

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Sodium Hypochlorite 5-6%

Product type(s)

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

PT04: Food and feed area

Authorisation number: SI-0032721-0000 1-1

R4BP asset number: SI-0032721-0005

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|--------------------------|
| Trade name(s) | Sodium Hypochlorite 5-6% |
|---------------|--------------------------|

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 1-1 | |
| <i>R4BP asset number</i> | SI-0032721-0005 | |
| 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 | | | 5 |
| Water | | Non-active substance | 7732-18-5 | 231-791-2 | 95 |

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>H410: Very toxic to aquatic life with long lasting effects.</p> <p>EUH031: Contact with acids liberates toxic gas.</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 protective 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>P391: Collect spillage.</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 #1.1 Hard surface disinfection indoor

| | |
|--|---|
| 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 Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data |
| Field(s) of use | indoor use Disinfection of hard surfaces (including floors) Not for use in healthcare areas |
| Application method(s) | Method: Spraying with trigger spray and wiping with cloth and bucket for distribution over the surface Detailed description: / |
| Application rate(s) and frequency | Application rate: ranges from 2180 - 5850 mg/L of active or available chlorine Dilution (%): products are used diluted Number and timing of application: 15 minutes contact time 1 application per day 1. Sodium Hypochlorite 10-11%: diluted to 2% or 5% (v/v) corresponding to 2340 mg/L or 5850 mg/L available chlorine, respectively 2. Sodium Hypochlorite 5-6%: diluted to 4% or 10% (v/v) corresponding to 2180 mg/L or 5450 mg/L available chlorine, respectively 3. Chlor-kleen Extra: diluted to 5% (v/v) corresponding to 2725 mg/L available chlorine 4. Blackwash: diluted to 2% (v/v) corresponding to 2340 mg/L available chlorine |

| | |
|-----------------------------------|---|
| 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

1. Sodium Hypochlorite 10-11%:Hard surface disinfectionPrepare a solution of 20 ml or 50 ml of product per litre of water (dilution at 2% or 5% (v/v), respectively). Apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. After 15 minutes contact time, rinse thoroughly with clean water.
2. Sodium Hypochlorite 5-6%:Hard surface disinfectionPrepare a solution of 40 ml or 100 ml of product per litre of water (dilution at 4% or 10% (v/v), respectively). Apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. After 15 minutes contact time, rinse thoroughly with clean water.
3. Chlor-Kleen Extra:Concrete surfaces and closed patiosClean down loose dirt by brushing or pressure washing with water. Add 5 litres per 100 litres of water (dilution at 5% (v/v)) and apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. Leave in contact for 15-30 minutes and rinse thoroughly with clean water.Due to the broad variation of patio slabs and other paving material, a small area should be tested first for suitability as colour variations may result from the use of Chlor-Kleen Extra on some materials.
4. Blackwash:Concrete surfaces and closed patiosClean down loose dirt by brushing or pressure washing with water. Add 2.5 litres per 100 litres of water (dilution at 2.5% (v/v)) and apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. Leave in contact for 15-30 minutes and rinse thoroughly with clean water.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

During mixing, loading and post-application steps, 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).During application (trigger spraying, mopping, wiping): wear chemical-resistant gloves, eye/face protection, protective clothing, closed footwear and respiratory protective equipment (PPE material to be specified by the authorisation holder within the product information).Spraying with trigger spray is only allowed in the downward direction.A mop or brush with a handle has to be used to apply the diluted solution by mopping to avoid exposure.Do not immerse hands in the diluted solution.For application by wiping, pour the solution directly on the surface and wipe with a cloth.Avoid contact with treated surfaces.After disinfection, treated surfaces should be thoroughly rinsed with water of drinking quality.Do not be present in the treatment area during the disinfection process. If it is necessary to be present, wear the same RPE and PPE as the professional user.Re-entry after application by mopping or wiping is only permitted once the air concentration of the chlorine has dropped below the reference value (0.5 mg avCl/m³).

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 #1.2 Hard surface disinfection outdoor

| | |
|--|---|
| 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 Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data |
| Field(s) of use | outdoor use Outdoor (T ≥20°C) Disinfection of hard surfaces (including floors, patios) |
| Application method(s) | Method: Spraying with trigger spray and wiping with cloth and bucket for distribution over the surface Detailed description: / |
| Application rate(s) and frequency | Application rate: ranges from 10900 - 35100 mg/L of active or available chlorine Dilution (%): products are used diluted Number and timing of application: 15 minutes contact time 1 application per day 1. Sodium Hypochlorite 10-11%: diluted to 10 - 30% (v/v) corresponding to 11700 - 35100 mg/L available chlorine 2. Sodium Hypochlorite 5-6%: diluted to 20% (v/v) corresponding to 10900 mg/L available chlorine |

| | |
|-----------------------------------|---|
| | 3. Blackwash: diluted to 10 - 20% (v/v) corresponding to 11700 - 23400 mg/L available chlorine |
| 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

1. Hypochlorite 10-11%:

Patio cleaning

Test a small area first before use as colour variation on some surfaces may occur. Wet surface before treatment to aid even distribution and clean down loose dirt by brushing or pressure washing.

Add 100 ml of product to 1 liter of water (dilution at 10% (v/v)) and apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. For heavy soiled areas add 200 - 300 ml of product to 1 liter of water (dilution at 20 - 30% (v/v)). Leave in contact for 15-30 minutes and wash off with clean water until all traces of solution have been removed. The product is effective at $\geq 20^{\circ}\text{C}$.

2. Sodium hypochlorite 5-6%:

Patio cleaning

Test a small area first before use as colour variation on some surfaces may occur. Wet surface before treatment to aid even distribution and clean down loose dirt by brushing or pressure washing.

Add 200 ml of product to 1 liter of water (dilution at 20% (v/v)) and apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. Leave in contact for 15-30 minutes and wash off with clean water until all traces of solution have been removed. The product is effective at $\geq 20^{\circ}\text{C}$.

3. Blackwash:

Mould removal

Add 5 - 10 litres of product per 50 litres of water (dilution at 10 - 20% (v/v)) and apply the product uniformly on the surface to be treated in sufficient quantity to wet the surface completely. Leave in contact for at least 15 minutes and rinse the surface with clean water and repeat process until clean. The product is effective at $\geq 20^{\circ}\text{C}$.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

During mixing, loading and post-application steps, 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).

During application (trigger spraying, mopping, wiping): wear chemical-resistant gloves, eye/face protection, protective clothing, closed footwear and respiratory protective equipment (PPE material to be specified by the authorisation holder within the product information).

Spraying with trigger spray is only allowed in the downward direction.

A mop or brush with a handle has to be used to apply the diluted solution by mopping to avoid exposure.
 Do not immerse hands in the diluted solution.
 For application by wiping, pour the solution directly on the surface and wipe with a cloth.
 Avoid contact with treated surfaces.
 After disinfection, treated surfaces should be thoroughly rinsed with water of drinking quality.
 Do not be present in the treatment area during the disinfection process. If it is necessary to be present, wear the same RPE and PPE as the professional user.
 Uninvolved persons, children and animals should not be present during disinfection.

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.

4.3. Use description

Table 3. Use #1.3 Toilet bowl 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 |
| Field(s) of use | indoor use Disinfection of toilet bowls, sinks Not for use in medical areas |
| Application method(s) | Method: pouring Detailed description: / |
| Application rate(s) and frequency | Application rate: RTU product 52500 mg/L active or available chlorine Number and timing of application: 15 minutes contact time 1 application per day |
| Category(ies) of users | professional |

| | |
|-----------------------------------|--|
| Pack sizes and packaging material | 5 litres HDPE bottle with HDPE vented cap. |
|-----------------------------------|--|

4.3.1. Use-specific instructions

Apply RTU Thick bleach product under the rim of the toilet and leave it to act for 15 minutes.
For disinfection of kitchen or bathroom drains and sinks, squirt the product into plugholes until it overflows.
Leave for 15 minutes and then rinse thoroughly with clean water.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

Wear chemical-resistant gloves, eye/face protection, protective clothing and closed footwear during application of the product (PPE material to be specified by the authorisation holder within the product information).
Avoid contact with treated surfaces.
Uninvolved persons, children and animals should not be present during disinfection.

4.3.4. 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.

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

See general directions use.

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

See general directions use.

4.4. Use description

Table 4. Use #1.4 Dairy plant disinfection, hot wash only

| | |
|--|---|
| 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 Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data |
| Field(s) of use | indoor use Pipeline disinfection Inner surfaces of milking equipment (bulk milk tanks and milking machines) |
| Application method(s) | Method: Closed system - CIP (hot wash solution) Detailed description: / |
| Application rate(s) and frequency | Application rate: 804 mg/L active or available chlorine Dilution (%): 0.67% (v/v) Number and timing of application: 10 minutes contact time 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. |

4.4.1. Use-specific instructions

Pre-rinse the plant with approximately 14 litres preferably lukewarm water to remove the milk residue. Use a solution of 300 ml BFS hotwash product in 45 litres of water (dilution at 0.67% (v/v)). Use preferably hot water at 30-35 °C and circulate for 10 minutes. Rinse out system well, using 14 litres of clean water per unit, until all traces of product are removed.

4.4.2. Use-specific risk mitigation measures

4.4.3. 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.

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

/

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

/

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

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4.5. Use description

Table 5. Use #1.5 Food plant disinfection, closed system

| | |
|--|--|
| 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 Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> |
| Field(s) of use | <p>indoor use</p> <p>Disinfection of inner surfaces around food plant</p> |
| Application method(s) | <p>Method: Closed system – CIP</p> <p>Detailed description: /</p> |
| Application rate(s) and frequency | <p>Application rate: ranges from 2180-5850 mg/L of active or available chlorine</p> <p>Dilution (%): products are used diluted</p> <p>Number and timing of application:</p> <p>15 minutes contact time 1 application per day</p> <p>1. Sodium Hypochlorite 10-11%:</p> |

| | |
|-----------------------------------|--|
| | <p>diluted to 2% or 5% (v/v) corresponding to 2340 mg/L or 5850 mg/L available chlorine, respectively</p> <p>2. Sodium Hypochlorite 5-6%: diluted to 4% or 10% (v/v) corresponding to 2180 mg/L or 5450 mg/L available chlorine, respectively</p> <p>—</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>5 litres HDPE bottle with HDPE vented cap.</p> <p>10 litres, 20 litres and 25 litres HDPE drum with HDPE vented cap.</p> <p>60 litres, 120 litres and 200 litres HDPE drum with PP vented bung.</p> <p>1000 litres IBC HDPE container with stainless steel frame & HDPE vented lid & discharge valve.</p> |

4.5.1. Use-specific instructions

Sodium Hypochlorite 10-11%:

Food Plant Sanitization:

Clean the plant first and add a solution of 900 ml or 2.25 litres of product in 45 litres of cold water (dilution at 2% or 5% (v/v), respectively). Circulate for 15 minutes. Rinse with water (14 litres per unit) until all traces of biocidal product have been removed to prevent TCM formation.

The same product solution can be added to an alkaline detergent to form a combination of detergent disinfectant, or it can be used for hot detergent wash. The same disinfection procedure is applied.

Final Rinse:

After each treatment of the equipment with the product and before the equipment is used again it must be thoroughly rinsed with clean water.

Sodium Hypochlorite 5-6%:

Food Plant Sanitization:

Clean the plant first and add a solution of 1.8 litres or 4.5 litres of product in 45 litres of cold water (dilution at 4% or 10% (v/v), respectively). Circulate for 15 minutes. Rinse with water (14 litres per unit) until all traces of biocidal product have been removed to prevent TCM formation.

The same product solution can be added to an alkaline detergent to form a combination of detergent disinfectant, or it can be used for hot detergent wash. The same disinfection procedure is applied.

Final Rinse:

After each treatment of the equipment with the product and before the equipment is used again it must be thoroughly rinsed with clean water.

4.5.2. Use-specific risk mitigation measures

4.5.3. 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.

4.5.4. 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.

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

See general directions use.

4.5.6. 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