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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

D-FDT

Product type(s)

PT02: Disinfectants and algacides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: EU-0027467-0000 1-9

R4BP asset number: EU-0027467-0020

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	D-FDT
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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 1-9
<i>R4BP asset number</i>		EU-0027467-0020
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	14,925
Propan-2-ol		active substance	67-63-0	200-661-7	44,73

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly 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 contents to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. hard non-porous small surface disinfection RTU wipes

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
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: Yeasts Development stage: no data Scientific name: other Common name: Enveloped viruses Development stage: no data
Field(s) of use	indoor use Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces For professional use only.
Application method(s)	Method: manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C) . The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete Coverage.
Application rate(s) and frequency	Application rate: Minimum exposure time: for the control of bacteria, yeasts and enveloped viruses: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box

	Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.
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4.1.1. Use-specific instructions

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See general directions for use of meta SPC 9

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 9

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 9

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 9

4.2. Use description

Table 2. hard non-porous small surface disinfection RTU wipes

Product type	PT04: Food and feed area
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Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	<p>Scientific name: other Common name: Bacteria Development stage: no data</p> <p>Scientific name: other Common name: Yeasts Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Health care facilities and food industry, for example patient-near surrounding, food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.</p>
Application method(s)	<p>Method: manual application</p> <p>Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C) . The surface to be disinfected is wetted with a sufficient amount of the product by wiping, ensuring complete coverage.</p>
Application rate(s) and frequency	<p>Application rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet.</p> <p>Dilution (%): Ready-to-use product</p> <p>Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.</p>
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box</p> <p>Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.</p>

4.2.1. Use-specific instructions

Surfaces should always be visibly clean prior to disinfection.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See general directions for use of meta SPC 9

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 9

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 9

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 9

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

For professional use only.

For wipes reseal the package after opening.

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.

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

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.

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