# Summary of product characteristics for a biocidal product family

Family name: L+R Propanol PT1 Family

**Product type(s):** PT01 - Human hygiene (Disinfectants)

**Authorisation number:** EU-0027466-00

**R4BP 3 asset reference number:** EU-0027466-0000

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#### Part I.- First information level

#### 1. Administrative information

#### 1.1. Family name

L+R Propanol PT1 Family

#### 1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

#### 1.3. Authorisation holder

Name and address of the authorisation holder

Name	Lohmann & Rauscher International GmbH & Co. KG
Address	Westerwaldstrasse 4 56579 Rengsdorf Germany
EU-0027466-00	

**Authorisation number** 

20 0021 100 00

R4BP 3 asset reference number

EU-0027466-0000

Date of the authorisation

31/07/2022

Expiry date of the authorisation

30/06/2032

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

Name of the manufacturer

Lohmann & Rauscher International GmbH & Co. KG

Address of the 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	1355 - Propan-2-ol
Name of the manufacturer	INEOS Solvent Cormany CmbH
Name of the manufacturer	INEOS Solvent Germany GmbH
Address of the manufacturer	Römerstrasse 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733 47443 Moers Germany
Active substance	1354 - Propan-1-ol
Name of the manufacturer	OQ Chemicals GmbH (formerly OXEA)
Address of the 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	1354 - Propan-1-ol
Active substance  Name of the manufacturer	1354 - Propan-1-ol Sasol Chemie GmbH & Co. KG
Name of the manufacturer	Sasol Chemie GmbH & Co. KG  Secunda Chemical Operations, Sasol Place, 50 Katherine Street 2090 Sandton South
Name of the manufacturer  Address of the manufacturer	Sasol Chemie GmbH & Co. KG  Secunda Chemical Operations, Sasol Place, 50 Katherine Street 2090 Sandton South Africa
Name of the manufacturer  Address of the manufacturer	Sasol Chemie GmbH & Co. KG  Secunda Chemical Operations, Sasol Place, 50 Katherine Street 2090 Sandton South Africa
Name of the manufacturer  Address of the manufacturer  Location of manufacturing sites	Sasol Chemie GmbH & Co. KG  Secunda Chemical Operations, Sasol Place, 50 Katherine Street 2090 Sandton South Africa  Secunda Chemical Operations, PDP Kruger Street 2302 Secunda South Africa
Name of the manufacturer  Address of the manufacturer  Location of manufacturing sites  Active substance	Sasol Chemie GmbH & Co. KG  Secunda Chemical Operations, Sasol Place, 50 Katherine Street 2090 Sandton South Africa  Secunda Chemical Operations, PDP Kruger Street 2302 Secunda South Africa  1354 - Propan-1-ol

### 2. Product family composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45 - 45
Propan-1-ol		Active Substance	71-23-8	200-746-9	30 - 30
Tetradecanol	Myristil alcohol	Non-active substance	112-72-1	204-000-3	0 - 0,95

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

AL - Any other liquid

### Part II.- Second information level - meta SPC(s)

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 1

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

#### 2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45 - 45

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30 - 30
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

Formulation(s)

AL - Any other liquid

#### 3. Hazard and precautionary statements of the meta SPC

#### **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

#### 4.1 Use description

#### Use 1 - Hygienic handrub

### **Product type** Where relevant, an exact description of the authorised

PT01 - Human hygiene (Disinfectants)

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 frequencies

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

#### Use 2 - Surgical handrub

**Product type** 

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Not relevant.

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 frequencies

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 1000ml 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 of the meta SPC

#### 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.

	20	
Call 112/ambulance for medical assistant After spilling: Take up with absorbent mat prescribed under "Disposal consideration	erial (for example sand, kieselgur, universal bind	der). When picked up, treat material as
5.4 Instructions for safe disr	osal of the product and its pack	aging
removal.	ng and when emptied completely disposed of in	
Incompletely emptied packaging must be	disposed of in the form of disposal specified by	the regional disposer.
_	d shelf-life of the product under r	normal conditions of storage
Technical measures and storage condition Shelf-life: 36 months		
Recommended storage temperature: 0-3		unlight.
Requirements for storage rooms and ves Containers which are opened must be ca	sels: refully closed and kept upright to prevent leakag	e. Always keep in containers of same
material as the original one. Advice on storage assembly:	tances; spontaneously combusting substances.	
Do not otoro togotrior with oxidizing outpo	tarious, operitariously combusting capetarious.	
6. Other information		
7. Third information level:	individual products in the me	ta SPC
	individual products in the me	
7.1 Trade name(s), authorisa	•	
7.1 Trade name(s), authorisa	•	
7.1 Trade name(s), authorisa product	tion number and specific compos	sition of each individual
7.1 Trade name(s), authorisa product	•	
7.1 Trade name(s), authorisa product Trade name(s)	tion number and specific compos	sition of each individual
7.1 Trade name(s), authorisa	tion number and specific compos	sition of each individual
7.1 Trade name(s), authorisa product Trade name(s)	tion number and specific compose  L+R handdisinfect blue	sition of each individual

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	45
Propan-1-ol		Active Substance	71-23-8	200-746-9	30
Tetradecanol	Myristil alcohol	Non-active substance	112-72-1	204-000-3	0,95

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 2

#### 1.2. Suffix to the authorisation number

1-2

#### 1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

### 2. Meta SPC composition

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

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

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

Formulation(s)

AL - Any other liquid

#### 3. Hazard and precautionary statements of the meta SPC

#### **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

#### 4.1 Use description

#### 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
	<ul> <li>hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients),</li> <li>hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands.</li> <li>for professional use only.</li> </ul>
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequencies	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.
	Industrial
Category(ies) of users	Professional
	i i iologgioriai

100ml, 500ml and 1000ml in transparent HDPE bottles with PP flip top cap.

Pack sizes and packaging material

#### 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

#### Use 2 - Surgical handrub

#### **Product type**

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT01 - Human hygiene (Disinfectants)

Not relevant.

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 frequencies

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 1000ml 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.

nstructions and emergency measures to protect the environment
See general directions for use of meta SPC 2.
.2.4 Where specific to the use, the instructions for safe disposal of the product and its ackaging
See general directions for use of meta SPC 2.
2.5 Where specific to the use, the conditions of storage and shelf-life of the product nder normal conditions of storage
See general directions for use of meta SPC 2.
. General directions for use of the meta SPC
For professional use only
For professional use only  2. Risk mitigation measures

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.

prescribed under "Disposal consideration	aterial (for example sand, kieselgur, universal bi ons".	nder). When picked up, treat material as
.4. Instructions for safe dis	sposal of the product and its pack	kaging
	aging and when emptied completely disposed of	n accordance with the regulations for waste
removal. Incompletely emptied packaging must b	oe disposed of in the form of disposal specified by	the regional disposer.
.5. Conditions of storage a	nd shelf-life of the product under	normal conditions of storage
Technical measures and storage condit Shelf-life: 36 months	ions:	
Recommended storage temperature: 0-		sunlight.
Requirements for storage rooms and ve Containers		
which are opened must be carefully clo leakage. Always keep in containers of s		
Advice on storage assembly:	ostances; spontaneously combusting substances	
. Other information		
. Other information		
Third information lavel	: individual products in the mo	eta SPC
. Timu imormation level		
	ation number and specific compo	
.1 Trade name(s), authoris	ation number and specific compo	
.1 Trade name(s), authoris	ation number and specific compo	
.1 Trade name(s), authoris	ation number and specific compo	
.1 Trade name(s), authoris roduct		osition of each individual
.1 Trade name(s), authoris product		osition of each individual
.1 Trade name(s), authoris roduct rade name(s)		osition of each individual

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

Trade name(s)

L+R handdisinfect 04

Market area: EU

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

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