

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Peracetic Acid 2%

Product type(s)

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

PT04: Food and feed area

Authorisation number: EU-0028970-0000 1-1

R4BP asset number: EU-0028970-0002

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Peracetic Acid 2% Talogen 2 iMClean Px
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Rigest Trading (Ireland) Limited
	Address	Mullingar Heifer Beef, Nolagh N91W896 Ballinalack Ireland
Authorisation number	EU-0028970-0000 1-1	
<i>R4BP asset number</i>	EU-0028970-0002	
Date of the authorisation	27/06/2024	
Expiry date of the authorisation	30/06/2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Peracetic acid
Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Airedale Mills, Skipton Road, Cross Hills BD20 7BX Keighley United Kingdom of Great Britain and Northern Ireland (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 (%)
Peracetic acid		active substance	79-21-0	201-186-8	2 % (w/w)
HEDP	etidronic acid	Non-Active substance	2809-21-4	220-552-8	1,2 % (w/w)

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H272: May intensify fire; oxidiser.</p> <p>H290: May be corrosive to metals.</p> <p>H314: Causes severe skin burns and eye damage.</p> <p>H302: Harmful if swallowed.</p> <p>H411: Toxic to aquatic life with long lasting effects.</p> <p>EUH071: Corrosive to the respiratory tract.</p>
Precautionary statements	<p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P234: Keep only in original packaging.</p> <p>P260: Do not breathe vapours.</p> <p>P260: Do not breathe spray.</p> <p>P264: Wash exposed skin thoroughly after handling.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves.</p> <p>P280: Wear protective clothing.</p> <p>P280: Wear eye protection.</p> <p>P280: Wear 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>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</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>P391: Collect spillage.</p>

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P501: Dispose of contents to a licensed hazardous-waste collection point.

P501: Dispose of container to a licensed hazardous-waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Cleaning in Place (CIP) including pharmaceutical and cosmetic industry

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: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	indoor use General (including pharmaceutical and cosmetic industry) Disinfection of hard, non-porous surfaces by CIP procedures (with circulation of the product solution in the production system)
Application method(s)	Method: CIP - Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment to be disinfected by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.
Application rate(s) and frequency	Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts: 0,02% PAA (e.g. 1% product with 2% PAA, that is 10 ml product/litre) • Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 5% product with 2% PAA, that is 50 ml product/litre) • Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of peracetic acid (PAA). Dilution (%): 2-7,5 % Number and timing of application: 1-2 applications per day

Category(ies) of users	industrial ; professional
Pack sizes and packaging material	High-density polyethylene (HDPE) bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with polypropylene (PP) bung: 200 litres HDPE intermediate bulk container (IBC) with HDPE screw cap: 1000 litres

4.1.1. Use-specific instructions

See general directions for use

4.1.2. Use-specific risk mitigation measures

See 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

See general directions for use

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

See 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

See general directions for use

4.2. Use description

Table 2. Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

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)	<p>Scientific name: - Common name: Bacteria Development stage: -</p> <p>Scientific name: - Common name: Yeasts Development stage: -</p> <p>Scientific name: - Common name: fungi Development stage: -</p> <p>Scientific name: - Common name: Viruses Development stage: -</p>
Field(s) of use	<p>indoor use</p> <p>General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pouring</p>
Application method(s)	<p>Method: Spraying or pouring (followed by wiping for a homogenous distribution)</p> <p>Detailed description: The diluted product must be placed in and sprayed with trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogeneous distribution).</p>
Application rate(s) and frequency	<p>Application rate: at room temperature, for 15 minutes contact time</p> <ul style="list-style-type: none"> • Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA , that is 75 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. <p>Dilution (%): 7,5 %</p> <p>Number and timing of application: 1-2 applications per day</p>
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres</p> <p>HDPE drum with PP bung: 200 litres</p> <p>HDPE IBC with HDPE screw cap: 1000 litres</p>

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4.2.1. Use-specific instructions

See general directions for use

4.2.2. Use-specific risk mitigation measures

See 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

See general directions for use

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

See 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

See general directions for use

4.3. Use description

Table 3. Disinfection of inner surfaces (e.g. tanks, pipes, vessels, filling machines) by CIP in food and feed industry

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts

	<p>Development stage: -</p> <p>Scientific name: - Common name: fungi Development stage: -</p> <p>Scientific name: - Common name: Viruses Development stage: -</p>
Field(s) of use	<p>indoor use</p> <p>In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by CIP procedures (with circulation).</p>
Application method(s)	<p>Method: Manual or automated dosing</p> <p>Detailed description: The diluted product shall be transferred to equipment to be disinfected by manual or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.</p>
Application rate(s) and frequency	<p>Application rate: at room temperature, for 15 minutes contact time • Active against bacteria and yeasts: 0,02% PAA (e.g. 1% product with 2% PAA, that is 10 ml product/litre) • Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 5% product with 2% PAA, that is 50 ml product/litre) • Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA.</p> <p>Dilution (%): 1-7,5 %</p> <p>Number and timing of application: 1-2 applications per day</p>
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres</p> <p>HDPE drum with PP bung: 200 litres</p> <p>HDPE IBC with HDPE screw cap: 1000 litres</p>

4.3.1. Use-specific instructions

See general directions for use

4.3.2. Use-specific risk mitigation measures

See general directions for use

4.3.3. 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

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

See general directions for use

4.3.5. 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

4.4. Use description

Table 4. Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	indoor use In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except

	in slaughterhouses and other processes with blood) Disinfection of hard and non-porous surfaces by spraying or pouring
Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	industrial ; professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres HDPE drum with PP bung: 200 litres HDPE IBC with HDPE screw cap: 1000 litres

4.4.1. Use-specific instructions

See general directions for use

4.4.2. Use-specific risk mitigation measures

See general directions for use

4.4.3. 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

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

See general directions for use

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

See section 5.5 for meta-SPC 1 in this document

4.5. Use description

Table 5. Disinfection by dipping in food and feed industry

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: - Common name: Bacteria Development stage: -</p> <p>Scientific name: - Common name: Yeasts Development stage: -</p> <p>Scientific name: - Common name: fungi Development stage: -</p> <p>Scientific name: - Common name: Viruses Development stage: -</p>
Field(s) of use	<p>indoor use</p> <p>In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard and non-porous surfaces) by dipping</p>
Application method(s)	<p>Method: Dipping</p> <p>Detailed description: The equipment to be disinfected shall be placed in a dipping bath. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.</p>
Application rate(s) and frequency	<p>Application rate: at room temperature, for 15 minutes contact time • Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (7,5% product with 2% PAA, that is 75 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA.</p> <p>Dilution (%): 7,5 %</p> <p>Number and timing of application: 1-2 applications per day</p>

Category(ies) of users	industrial ; professional
Pack sizes and packaging material	<p>HDPE bottle/pail with HDPE screw cap: 5 litres, 25 litres, 30 litres</p> <p>HDPE drum with PP bung: 200 litres</p> <p>HDPE IBC with HDPE screw cap: 1000 litres</p>

4.5.1. Use-specific instructions

See general directions for use

4.5.2. Use-specific risk mitigation measures

See general directions for use

4.5.3. 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

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

See general directions for use

4.5.5. 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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Disinfection cycle (for surface disinfection ONLY):

- the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;
- products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

- Disinfection procedures by CIP:

- final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

- Disinfection procedures by dipping:

- the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

- Disinfection procedures by spraying:

- wet the surface completely

(application rate > 20 ml/m² but maximum 100ml/m²) in order to keep the surface wet during the required contact time.

- do not use equipment until product is completely absorbed to the surface or air dried.

5.2. Risk mitigation measures

- Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) to be specified by the authorisation holder within the product information. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full titles of the EN standards and legislation.

- Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.

- When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m³ and 1,25 mg/m³ respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.

- Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

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

- Keep out of reach of children and non-target animals and pets.

- Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m³ for PAA & 1,25 mg/m³ for hydrogen peroxide)

- No bystanders are allowed in treated area during the application phase.

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

- 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.

- IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.

- Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE

- 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 INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

- Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.

- If symptoms: Call 112/ambulance for medical assistance.

- If no symptoms: Call a POISON CENTRE or a doctor.

- Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

- This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC of the European Parliament and of the Council. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.

- Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

- Store between 0°C and 30°C

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- Store in dark conditions
 - Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.
 - Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.
 - Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.
 - Shelf-life: Meta-SPC 1 (2% PAA): 6 months

6. OTHER INFORMATION

With respect to the "Category (ies) of users" note:

Professionals (including industrial users) means trained professionals if this is required by national legislation.

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321– Eye and face protection for occupational users – Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).