

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

INDAL PAA 3.5-BG-en

Product type(s)

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

PT04: Food and feed area

Authorisation number: 3260-1 1-1

R4BP asset number: BG-0024556-0001

| | |
|--|----|
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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|--------------------------|
| Trade name(s) | INDAL PAA 3.5 PAA 2.5 |
|---------------|--------------------------|

1.2. Authorisation holder

| | | |
|--|---------|---|
| Name and address of the authorisation holder | Name | STOCKMEIER FRANCE SAS |
| | Address | 3 rue de la Buhotière 35091 RENNES France |
| Authorisation number | | 3260-1 1-1 |
| <i>R4BP asset number</i> | | BG-0024556-0001 |
| Date of the authorisation | | 29/11/2021 |
| Expiry date of the authorisation | | 10/08/2030 |

1.3. Manufacturer(s) of the product

| | |
|---------------------------------|---|
| Name of manufacturer | QUARON SAS |
| Address of manufacturer | 3 Rue de la Buhotière 35091 Rennes France |
| Location of manufacturing sites | 3 Rue de la Buhotière 35091 Rennes France |

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

| | |
|---------------------------------|---|
| Active substance | Peracetic acid |
| Name of manufacturer | QUARON SAS |
| Address of manufacturer | 3 Rue de la Buhotière 35091 Rennes France |
| Location of manufacturing sites | 3 Rue de la Buhotière 35091 Rennes France |

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 | 2,6 |
| Hydrogen peroxide | | Non-active substance | 7722-84-1 | 231-765-0 | 25 |
| Acetic acid | | Non-active substance | 64-19-7 | 200-580-7 | 5 |
| Sulphuric acid | | Non-active substance | 7664-93-9 | | 0,96 |

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|--------------------------|--|
| Hazard statements | H290: May be corrosive to metals. H302+H332: Harmful if swallowed or if inhaled. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P234: Keep only in original packaging. P273: Avoid release to the environment. P280: Wear protective gloves. P280: Wear protective clothing. P280: Wear eye protection. P280: Wear 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. P260: Do not breathe dust. P260: Do not breathe fume. P260: Do not breathe gas. P260: Do not breathe mist. P260: Do not breathe vapours. P260: Do not breathe spray. |

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories

| | |
|--|--|
| 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: fungi/yeasts Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data |
| Field(s) of use | indoor use Indoors disinfection of wasted water, leachates and liquid laboratory waste in closed systems in medical biology laboratories. |
| Application method(s) | Method: closed system Detailed description: The concentrate solution is automatically diluted in the waste water to treat at 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system according to use instructions of the proper application equipment. The product is applied at ambient temperature with a contact time with liquid waste and surfaces of 30 minutes. The product can be applied on dirty surfaces of the equipment to disinfect them. The treated surfaces are rinsed with drinking water after the indicated contact time. The treated liquid waste, and the rinse water are discharged in sewers to be treated in a STEP. |
| Application rate(s) and frequency | Application Rate: The application is continuous during the time of treatment. Dilution (%): 0.1 to 4 (v/v) Number and timing of application: The product is used once a day, 220 days per year. |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 0.25-1-5-10-20-200-1000L HDPE |

4.1.1. Use-specific instructions for use

4.1.2. Use-specific risk mitigation measures

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

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

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

4.2. Use description

Table 2. Disinfection of closed circulation circuits for cleaning in place in private and public pharmaceutical and cosmetic industries and institutions

| | |
|--|--|
| 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: fungi/yeasts Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data |
| Field(s) of use | indoor use outdoor use Indoors and outdoors disinfection of closed circulation circuits for cleaning in place pharmaceutical and cosmetic industries and institutions. |
| Application method(s) | Method: closed system Detailed description: The concentrate solution is diluted in tap water from 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. |
| Application rate(s) and frequency | Application Rate: The application is continuous during the time of treatment. |

| | |
|-----------------------------------|---|
| | Dilution (%): 0.1 to 4 (v/v) Number and timing of application: The product is used once a day, 220 days per year. |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 0,25-1-5-10-20-200-1000L HDPE |

4.2.1. Use-specific instructions for use

4.2.2. Use-specific risk mitigation measures

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

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

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

4.3. Use description

Table 3. Surface disinfection by manual spraying in agri-food 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: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: fungi/yeasts Development stage: no data</p> <p>Scientific name: no data Common name: Viruses Development stage: no data</p> <p>Scientific name: no data Common name: Spores Development stage: no data</p> <p>Scientific name: no data Common name: Biofilms Development stage: no data</p> |
| Field(s) of use | <p>indoor use</p> <p>Indoors disinfection of open surfaces, materials or equipments, walls or floors by manual spraying in agri-food industry.</p> |
| Application method(s) | <p>Method: spraying</p> <p>Detailed description: The concentrate solution is diluted in tap water from 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system and then applied manually</p> |

| | |
|-----------------------------------|--|
| | by spraying on surfaces. The diluted product is then applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. |
| Application rate(s) and frequency | Application Rate: The application dose is 20mL/m ² . Dilution (%): 0.1 to 4 (v/v) Number and timing of application: The product is used once a day, 220 days per year. |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 0.25-1-5-10-20-200-1000L HDPE |

4.3.1. Use-specific instructions for use

4.3.2. Use-specific risk mitigation measures

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

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

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

4.4. Use description

Table 4. Disinfection of closed circulation circuits for cleaning in place in agri food 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: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: fungi/yeasts Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data Scientific name: no data Common name: Spores Development stage: no data Scientific name: no data Common name: Biofilms Development stage: no data |
| Field(s) of use | indoor use |

| | |
|-----------------------------------|--|
| | Indoors disinfection of closed circulation circuits for cleaning in place in agri-food industry. |
| Application method(s) | Method: closed system Detailed description: The concentrate solution is diluted in tap water from 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed systems for cleaning-in-place. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time. |
| Application rate(s) and frequency | Application Rate: The application is continuous during the time of treatment. Dilution (%): 0.1 to 4 (v/v) Number and timing of application: The product is used once a day, 220 days per year. |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 0.25-1-5-10-20-200-1000L HDPE |

4.4.1. Use-specific instructions for use

4.4.2. Use-specific risk mitigation measures

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

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

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

4.5. Use description

Table 5. Surfaces disinfection by manual dipping in agri-food 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: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: fungi/yeasts Development stage: no data Scientific name: no data Common name: Viruses Development stage: no data Scientific name: no data |

| | |
|-----------------------------------|--|
| | <p>Common name: Spores Development stage: no data</p> <p>Scientific name: no data Common name: Biofilms Development stage: no data</p> |
| Field(s) of use | <p>indoor use</p> <p>Indoors disinfection of surfaces by manual dipping in agri-food industry. This use also includes a foot bath disinfection</p> |
| Application method(s) | <p>Method: open system: dip treatment</p> <p>Detailed description: The concentrate solution is diluted in tap water from 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system and then applied manually by dipping on surfaces. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 to 30 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time.</p> |
| Application rate(s) and frequency | <p>Application Rate: -</p> <p>Dilution (%): 0.1 to 4 (v/v)</p> <p>Number and timing of application: The product is used once a day, 220 days per year.</p> |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 5-10-20-200-1000L HDPE |

4.5.1. Use-specific instructions for use

4.5.2. Use-specific risk mitigation measures

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

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

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

4.6. Use description

Table 6. Disinfection by automated spraying in closed professional washing machines in agri food industry and institutions, and institutional kitchens

| | |
|--|--|
| 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: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: fungi/yeasts</p> |

| | |
|-----------------------------------|---|
| | <p>Development stage: no data</p> <p>Scientific name: no data Common name: Viruses Development stage: no data</p> <p>Scientific name: no data Common name: Spores Development stage: no data</p> <p>Scientific name: no data Common name: Biofilms Development stage: no data</p> |
| Field(s) of use | <p>indoor use</p> <p>Indoors disinfection of materials and small equipments in closed professional washing machines in agri-food industry and institutions, and institutional kitchens.</p> |
| Application method(s) | <p>Method: closed system</p> <p>Detailed description: The concentrate solution is diluted in tap water from 0.1% to 4% (v/v), via a proportional automatic dosage system or a venturi system. The product is then applied automatically and continuously during the time of treatment in closed professional washing machines. The diluted product is applied at ambient temperature with a contact time with surfaces of 5 minutes. The product should be applied on clean surfaces. The treated surfaces are rinsed with drinking water after the indicated contact time.</p> |
| Application rate(s) and frequency | <p>Application Rate: The application is continuous during the time of treatment.</p> <p>Dilution (%): 0.1 to 4 (v/v)</p> <p>Number and timing of application: The product is used once a day, 220 days per year.</p> |
| Category(ies) of users | trained professional |
| Pack sizes and packaging material | 0.25-1-5-10-20-200-1000L HDPE |

4.6.1. Use-specific instructions for use

4.6.2. Use-specific risk mitigation measures

4.6.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Please refer to the authorised uses.

5.2. Risk mitigation measures

- 1) For Automatic pumping/mixing and loading applications for PT2 and 4: gloves, a protective coat, a face shield and a Full mask (P2 type) is required.
- 2) For manual spraying for PT 4 applications in agri-food industries: gloves, a protective coat and a half-mask (P1 type) is required.
- 3) For manual spraying application in slaughter houses and for manual dipping for all PT 4 applications: gloves and a protective coat are required. No respiratory protective equipment (RPE) is necessary.
- 4) For manual rinsing and manual draining for PT 2 and PT 4 applications: no personal protective equipment (PPE) and RPE is required.
- 5) In order to protect the environment, a thiosulfate neutralization can be performed in order to decompose peracetic acid and hydrogen peroxide that could potentially persist after treatment. For this neutralization, sodium thiosulfate as a powder (technical Na₂S₂O₃ 5H₂O, purity > 98.5%) can be directly added in the water. This neutralization could be required when the product is applied for waste disinfection (Use 1).

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

Likely direct or indirect effects:

- May be corrosive to metals.
- Harmful if swallowed or inhaled.
- Causes severe skin burns and eye damage.
- May cause respiratory irritation.
- Very toxic to aquatic life with long lasting effects.

First aid instructions:

- IF SWALLOWED : Rinse mouth. DO NOT induce vomiting.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Emergency measures to protect the environment:

- Avoid release to the environment
- Keep only in original container

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

- Avoid release to the environment.
- Keep only in original container.

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

Store at ambient temperature.

Shelf-life under normal conditions of storage: 2 years.

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

6. OTHER INFORMATION