#### **ANNEX**

#### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

#### F-FDT

## **Product type(s)**

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

PT04: Food and feed area

Authorisation number: EU-0027467-0000 1-8

**R4BP asset number:** EU-0027467-0018

#### 1. ADMINISTRATIVE INFORMATION

## 1.1. Trade name(s) of the product

Trade name(s)	F-FDT

#### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	Knieler & Team GmbH
ivalile and address of the authorisation holder	Address	Kattrepelsbrücke 1 20095 Hamburg Germany
Authorisation number		EU-0027467-0000 1-8
R4BP asset number		EU-0027467-0018
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 Corperation (formerly Oxea Coperation), 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	25
Propan-2-ol		active substance	67-63-0	200-661-7	30

## 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 or doctor/physician
	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. hard non-porous small surface disinfection RTU wipes

Product type	PT02: Disinfectants and algaecides 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: viruses (limited spectrum virucidal activity) 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 • for the control of viruses (limited spectrum virucidal activity): 5 min; 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 white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% Viscose and 70% Polyethylene Terephtalate (VIS/PET) wipes. Exclusively for C-FDT (product 8.2):

#### 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 8.

# 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 8.

## 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 8

## 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 8

#### 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)	Scientific name: other Common name: Bacteria Development stage: no data		
	Scientific name: other Common name: Yeasts Development stage: no data		
Field(s) of use	indoor use		
	Health care facilities and food industry, for example food preparation and handling in kitchens/restaurants): 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 ( $20\pm2$ °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product by wiping, ensuring complete coverage.		
Application rate(s) and frequency	Application rate: Minimum exposure time: • for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet		
	Dilution (%): Ready-to-use product		
	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.		
Category(ies) of users	industrial; professional		
Pack sizes and packaging material	Flow-pack of white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% viscose and 70% polyethylene terephtalate (VIS/PET) wipes.  Exclusively for C-FDT (product 8.2):  Transparent high-density polyethylene (HDPE) Canister with PP screwed cap, containing 30 PET wipes;  Dispenser bag of white PE composite foil, containing 30 or 90 PET wipes used with dispenser box.		

## **4.2.1.** Use-specific instructions

Surfaces should always be visibly clean prior to disinfection.

4.2.2.	<b>Use-specifi</b>	c risk	mitigation	measures
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#### 4.2.3. Use-specific risk mitigation measures

See general directions for use of meta SPC 8

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 8

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 8

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 8

#### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### **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.

<sup>&</sup>lt;sup>1</sup>Instructions 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:  $0-30^{\circ}C$ Do not store at temperatures below  $0^{\circ}C$ 

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

## 6. OTHER INFORMATION