Summary of product characteristics for a biocidal product

Product name: BE-CLR

 $\mbox{\sc PT02}$ - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) Product type(s):

PT05 - Drinking water (Disinfectants)

Authorisation number: 2023-12-12-B01

R4BP 3 asset reference number: MT-0031432-0000

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Administrative information

1.1. Trade names of the product

| BE-CLR | | | |
|--------|--|--|--|
| | | | |

1.2. Authorisation holder

| 1.2. Authorisation holder | | |
|----------------------------------|-----------------|---|
| Name and address of the | Name | BONDALTI CHEMICALS, S.A. |
| authorisation holder | Address | Quinta da Industria Beduido 3860-680 Estarreja Portugal |
| Authorisation number | 2023-12-12-B01 | |
| R4BP 3 asset reference number | MT-0031432-0000 | |
| Date of the authorisation | 12/12/2023 | |
| Expiry date of the authorisation | 30/04/2033 | |

1.3. Manufacturer(s) of the biocidal products

| Name of the manufacturer | Bondalti Chemicals S.A |
|---------------------------------|--|
| Address of the manufacturer | Rua do Amoníaco Português nº 10, Beduído 3860-680 Estarreja Portugal |
| Location of manufacturing sites | Rua do Amoníaco Português nº 10, Beduído 3800-638 Estarreja Portugal |

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

| Active substance | 1265 - Active chlorine released from chlorine |
|---------------------------------|--|
| Name of the manufacturer | Bondalti Chemicals S.A |
| Address of the manufacturer | Rua do Amoníaco Português nº 10, Beduído 3800-638 Estarreja Portugal |
| Location of manufacturing sites | Rua do Amoníaco Português nº10, Beduído 3800-638 Estarreja Portugal |

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|----------------------|------------|-----------|-------------|
| Active chlorine released from chlorine | | Active Substance | | | 100 |
| | | | | | |
| chlorine | chlorine | Non-active substance | 7782-50-5 | 231-959-5 | 100 |

2.2. Type of formulation

GA - Gas

3. Hazard and precautionary statements

| Hazard statements | May cause or intensify fire; oxidiser | | |
|--------------------------|--|--|--|
| nazara statements | Causes skin irritation. | | |
| | Causes serious eye irritation. | | |
| | Toxic if inhaled. | | |
| | May cause respiratory irritation. | | |
| | Very toxic to aquatic life. | | |
| | Contains gas under pressure; may explode if heated | | |
| | | | |
| Precautionary statements | Keep away from clothing and other combustible materials. | | |
| | Do not breathe gas. | | |
| | l l | | |

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

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.

Collect spillage.

Store in a well-ventilated place. Keep container tightly closed.

Store locked up.

Protect from sunlight. Store in a well-ventilated place.

In case of fire:Stop leak if safe to do so.

Dispose of contents to local regulation.

Keep valves and fittings free from oil and grease.

Call a doctor if you feel unwell.

Avoid breathing gas.

Wash hands thoroughly after handling.

Use only outdoors or in a well-ventilated area.

IF ON SKIN: Wash with plenty of water.

Call a Poison center/doctor.

Specific treatment (see reference to supplemental first aid instruction on this label).

If skin irritation occurs:Get medical advice.

If eye irritation persists:Get medical advice.

Take off contaminated clothing. And wash it before reuse.

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of waste water after the waste water plant

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

I and the second second

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Field(s) of use

Indoor

Outdoor

Disinfection of waste water after the waste water plant, by shock dosing (in case of contamination).

Application method(s)

Method: Closed system Detailed description:

Automated dosing system.

Application rate(s) and frequencies

Application Rate: Shock dosing: 477 mg/l active chlorine (AC) under dirty conditions.

Dilution (%): -

Number and timing of application:

Contact time: 30 minutes

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Cylinder: 4,8 - 140 | (6-175 kg Cl2) Drum: 400-1 000 | (500-1 250 kg Cl2)

Railway tanks: 43 000 - 44 000 I (53 750 - 55 000 kg Cl2)

Carbon/stainless steel

4.1.1 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated dosing system, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rate indicated above.

4.1.2 Use-specific risk mitigation measures

Reduce residual concentrations of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the waste water to surface water. Alternatively, water can be retained in a buffer before discharge.

Regular water quality assessments should be performed to assure the effluent meets all required quality standards.

| | se, the particulars of likely direct or indirect effects, first aid measures to protect the environment | |
|--|--|--|
| See Section 5 General directions for use | | |
| 4.1.4 Where specific to the upackaging | se, the instructions for safe disposal of the product and its | |
| See Section 5 General directions for use | | |
| 4.1.5 Where specific to the usunder normal conditions of subsection 5 General directions for use | | |
| 4.2 Use description Use 2 - Disinfection of drinking | water at drinking water suppliers | |
| Product type | PT05 - Drinking water (Disinfectants) | |
| Where relevant, an exact description of the authorised use | | |
| Target organism(s) (including development stage) | Scientific name: bacteria Common name: Bacteria Development stage: | |
| | Scientific name: viruses Common name: Viruses Development stage: | |
| Field(s) of use | Indoor Outdoor Disinfection at the drinking water suppliers and their water distribution systems, by continuous dosing. | |
| Application method(s) | Method: Closed system Detailed description: Automated dosing system Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance ¹ , the technical rules for dosing set out in the Deutscher Verein des Gas Wasserfaches e.V ² -working sheets W 229, W | |

296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequencies

Application Rate: 0,5 mg/l active chlorine (AC) as residual concentration in the system

Dilution (%):

Number and timing of application: Frequency: continuous dosing

Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44 (5) of Regulation (EU) No 528/2012:

In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance (See section 6 for further reference)4

Application rate:

Maximum addition 1,2 mg/l free Cl2;

Concentration range after completion of treatment: maximum 0,3 mg/l free Cl2, minimum 0,1 mg/l free Cl2 (including the amounts before treatment and from other treatments) as residual concentration in the system

In exceptional cases an addition of up to 6 mg/l free Cl2 and concentration of up to 0,6 mg/l free Cl2 after treatment is acceptable as residual concentration in the system, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by ammonium.

Category(ies) of users

Professional

Pack sizes and packaging material

Cylinder: 4,8 - 140 | (6-175 kg Cl2) Drum: 400-1 000 l (500-1 250 kg Cl2) Railway tanks: 43 000 - 44 000 l (53 750 - 55 000 kg Cl2)

Carbon/stainless steel

4.2.1 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rate indicated above.

Please note that some Member States after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as "Secondary disinfection: 0,1 to 0,5 mg/l available chlorine (residual)" has been considered as covered by the primary disinfection".

4.2.2 Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limits before consumption.
Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.3 Use description

Use 3 - Disinfection of water in reservoirs

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT05 - Drinking water (Disinfectants)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Field(s) of use

Indoor

Outdoor

Disinfection of water (with water coming from tap water network), in reservoirs/tanks, by continuous dosing.

Application method(s)

Method: Closed system Detailed description:

Automated dosing system. The disinfection is carried out in the inlet of the reservoir, in order to assure proper distribution of the disinfectant in the water.

Adjustment applicable in the territory of the Federal Republic of Germany in accordance

with Article 44(5) of Regulation (EU) No 528/2012:

In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹, the technical rules for dosing set out in the Deutscher DeutscherVerein des Gas Wasserfaches e.V²-working sheets W 229, W 296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequencies

Application Rate: 0,5 mg/l Active Chlorine (AC) as residual concentration in the system. Dilution (%): -

Number and timing of application:

Frequency: continuous dosing

Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012:

In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹. (See section 6 for further reference)⁴.

Application rate: maximum addition 1,2 mg/l free Cl2;

Concentration range after completion of treatment: maximum 0,3 mg/l free Cl2, min 0,1 mg/L free Cl2 (including the amounts before treatment and from other treatments) In exceptional cases an addition of up to 6 mg/l free Cl2 and concentration up to 0,6 mg/l free Cl2 after treatment is acceptable, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by the presence of ammonium.

Category(ies) of users

Professional

Pack sizes and packaging material

Cylinder: 4,8 - 140 l (6-175 kg Cl2) Drum: 400-1 000 l (500-1 250 kg Cl2)

Railway tanks: 43 000 - 44 000 I (53 750 - 55 000 kg Cl2)

Carbon/stainless steel

4.3.1 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above.

4.3.2 Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limit before consumption. Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in (EU) Directive 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.4 Use description

Use 4 - Disinfection of water in collective systems

Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT05 - Drinking water (Disinfectants)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Scientific name: legionella pneumophila Common name: Bacteria Development stage:

Field(s) of use

Indoor

Outdoor

In Public institutions, healthcare facilities

Disinfection of drinking water in collective drinking water systems by continuous dosing

Application method(s)

Method: Closed system Detailed description:

Automated dosing system

Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44 (5) of Regulation (EU) No 528/2012:

In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance, the requirements set out in the Deutscher Verein des Gas Wasserfaches e.V² -working sheets W 229, W 296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequencies

Application Rate: 1 mg/l active chlorine (AC) as residual concentration in the system Dilution (%): -

Number and timing of application:

Frequency: continuous dosing

Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44 (5) of Regulation (EU) No 528/2012:

In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹. (See section 6 for further reference)⁴

Application rate: maximum addition 1,2 mg/l free Cl2;

Concentration range after completion of treatment: maximum 0,3 mg/l free Cl2, min 0,1 mg/L free Cl2 (including the amounts before treatment and from other treatments)

In exceptional cases an addition of up to 6 mg/l free Cl2 and concentration up to 0,6 mg/l free Cl2 after treatment is acceptable, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by the presence of ammonium.

Category(ies) of users

Professional

Pack sizes and packaging material

Cylinder: 4,8 - 140 l (6-175 kg Cl2) Drum: 400-1 000 l (500-1 250 kg Cl2)

Railway tanks: 43 000 - 44 000 I (53 750 - 55 000 kg Cl2)

Carbon/stainless steel

4.4.1 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above.

4.4.2 Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limit before consumption. Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in (EU) Directive 2020/2184 of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 General directions for use

4.5 Use description

Use 5 - Disinfection of drinking water for animals

| Product | type |
|---------|------|
|---------|------|

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT05 - Drinking water (Disinfectants)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Field(s) of use

Indoor

Outdoor

Disinfection of drinking water for animals (with water coming from tap water network) in agricultural areas, by continuous dosing.

Application method(s)

Method: Closed system Detailed description:

Automated dosing system

Application rate(s) and frequencies

Application Rate: 0,5 mg/l active chlorine (AC) as residual concentration in the system.

Number and timing of application: Frequency: continuous dosing

Professional Category(ies) of users Cylinder: 4,8 - 140 I (6-175 kg Cl2) Pack sizes and packaging Drum: 400-1 000 I (500-1 250 kg Cl2) material Railway tanks: 43 000 - 44 000 I (53,750 - 55,000 kg Cl2) Carbon/stainless steel 4.5.1 Use-specific instructions for use Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above. 4.5.2 Use-specific risk mitigation measures For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products (OJ L 178, 8.6.2020, p. 7). 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 Section 5 General directions for use 4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging See Section 5 General directions for use

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

5. General directions for use

under normal conditions of storage
See Section 5 General directions for use

-

5.2. Risk mitigation measures

5.1. Instructions for use

For connecting or disconnecting the product containers as well as for maintenance or repair of the gas pipe system, the following risk mitigation measures (RMMs) are mandatory:

- an alarm system (trigger value corresponding to the acute exposure concentration (AEC): 0,5 mg active chlorine /m³ (or lower according to national legislation) which initiates safety procedures like wearing respiratory protective equipment (RPE) according to CEN standard EN14387: Respiratory protective devices Gas filter(s) and combined filter(s) Requirements, testing, marking (or equivalent):
- application of local exhaust ventilation (LEV) (according to the national legislation) and low-pressure/vacuum are in place to avoid chlorine emission;
- the electrochemical sensors used for measurements to detect various chlorinated species in addition to chlorine itself;
- sensors to measure exposure also when the operators are using RPE according to CEN standard EN141 or equivalent.

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

Avoid breathing this toxic gas as much as possible. IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

Information for healthcare personnel/doctor:

Immediately initiate life support measures, thereafter call a POISON CENTRE.

IF SWALLOWED: Not applicable.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements.

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) or down the drains.

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

Storage conditions:

Airtight pressure tanks: Due to its chemical and physical properties, chlorine gas is always stored in dedicated carbon/steel recipients with special, dedicated valves. Chlorine packages for use within the EU should be constructed and labelled according to Directive 2010/35/EU of the European Parliament and of the Council⁵ and the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) done at Geneva on 30 September 1957. See section 6 for further reference. Maximum filling 1,25 kg/l (80 % of volume approx.).

Keep containers with chlorine tightly closed and store in a cool, dry and well-ventilated place. Tightly screw on the valve outlet protection seal and the valve protection cap when storing. Prevent cylinders from falling over. Protect from heat and direct sunlight, the temperature of the container should never be below 15°C or above 50°C.

Chlorine should be kept away from reactive products (materials to avoid: reducing agents, combustible materials, metals in powder, acetylene, hydrogen, ammonia, hydrocarbons and organic materials).

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.

¹German Drinking Water Ordinance: Trinkwasserverordnung in der Fassung der Bekanntmachung vom 10. März 2016 (BGBI. I S. 459), die zuletzt durch Artikel 1 der Verordnung vom 22. September 2021 (BGBI. I S. 4343) geändert worden ist; list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance: Bekanntmachung des Umweltbundesamtes der Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnung – 21. Änderung – (Stand: Dezember 2019).

²Deutscher Verein des Gas- und Wasserfaches e.V. (German Technical and Scientific Association for Gas and Water).

- ³ Part II, Lfd. Nr.4 of the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance
- 4 Part I c, Lfd. Nr.2 of the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance.
- ⁵ Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).