

Summary of product characteristics for a biocidal product

Product name: L+R handdisinfect 04

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

PT01 - Human hygiene (Disinfectants)

Authorisation number: EU-0027466-00

R4BP 3 asset reference number: EU-0027466-0003

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Administrative information

1.1. Trade names of the product

L+R handdisinfect 04

1.2. 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-0027466-00 1-2

R4BP 3 asset reference number

EU-0027466-0003

Date of the authorisation

31/07/2022

Expiry date of the authorisation

30/06/2032

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Lohmann & Rauscher International GmbH & Co. KG
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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
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1.4. Manufacturer(s) of the active substance(s)

Active substance	1355 - Propan-2-ol
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
Name of the manufacturer	Sasol Chemie GmbH & Co. KG
Address of the 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	1354 - Propan-1-ol
Name of the manufacturer	BASF SE
Address of the manufacturer	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38 67056 Ludwigshafen Germany

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

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

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

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)

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 - 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 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 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 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

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:

<p>Scientific name: other Common name: Yeasts Development stage:</p> <p>Scientific name: other Common name: Mycobacteria Development stage:</p> <p>Scientific name: other Common name: viruses (limited spectrum of virucidal activity) Development stage:</p>
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Field(s) of use

<p>Indoor</p> <p>Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.</p>

Application method(s)

<p>Method: Manual application Detailed description: Rubbing</p>

Application rate(s) and frequencies

<p>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.</p>
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Category(ies) of users

<p>Professional</p>

Pack sizes and packaging material

<p>100ml, 500ml and 1000ml in transparent HDPE bottles with PP flip top cap.</p>
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4.2.1 Use-specific instructions for use

<p>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.</p>

4.2.2 Use-specific risk mitigation measures

<p>See general directions for use of meta SPC 2.</p>
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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

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

6. Other information