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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Aquasan

Product type(s)

PT04: Food and feed area

Authorisation number: IE/BPA 70762 1-4

R4BP asset number: IE-0032722-0009

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Aquasan Agri-san Rezult

1.2. Authorisation holder

Name and address of the authorisation holder	Name	BIOCEL LTD.
	Address	ROCKGROVE INDUSTRIAL ESTATE 00000 LITTLE ISLAND Ireland
Authorisation number		IE/BPA 70762 1-4
R4BP asset number		IE-0032722-0009
Date of the authorisation		17/06/2024
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			3,5
Acusol 445N Polymer		Non-active substance			1
Water		Non-active substance	7732-18-5	231-791-2	78,5
Sodium hydroxide	Sodium hydroxide	Non-active substance	1310-73-2	215-185-5	17

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H290: May be corrosive to metals.
	H314: Causes severe skin burns and eye damage.
	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P234: Keep only in original packaging.
	P260: Do not breathe vapours.
	P260: Do not breathe spray.
	P273: Avoid release to the environment.
	P280: Wear gloves/protective clothing/eye protection/ face protection..
	P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
	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.
	P310: Immediately call a doctor.
	P363: Wash contaminated clothing before reuse.
	P390: Absorb spillage to prevent material damage.
	P391: Collect spillage.
	P405: Store locked up.
	P501: Dispose of contents to in accordance with local/ national regulations.
	P501: Dispose of container to in accordance with local/national regulations.

4. AUTHORISED USE(S)

4.1.   Use description

Table 1. Use #4.2 Dairy plant disinfection - cold/hot wash and bulk tank cleaning

Product type	PT04: Food and feed area
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: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of inner surfaces of milking equipment (bulk milk tanks and milking machines)
Application method(s)	Method: Closed system - CIP (cold and/or hot solution circulated in dairy plant) and automatic dosing for bulk milk tanks Detailed description: /
Application rate(s) and frequency	Application rate: rate ranges from 347 to 434 mg/L active or available chlorine Dilution (%): products are used diluted Number and timing of application: 10 minutes contact time 1. CIP - cold circulation and automatic dosing: 1 % (v/v) corresponding to 434 mg/L available chlorine 2 applications per day: one in the morning and one in the evening 2. CIP - hot circulation: 0.8 % (v/v) corresponding to 347 mg/L available chlorine 2 applications per day: one in the morning and one in the evening 3. Automatic bulk tank cleaning: 1 % (v/v) corresponding to 434 mg/L active chlorine 1 application 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

CIP - cold circulation

1. Wash jetters and outside of clusters and attach to jetters
2. Rinse plant with approximately 14 litres of clean water for each unit (preferably water at 36 °C).
3. Prepare product solution using 450 ml of product per 45 litres of water (dilution at 1% (v/v)), which is sufficient for 5-6 units. Add additional 9 litres of solution for each extra unit.
4. Circulate solution for 10 minutes.
5. Rinse out well until all traces of product are removed. Use 14 litres of cold, clean water per unit.
Use same procedure in the morning and the evening.
When using a cold circulation, include a hot wash at a temperature of 70 – 80 °C once to twice weekly.

CIP - hot circulation:
Follow the same procedure as for cold circulation but use 360 ml per 45 litres of water (dilution at 0.8 % (v/v)). Use hot (70 – 80 °C) water to prepare solution. This is sufficient for 5 to 6 units. Add additional 9 litres of solution for each extra unit. Do not re-use prepared solution.

Automatic dosing (bulk milk tank):
1. Turn off refrigeration system.
2. Select the wash program and set up the wash.
3. Tanks with automatic dosing of product should be set to use 1% (v/v) solution.
4. Washing solution is made by adding 450 ml of product in 45 litres of water to the detergent bowl, attached to the water box of the automatic washer.
5. For hot cleaning use water at 70 – 80 °C.
5. Operate the wash programme according to the manufacturer's instructions. Minimum contact time of 10 minutes.

4.1.2.   Use-specific risk mitigation measures

4.1.3.   Use-specific risk mitigation measures

For mixing and loading task, maintenance of pipeline/stock tank and processing circuit 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).
For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in regulation 2020/749.

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.

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5. GENERAL DIRECTIONS FOR USE[1]

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 national regulations.

5.5.   Conditions of storage and shelf-life of the product under normal conditions of storage
Store locked up.
Shelf-life: 2 months
Store the product in cool (0 - 25 °C) and protect from frost.

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

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6. OTHER INFORMATION