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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Kortol

Product type(s)

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

Authorisation number: SI-0032721-0000 1-2

R4BP asset number: SI-0032721-0007

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Kortol
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	BIOCEL LTD.
	Address	ROCKGROVE INDUSTRIAL ESTATE 00000 LITTLE ISLAND Ireland
Authorisation number	SI-0032721-0000 1-2	
<i>R4BP asset number</i>	SI-0032721-0007	
Date of the authorisation	05/06/2024	
Expiry date of the authorisation	05/06/2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	Biocel Ltd
Address of manufacturer	Rockgrove Industrial Estate T45 CY51 Little Island, Co. Cork Ireland
Location of manufacturing sites	Biocel Ltd site 1 Rockgrove Industrial Estate T45 CY51 Little Island, Co. Cork Ireland

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Micro-Bio (Ireland) Ltd.
Address of manufacturer	Industrial Estate P61 X977 Fermoy, Co. Cork Ireland
Location of manufacturing sites	Micro-Bio (Ireland) Ltd. site 1 Industrial Estate P61 X977 Fermoy, Co. Cork Ireland

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 (%)
Active chlorine released from sodium hypochlorite		active substance			2
Sodium chloride		Non-active substance	7647-14-5	231-598-3	16,5
Water		Non-active substance	7732-18-5	231-791-2	81,5

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H314: Causes severe skin burns and eye damage.</p> <p>H412: Harmful to aquatic life with long lasting effects.</p> <p>EUH071: Corrosive to the respiratory tract.</p>
Precautionary statements	<p>P260: Do not breathe vapours.</p> <p>P260: Do not breathe spray.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear gloves/protective clothing/eye protection/face protection..</p> <p>P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER.</p> <p>P310: Immediately call a doctor.</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to in accordance with local/national regulations.</p> <p>P501: Dispose of container to in accordance with local/national regulations.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use #2.1 Hard surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Disinfection of pre-cleaned hard surfaces in household
Application method(s)	Method: Spraying and wiping with mop/cloth and bucket to distribute disinfectant on the surface Detailed description: /
Application rate(s) and frequency	Application rate: 414 mg/L active or available chlorine Dilution (%): 1.8% (v/v) product dilution Number and timing of application: 15 minutes contact time 1 application post-use and per day
Category(ies) of users	professional
Pack sizes and packaging material	5 litres HDPE bottle with HDPE vented cap. 10 litres, 20 litres and 25 litres HDPE drum with HDPE vented cap. 60 litres, 120 litres and 200 litres HDPE drum with PP vented bung. 1000 litres IBC HDPE container with stainless steel frame & HDPE vented lid & discharge valve.

4.1.1. Use-specific instructions

Clean the surface before disinfection.

Add 90 ml in 5 litres of cold water (dilution at 1.8% (v/v)) and apply the product solution uniformly on the surface to be treated in sufficient quantity to wet the surface completely. Surfaces are disinfected after 15 minutes contact time.

Fresh solution should be made up daily.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

During mixing and loading, wear chemical-resistant gloves, eye/face protection, protective clothing and closed footwear (PPE material to be specified by the authorisation holder within the product information).

Uninvolved persons, children and animals should not be present during mixing and loading of the product.

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 use.

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

See general directions use.

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 use.

4.2. Use description

Table 2. Use #2.2 Medical equipment disinfection

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data
Field(s) of use	indoor use Disinfecting of pre-cleaned equipment (e.g. breastfeeding equipment, etc.) in hospitals and healthcare facilities
Application method(s)	Method: Immersion of equipment by dipping/soaking Detailed description: /

Application rate(s) and frequency	Application rate: 414 mg/L active or available chlorine Dilution (%): 1.8% (v/v) product dilution Number and timing of application: 30 minutes contact time 1 application post-use and per day
Category(ies) of users	professional
Pack sizes and packaging material	5 litres HDPE bottle with HDPE vented cap. 10 litres, 20 litres and 25 litres HDPE drum with HDPE vented cap. 60 litres, 120 litres and 200 litres HDPE drum with PP vented bung. 1000 litres IBC HDPE container with stainless steel frame & HDPE vented lid & discharge valve.

4.2.1. Use-specific instructions

Equipment has to be thoroughly pre-cleaned before disinfection.

Add 90 ml of product to 5 litres of water (dilution at 1.8% (v/v)) and immerse the equipment in the prepared product solution for minimum of 30 minutes.

Ensure that no air bubble is trapped inside the bottles. Wash your hands before taking the equipment out of the solution. Shake off any excess of solution.

Fresh solution should be made up daily.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

During mixing and loading, wear chemical-resistant gloves, eye/face protection, protective clothing and closed footwear (PPE material to be specified by the authorisation holder within the product information).

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 use.

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

See general directions use.

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 use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See use-specific instructions for each use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

See precautionary statements.

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

Dispose of contents/container in accordance with local/national regulations.

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

Store locked up.

Shelf-life: 3 months

Store the product in cool (0 - 25 °C) and protect from frost.

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

6. OTHER INFORMATION