbent material (for example sand, kieselgur, universal binder). When picked up, treat material as prescribed under "Disposal considerations".

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

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal.

Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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

Technical measures and storage conditions:

Shelf-life: 36 months

Keep container tightly closed and dry in a cool, well-ventilated place. Protect from direct sunlight.

Recommended storage temperature: 0-30°C

Requirements for storage rooms and vessels:

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original one.

Advice on storage assembly:

Do not store together with: oxidizing substances; spontaneously combusting substances

⁽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.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	L+R handdisinfect 03		Market area: EU		
Authorisation number	EU-0027466-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0

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

Trade name(s)	L+R handdisinfect 04		Market area: EU		
Authorisation number	EU-0027466-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0