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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

calgonit Des-H

Product type(s)

PT01: Human hygiene

Authorisation number: 3564-1

R4BP asset number: BG-0032047-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	calgonit Des-H Renosan Händedesinfektion HD
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Calvatis GmbH
	Address	Am Hafen 16 68526 Ladenburg Germany
Authorisation number		3564-1
<i>R4BP asset number</i>		BG-0032047-0000
Date of the authorisation		28/03/2024
Expiry date of the authorisation		21/12/2033

1.3. Manufacturer(s) of the product

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr.-Albert-Reimann-Str. 16a 68526 Ladenburg Germany
Location of manufacturing sites	Dr.-Albert-Reimann-Str. 16a 68526 Ladenburg Germany Am Nordseekai 22 D 73207 Plochingen Germany

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

Active substance	Propan-1-ol
Name of manufacturer	Oxea GmbH
Address of manufacturer	Rheinpromenade 4A 40789 Monheim Germany
Location of manufacturing sites	Rheinpromenade 4A 40789 Monheim Germany

Active substance	Propan-1-ol
Name of manufacturer	Sasol Chemie GmbH & Co. KG
Address of manufacturer	Anckelmannsplatz 1 20537 Hamburg Germany
Location of manufacturing sites	Anckelmannsplatz 1 20537 Hamburg Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK Vodelingenenplaat, Rotterdam Netherlands (the)
Location of manufacturing sites	Vondelingenweg 601 3196 KK Vodelingenenplaat, Rotterdam Netherlands (the)

Active substance	Propan-2-ol
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Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway LA 70897 Baton Rouge, Louisiana United States (the)
Location of manufacturing sites	4999 Scenic Highway LA 70897 Baton Rouge, Louisiana United States (the)

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	H225: Highly flammable liquid and vapour. H318: Causes serious eye damage. H336: May cause drowsiness or dizziness.
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. P280: Wear eye protection. 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 doctor. P370+P378: In case of fire: Use CO2, sand, fire-extinguishing powder to extinguish. P501: Dispose of contents to container in accordance with local regulations..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1 - Hygienic hand disinfection via pump dispenser

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data Scientific name: Fungi Common name: fungi Development stage: no data Scientific name: Viruses Common name: Viruses (Limited spectrum virucidal activity) Development stage: no data
Field(s) of use	indoor use The RTU product is used primarily in the food industry, e.g. slaughterhouses, beverage industry and also in the hotel and gastronomy industry.
Application method(s)	Method: Pump dispenser Detailed description: Hygienic hand rub
Application rate(s) and frequency	Application Rate: 4 mL Dilution (%): - Number and timing of application: The product will be applied maximum 5 times a day.
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	1. Bottle: 1 L (HDPE) 2. Jerrycan: 5 L (HDPE)

4.1.1. Use-specific instructions for use

The RTU product is applied on cleaned and dried hands via a pump dispenser, and then hands are rubbed intensively for 30-60 seconds. The disinfectant is left on the skin until it evaporates completely.

4.1.2. Use-specific risk mitigation measures

Please refer to general directions for use.

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

Please refer to general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to general directions for use.

4.2. Use description

Table 2. Use 2 - Hygienic hand disinfection via electronic dispenser

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data Scientific name: Fungi Common name: fungi Development stage: no data Scientific name: Viruses Common name: Viruses (Limited spectrum virucidal activity) Development stage: no data
Field(s) of use	indoor use The RTU product is applied on cleaned and dried hands via electronic dispenser, and then hands are rubbed intensively for 30-60 seconds. The disinfectant is left on the skin until it evaporates completely.
Application method(s)	Method: Electronic dispenser Detailed description: -
Application rate(s) and frequency	Application Rate: 4 mL Dilution (%): - Number and timing of application: The product will be applied maximum 5 times a day.
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	Bottle: 1 L (HDPE) Jerrycan: 5 L (HDPE)

4.2.1. Use-specific instructions for use

The RTU product is applied via an electronic dispenser on cleaned and dried hands, and then hands are rubbed intensively for 30-60 seconds. The disinfectant is left on the skin until it evaporates completely.

4.2.2. Use-specific risk mitigation measures

Please refer to general directions for use.

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

Please refer to general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to general directions for use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See use-specific instruction for use.

5.2. Risk mitigation measures

Ensure good ventilation at the workplace. Avoid splashes or spray in enclosed areas. Fumes can combine with air to form an explosive mixture. Keep ignition sources away – do not smoke.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

Call a POISON CENTER or doctor/physician if you feel unwell.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. If eye irritation persists, get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician

Protection of the environment:

Do not allow product to reach sewage systems or water bodies in great quantities.

Absorb with liquid-binding material (sand, diatomite, or universal binder).

Do not use combustible material like sawdust.

Dispose of the material collected according to regulations.

Ensure adequate ventilation.

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

Contaminated packages must be completely emptied and may be reused after proper cleaning.

Disposal must be made according to official regulations.

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

Store cool (not above 30°C) and protect from frost.

Shelf-life: 24 month (to be verified during the long term storage at ambient temperature test)

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

6. OTHER INFORMATION