



2024/2424

16.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2424

of 13 September 2024

granting a Union authorisation for the single biocidal product ‘SANICALCO S’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 20 April 2018, CARMEUSE EUROPE S.A. submitted an application to the European Chemicals Agency (‘the Agency’) in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named ‘SANICALCO S’, of product-types 2 and 3, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-NE038810-48 in the Register for Biocidal Products. The application also indicated the case number of the related reference single biocidal product ‘EuLA hydra-lime 23’ later authorised by Commission Implementing Regulation (EU) 2023/2701 ⁽³⁾, recorded in that register under case number BC-JR038510-32.
- (2) The single biocidal product ‘SANICALCO S’ contains calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 3.
- (3) On 8 September 2022, the Agency submitted to the Commission its opinion ⁽⁴⁾ and the draft summary of the biocidal product characteristics (‘SPC’) of ‘SANICALCO S’ in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) In its opinion, the Agency concludes that the proposed differences between the single biocidal product ‘SANICALCO S’ and the related reference single biocidal product ‘EuLA hydra-lime 23’ are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁵⁾, and that based on the assessment of the related reference single biocidal product ‘EuLA hydra-lime 23’ and subject to compliance with the draft SPC, the same single biocidal product ‘SANICALCO S’ meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

⁽³⁾ Commission Implementing Regulation (EU) 2023/2701 of 4 December 2023 granting a Union authorisation for the single biocidal product EuLA hydra-lime 23 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2023/2701, 5.12.2023 ELI: http://data.europa.eu/eli/reg_impl/2023/2701/oj).

⁽⁴⁾ European Chemicals Agency opinion of 8 September 2022 on the Union authorisation of the same single biocidal product ‘BIOCALCO S’ (<https://echa.europa.eu/opinions-on-union-authorisation>).

⁽⁵⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

- (5) On 23 February 2024, the Agency transmitted to the Commission the revised SPC of 'SANICALCO S' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'SANICALCO S'.
- (7) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference single biocidal product 'EuLA hydra-lime 23'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0029398-0000 is granted to CARMEUSE EUROPE S.A. for the making available on the market and use of the same single biocidal product 'SANICALCO S' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 6 October 2024 until 30 November 2033.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

SANICALCO S

Product type(s)

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

PT03: Veterinary hygiene

Authorisation number: EU-0029398-0000**R4BP asset number:** EU-0029398-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

| | |
|---------------|-------------|
| Trade name(s) | SANICALCO S |
|---------------|-------------|

1.2. Authorisation holder

| | | |
|--|------------------|--|
| Name and address of the authorisation holder | Name | CARMEUSE EUROPE S.A. |
| | Address | Boulevard de Lauzelle 65, 1348 Ottignies Louvain-La-Neuve, Belgium |
| Authorisation number | EU-0029398-0000 | |
| R4BP asset number | EU-0029398-0000 | |
| Date of the authorisation | 6 October 2024 | |
| Expiry date of the authorisation | 30 November 2033 | |

1.3. Manufacturer(s) of the product

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Chaux |
| Address of manufacturer | 215 route d'Arras, 62320 Bois Bernard, France |
| Location of manufacturing sites | Carmeuse Chaux site 1, 215 route d'Arras, 62320 Bois Bernard, France |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Czech Republic s.r.o. |
| Address of manufacturer | Mokrá 359, 664 04 Mokrá, Czechia |
| Location of manufacturing sites | Carmeuse Czech Republic s.r.o. site 1, závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czechia |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Holding Srl |
| Address of manufacturer | Str. Carierei Nr.127A, 500047 Brasov, Romania |
| Location of manufacturing sites | Carmeuse Holding Srl site 1, Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Pravat, 117805 Campulung, Romania |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Hungaria kft |
| Address of manufacturer | HRSZ 064/1, Beremend 7827, Hungary |
| Location of manufacturing sites | Carmeuse Hungaria kft site 1, HRSZ 064/1, Beremend 7827, Hungary |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Nederland BV |
| Address of manufacturer | Nijverheidsstraat 32, 2802 AL Gouda, Netherlands (the) |
| Location of manufacturing sites | Carmeuse Nederland BV site 1, Nijverheidsstraat 32, 2802 AL Gouda, Netherlands (the) |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse SA |
| Address of manufacturer | Rue du Château 13a, 5300 Seilles, Belgium |
| Location of manufacturing sites | Carmeuse SA site 1, Rue du Val Notre Dame 300, 4520 Moha, Belgium Carmeuse SA site 2, Rue du Château 13a, 5300 Seilles, Belgium |

| | |
|---------------------------------|--|
| Name of manufacturer | Carmeuse Slovakia s.r.o. |
| Address of manufacturer | Slavec, 049 11 Slavec, Slovakia |
| Location of manufacturing sites | Carmeuse Slovakia s.r.o. site 1, závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia |

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

| | |
|---------------------------------|--|
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Chaux |
| Address of manufacturer | 215 route d'Arras, 62320 Bois Bernard, France |
| Location of manufacturing sites | Carmeuse Chaux site 1, 215 route d'Arras, 62320 Bois Bernard, France |

| | |
|-------------------------|--|
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Czech Republic s.r.o. |
| Address of manufacturer | Mokrá 359, 664 04 Mokrá, Czechia |

| | |
|---------------------------------|---|
| Location of manufacturing sites | Carmeuse Czech Republic s.r.o. site 1, závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czechia |
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Holding Srl |
| Address of manufacturer | Str. Carierei Nr.127A, 500047 Brasov, Romania |
| Location of manufacturing sites | Carmeuse Holding Srl site 1, Str Principala 1, 337457 Com. Soimus, Romania Carmeuse Holding Srl site 2, Valea Mare Pravat, 117805 Campulung, Romania |
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Hungaria kft |
| Address of manufacturer | HRSZ 064/1, Beremend 7827, Hungary |
| Location of manufacturing sites | Carmeuse Hungaria kft site 1, HRSZ 064/1, Beremend 7827, Hungary |
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Nederland BV |
| Address of manufacturer | Nijverheidsstraat 32, 2802 AL Gouda, Netherlands (the) |
| Location of manufacturing sites | Carmeuse Nederland BV site 1, Nijverheidsstraat 32, 2802 AL Gouda, Netherlands (the) |
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse SA |
| Address of manufacturer | Rue du Château 13a, 5300 Seilles, Belgium |
| Location of manufacturing sites | Carmeuse SA site 1, Rue du Val Notre Dame 300, 4520 Moha, Belgium Carmeuse SA site 2, Rue du Château 13a, 5300 Seilles, Belgium |
| Active substance | Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime |
| Name of manufacturer | Carmeuse Slovakia s.r.o |
| Address of manufacturer | Slavec, 049 11 Slavec, Slovakia |
| Location of manufacturing sites | Carmeuse Slovakia s.r.o site 1, závod Vápenka Slavec 179, 04911 Slavec, Slovakia |

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 (%) |
|--|------------|------------------|------------|-----------|-------------|
| Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime | | active substance | 1305-62-0 | 215-137-3 | 100 % (w/w) |

2.2. Type(s) of formulation

DP – Dustable powder WP – Wettable powder (only for use for disinfection of animal accommodations; limewashing of walls)

3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|--------------------------|---|
| Hazard statements | H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. |
| Precautionary statements | P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves, protective clothing, eye protection and face protection. P302 + P352: IF ON SKIN: Wash with plenty of water. P321: Specific treatment (see instructions on this label). P332 + P313: If skin irritation occurs: Get medical advice. P362 + P364: Take off contaminated clothing and wash it before reuse. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/physician. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of container to accordance with local regulations. |

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Disinfection of sewage sludge

| | |
|--|---|
| 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: Bacteria Common name: Bacteria Development stage: – Scientific name: Endoparasites Common name: Helminth eggs Development stage: – |
| Field(s) of use | indoor use |
| Application method(s) | Method: Automatic direct application Detailed description: The product is dosed into the sewage sludge and mixed by means of a blender. The dry product is mixed with the sewage sludge in an open mixer. The product shall be loaded by fully automated processes. |
| Application rate(s) and frequency | Application rate: 0,2-2 kg product/kg dry weight of substrate; typical dry solids content – 12-25 % in sewage sludge. The application rate must be sufficient to maintain a pH > 12 during the contact time. Dilution (%): – Ready-to-use (RTU) product Number and timing of application: Contact time: 24 hours to 90 days for endoparasites (helminth eggs) – the specific contact time depends on several parameters (e.g. temperature, content of dry matter, etc.). Preliminary laboratory tests must be performed to guarantee efficacy. |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Bulk powder Big bags or sacks (with Polypropylene (PP) or polyethylene (PE) inner layer): 500-1 000 kg |

4.1.1. Use-specific instructions

- The dose must be sufficient to maintain a pH > 12 during the contact time.
- Application rate: 0,2-2 kg product/kg dry weight of substrate; typical dry solids content – 12-25 % in sewage sludge.

- The ratios may vary between applications and treatment plant designs. The user should ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case.

4.1.2. *Use-specific risk mitigation measures*

- The loading of the product into the treatment unit and the application must be done fully automatically. The loading into the treatment unit and the disposal of empty bags and sacs must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags, wear:
 - respiratory protective equipment (RPE) of at least assigned protection factor (APF) 40 (airtight face piece covering eyes, nose, mouth and chin according to European Standard (EN) 149 with a P3 filter or equivalent);
 - chemical resistant gloves classified under EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).
- During the treatment of sewage sludge, the wearing of air-fed or canister RPE specific for ammonia gas in accordance with EN 14387 or equivalent, is recommended in the absence of collective management measures to estimate and prevent an exposure greater than the EU occupational exposure limit value (OEL) of 14 mg/m³ for that gas.
- During the manual handling of treated sewage sludge wear protective gloves in accordance with EN 374 or equivalent and protective coverall in accordance with EN 14126 or equivalent protecting against the intrinsic properties of the sewage sludge.
- The provisions on personal protective equipment are 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
- The cleaning of the unit treatment must be avoided or performed with an automated process with no exposure of the professional.

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*

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

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

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4.2. **Use description**

Table 2

Disinfection of manure

| | |
|--|--------------------------|
| Product type | PT03: Veterinary hygiene |
| Where relevant, an exact description of the authorised use | — |

| | |
|--|---|
| Target organism(s) (including development stage) | <p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Viruses Common name: Viruses Development stage: no data</p> <p>Scientific name: Endoparasites Common name: Helminth eggs Development stage: no data</p> |
| Field(s) of use | indoor use |
| Application method(s) | <p>Method: Automatic direct application</p> <p>Detailed description: The product is mixed with the manure. The product is dosed into the manure and mixed by means of a blender. The product should be loaded by fully automated processes.</p> |
| Application rate(s) and frequency | <p>Application rate: –</p> <p>Dilution (%): – RTU product</p> <p>Number and timing of application: The application rate must be sufficient to maintain a pH > 12 during the contact time. Contact time: 72 hours to 90 days for endoparasites (helminth eggs) – the specific contact time depends on several parameters (e.g. temperature, content of dry matter, etc.). Preliminary laboratory tests must be performed to guarantee efficacy.</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>Bulk powder</p> <p>Big bags or sacks (with PP or PE inner layer): 500-1 000 kg</p> |

4.2.1. Use-specific instructions

- The dose must be sufficient to maintain a pH > 12 during the contact time.
- Do not apply more than 100 kg product/m³ of manure
- After the necessary contact time, remove the treated manure from the animal house. Use of the treated manure according to local legislation.

4.2.2. Use-specific risk mitigation measures

- The loading of the product into the treatment unit and the application must be done fully automatically.
- The loading into the treatment unit and the disposal of empty bags and sacs must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags, wear:
 - chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);

- a protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information);
- RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent).
- During the treatment of manure, the wearing of air-fed or canister RPE specific for ammonia gas in accordance with EN 14387 or equivalent, is recommended in the absence of collective management measures to estimate and prevent an exposure greater than the EU occupational exposure limit value (OEL) of 14 mg/m³ for that gas.
- During the manual handling of treated manure wear protective gloves in accordance with EN 374 or equivalent and protection coverall in accordance with EN 14126 or equivalent protecting against the intrinsic properties of the manure.
- The provisions on personal protective equipment are 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.
- The cleaning of the unit treatment must be avoided or performed with an automated process with no exposure of the professional.
- Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water.

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*

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

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

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4.3. Use description

Table 3

Disinfection of indoor floor surfaces of animal accommodations and transportation

| | |
|--|--|
| Product type | PT03: Veterinary hygiene |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | <p>Scientific name: Bacteria Common name: Bacteria Development stage: —</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: —</p> <p>Scientific name: Fungi Common name: fungi Development stage: —</p> <p>Scientific name: viruses Common name: Viruses Development stage: —</p> |

| | |
|-----------------------------------|--|
| Field(s) of use | indoor use |
| Application method(s) | Method: Direct application Detailed description: The product is spread directly onto the floors of animal accommodations using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader. |
| Application rate(s) and frequency | Application rate: 800 g product/m ² Dilution (%): – RTU product Number and timing of application: Frequency in animal housing: before each production cycle. Frequency in animal transportation: after each animal transport. Contact time: 48 hours |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Bulk powder Big bags or sacks (with PP or PE inner layer): 500-1 000 kg Paper sacks (with PP or PE inner layer): 25 kg |

4.3.1. Use-specific instructions

The product is spread directly onto the floors of animal accommodations and transportation, using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.

A. On concrete floors:

1. Wash the surface with running water;
2. Sprinkle 800 g of product per m² to cover the damp ground and add 0,9 litre/m² of water;
3. Leave to act for at least 48 hours;
4. After treatment, remove the lime by brushing.

B. On beaten-earth floors:

1. Brush and wet the surface;
2. Sprinkle 800 g of product per m² on the damp ground and add 0,9 litre/m² of water;
3. Leave to act for at least 48 hours.
4. After treatment, remove the lime by brushing.

4.3.2. Use-specific risk mitigation measures

- During the loading, the application of the product and the disposal of empty bags and sacs, wear:
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);

- chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
- protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).
- For the use of big bags (500-1 000 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- During the loading of small bags (25 kg), thoroughly empty out the bag in order to minimise the remaining powder.
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- During the disposal of the product after the application, wear:
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent);
 - chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13982 or equivalent (coverall material to be specified by the authorisation holder within the product information).
- The provisions on personal protective equipment are 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.
- Animals shall not be present during all the treatment duration.
- Remove residues of the product on the ground by thorough sweeping before re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application of the product.
- Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water.

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*

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

- After treatment, remove the lime by brushing. Collect the resulting dry waste and recycle them as agricultural liming material or dispose the dry waste according to local requirements.
- For animal transportation use only: after brushing and the required contact time, rinse and clean the vehicle.

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

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4.4. Use description

Table 4

Disinfection of animal accommodations; limewashing of walls

| | |
|--|--|
| Product type | PT03: Veterinary hygiene |
| Where relevant, an exact description of the authorised use | – |
| Target organism(s) (including development stage) | <p>Scientific name: Bacteria Common name: Bacteria Development stage: –</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: –</p> <p>Scientific name: Fungi Common name: fungi Development stage: –</p> <p>Scientific name: Viruses Common name: Viruses Development stage: –</p> |
| Field(s) of use | indoor use |
| Application method(s) | <p>Method: Direct application with a brush</p> <p>Detailed description: –</p> |
| Application rate(s) and frequency | <p>Application rate: 800 g product/m²</p> <p>Dilution (%): –</p> <p>Number and timing of application: The product is suspended in water (50 % w/v) prior to its application by brushing on the walls. Contact time: 48 hours Frequency: before each production cycle</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>Bulk powder</p> <p>Big bags or sacks (with PP or PE inner layer): 500-1 000 kg</p> |

4.4.1. Use-specific instructions

For one layer:

Application method for 150 to 200 m² of wall (depending on the porosity of the wall):

1. Clean the surface with running water before the application of the product.
2. Introduce 25 kg of product into 50 litres of water;
3. Let the mixture rest for 12 hours;
4. Mix the resulting mixture and brush onto the wall;
5. Leave to act for at least 48 hours

The application rate is 125-167 g product/m² for a single layer. A final application rate of 800 g product/m² is required, therefore 5-7 coats should be applied, depending on the porosity of the wall.

Stir before and during application.

The product must be first fully automatically transferred to a medium lower volume tank. Then, the product is manually loaded from the medium tank to a bucket.

4.4.2. Use-specific risk mitigation measures

- During the loading of the product and the disposal of empty bags and sacs, wear:
 - chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13982 (coverall material to be specified by the authorisation holder within the product information);
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P3 filter or equivalent).
- During the application of the product on the walls, wear:
 - chemical resistant gloves in accordance with EN 374 (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13034 (coverall material to be specified by the authorisation holder within the product information);
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to EN 149 with a P1 filter or equivalent).
- The provisions on personal protective equipment are 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.
- The loading of the product and the disposal of empty bags and sacs must be performed fully automatically using a telehandler (including a closed cabin).
- Minimise splashes and spills during application.
- Do not let bystanders (including co-workers and children) touch treated surfaces until completely dry.
- Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water.
- Animals shall not be present during all the treatment duration.
- Do not let animal re-enter the accommodations before complete drying of surfaces.
- Feed and drinking water must be carefully covered or removed during the application of the product.

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

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

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4.4.5. 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

Disinfection of floors of outdoor animal enclosures

| | |
|--|--|
| Product type | PT03: Veterinary hygiene |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | <p>Scientific name: Bacteria Common name: Bacteria Development stage: —</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: —</p> <p>Scientific name: Fungi Common name: fungi Development stage: —</p> <p>Scientific name: Viruses Common name: Viruses Development stage: —</p> |
| Field(s) of use | outdoor use |
| Application method(s) | <p>Method: Direct application</p> <p>Detailed description: The product is spread directly onto the surfaces (floors) of animal enclosures using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.</p> |
| Application rate(s) and frequency | <p>Application rate: 800 g product/m²</p> <p>Dilution (%): — RTU product</p> <p>Number and timing of application: Contact time 48 hours Frequency: maximum two applications per year.</p> |
| Category(ies) of users | professional |
| Pack sizes and packaging material | <p>Bulk powder</p> <p>Big bags or sacks (with PP or PE inner layer): 500-1 000 kg</p> <p>Paper sacks (with PP or PE inner layer): 25 kg</p> |

4.5.1. Use-specific instructions

— Brush and wet the floor before the application of the product.

— At the beginning of a production cycle, spread 800 g product/m² of the product onto the ground and then add 0,9 litre/m² of water.

- Leave to act for at least 48 hours before bringing animals in the treated area.
- For outdoor uses of the product, do not apply in the case of wind or rain.

4.5.2. *Use-specific risk mitigation measures*

- During the loading, the application of the product and the disposal of empty bags and sacs, wear:
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter or equivalent);
 - chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13982 (coverall material to be specified by the authorisation holder within the product information).
- For the use of big bags (500-1 000 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimise the remaining powder.
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- During the disposal of the product after the application, wear:
 - RPE of at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter or equivalent);
 - chemical resistant gloves in accordance with EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information);
 - protective coverall in accordance with EN 13982 (coverall material to be specified by the authorisation holder within the product information).
- The provisions on personal protective equipment are 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.
- Do not exceed two applications per year.
- Animals shall not be present during all the treatment duration.
- Remove residues of the product on the ground by thorough brushing before re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application of the product.

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*

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

- After treatment, remove the lime by brushing. Collect the resulting dry waste and recycle them as agriculture liming material or dispose the dry waste according to local requirements.

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

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5. GENERAL DIRECTIONS FOR USE ⁽¹⁾

5.1. Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product.
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- For outdoor use of the product, do not apply in the case of wind or rain.

5.2. Risk mitigation measures

- Do not let bystanders (including co-workers and children) and pets enter the treatment area during the entire treatment duration (including the loading, the application of the product, the disposal of empty bags and sacs, the agreed contact time and the subsequent removal of the product and its residues from the ground).
- Use only in a well-ventilated area.

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

- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
- 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. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTER or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and ease 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 chemical (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

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

- Do not discharge unused product on the ground, into water courses, into pipes (e.g. of sinks, toilets) or down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Do not store at a temperature above 30 °C.
- Protect from humidity.
- Shelf-life: 15 months.

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

6. OTHER INFORMATION

Full titles of EN standards and legislation referred to in sections 4.1.2-4.5.2:

EN 149 – Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking;

EN 374 – EN ISO 374-1: 2018: Protective gloves against dangerous chemicals and micro-organisms – Part 1: terminology and performance requirements for chemical risks;

EN 13982 – Protective clothing for use against solid particulates – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates;

EN 14387 – EN 14387:2021: Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking;

EN 14126 – BS EN 14126: 2003 – Protective clothing. Performance requirements and tests methods for protective clothing against infective agent;

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).
