

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

I-HDL 01

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0027467-0000 1-1

R4BP asset number: EU-0027467-0022

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|----------|
| Trade name(s) | I-HDL 01 |
|---------------|----------|

1.2. Authorisation holder

| | | |
|--|---------|--|
| Name and address of the authorisation holder | Name | Knieler & Team GmbH |
| | Address | Kattrepelsbrücke 1 20095 Hamburg Germany |
| Authorisation number | | EU-0027467-0000 1-1 |
| <i>R4BP asset number</i> | | EU-0027467-0022 |
| Date of the authorisation | | 11/08/2022 |
| Expiry date of the authorisation | | 31/07/2032 |

1.3. Manufacturer(s) of the product

| | |
|---------------------------------|---|
| Name of manufacturer | Knieler & Team GmbH |
| Address of manufacturer | Kattrepelsbrücke 1 20095 Hamburg Germany |
| Location of manufacturing sites | Knieler & Team GmbH, Kattrepelsbrücke 1 20095 Hamburg Germany A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto-Brenner-Straße 16-18 21337 Lüneburg Germany |

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

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

| | |
|---------------------------------|--|
| 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 |

| | |
|---------------------------------|---|
| 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-2-ol |
| Name of manufacturer | Stockmeier Chemie GmbH & Co. KG |
| Address of manufacturer | Am Stadtholz 37 33609 Bielefeld Germany |
| Location of manufacturing sites | INEOS Solvent Germany GmbH, Römerstrasse 733 47443 Moers Germany |

| | |
|---------------------------------|--|
| Active substance | Propan-2-ol |
| Name of manufacturer | Brenntag GmbH |
| Address of manufacturer | Stinnes-Platz 1 45472 Mülheim an der Ruhr Germany |
| Location of manufacturing sites | Shell Nederland Raffinaderij B.V. 3196 KK Rotterdam-Pernis Netherlands (the) Exxon Mobil LA 70805 Baton Rouge United States (the) |

| | |
|---------------------------------|--|
| Active substance | Propan-2-ol |
| 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 INEOS Solvent Germany GmbH, Shamrockstrasse 88 44623 Herne Germany |

2. PRODUCT COMPOSITION AND FORMULATION

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

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

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|--------------------------|--|
| Hazard statements | H226: Flammable liquid and vapour. H318: Causes serious eye damage. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of container to an authorised waste collection point. |

4. AUTHORISED USE(S)

4.1. Use description

Table 1. hygienic handrub, liquid

| | |
|--|--|
| Product type | PT01: Human hygiene |
| 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: no data Scientific name: other Common name: Mycobacteria Development stage: no data Scientific name: other Common name: Yeasts Development stage: no data Scientific name: other Common name: Enveloped viruses Development stage: no data |
| Field(s) of use | indoor use - 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) Contact time: 30 s 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 | 100, 125, 500, 1000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; |

| | |
|--|--|
| | <p>5000 ml transparent/white HDPE canister with HDPE screwed cap.</p> <p>In addition, exclusively for E-HDL (product 1.2): 500 and 1000 ml in transparent HDPE lightweight bottle with integrated PP pump.</p> |
|--|--|

4.1.1. Use-specific instructions

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.

Do not refill.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See general directions for use of meta SPC 1

4.1.4. 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

4.1.5. 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

4.1.6. 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. surgical handrub, liquid

| | |
|--|---|
| Product type | PT01: Human hygiene |
| 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: no data Scientific name: other Common name: Mycobacteria Development stage: no data Scientific name: other Common name: Yeasts Development stage: no data Scientific name: other Common name: enveloped viruses Development stage: no data |
| Field(s) of use | indoor use 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: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s 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 | 100, 125, 500, 1000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for E-HDL (product 1.2): 500 and 1000 ml in transparent HDPE lightweight bottle with integrated PP pump. |

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4.2.1. Use-specific instructions

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.

Do not refill.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See general directions for use of meta SPC 1

4.2.4. 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

4.2.5. 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

4.2.6. 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 USE¹

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

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

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 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.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION