

Summary of product characteristics for a biocidal product

Product name: BIOCALCO M35

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

PT03 - Veterinary hygiene (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: FR-2023-0079

R4BP 3 asset reference number: FR-0031594-0007

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	3
2.1. Qualitative and quantitative information on the composition of the biocidal product	3
2.2. Type of formulation	3
3. Hazard and precautionary statements	4
4. Authorised use(s)	4
5. General directions for use	11
5.1. Instructions for use	11
5.2. Risk mitigation measures	12
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	12
5.4. Instructions for safe disposal of the product and its packaging	12
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	12
6. Other information	13

Administrative information

1.1. Trade names of the product

BIOCALCO M35

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

FR-2023-0079 1-3

**R4BP 3 asset reference
number**

FR-0031594-0007

Date of the authorisation

26/12/2023

**Expiry date of the
authorisation**

25/12/2033

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Carmeuse Europe S.A.
Address of the manufacturer	Boulevard de Lauzell, 651348 Ottignies Louvain-La-Neuve Belgium
Location of manufacturing sites	215 route d'Arras, 62320 Bois Bernard France
	závod Vápenka Mokrá, Mokrá 359,664 04 Mokrá Czech Republic
	Str Principala 1, 337457 Com. Soimus Romania
	Valea Mare Privat, 117805 Campulung Romania
	HRSZ 064/1, 7827 Beremend Hungary
	Rue du Val Notre Dame 300, 4520 Moha, Belgium Moha Belgium
	Rue du Château 13a, 5300 Seilles Belgium
	závod Vápenka Slavec, Slavec 179, 049 11 Slavec Slovakia
	Nijverheidsstraat 32, 2802 AL Gouda Netherlands

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

Active substance	1255 - Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Name of the manufacturer	Carmeuse Europe S.A,
Address of the manufacturer	Boulevard de Lauzell, 65 1348 Ottignies Louvain-La-Neuve Belgium
Location of manufacturing sites	215 route d'Arras, 62320 Bois Bernard, France
	závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czech Republic
	Str Principala 1, 337457 Com. Soimus, Romania
	Valea Mare Pravat, 117805 Campulung Romania
	HRSZ 064/1, 7827 Beremend, Hungary
	Nijverheidsstraat 32, 2802 AL Gouda, Netherlands
	Rue du Val Notre Dame 300, 4520 Moha, Belgium
	Rue du Château 13a, 5300 Seilles Belgium
	závod Vápenka Slavec, Slavec 179, , 049 11 Slavec Slovakia

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 (%)
Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime		Active Substance	1305-62-0	215-137-3	35

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Causes skin irritation.
Causes serious eye damage.
May cause respiratory irritation.

Precautionary statements

Wear protective gloves/protective clothing/eye protection/ face protection.
IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER.
IF ON SKIN:Wash with plenty of water.
Avoid breathing dust.
IF INHALED:Remove person to fresh air and keep comfortable for breathing.
Dispose of container to NATIONAL REGULATIONS.
Wash hands thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Specific treatment (see instructions on this label).
If skin irritation occurs:Get medical advice.
Take off contaminated clothing.And wash it before reuse.
Call a poison center/doctor if you feel unwell.
Store in a well-ventilated place.Keep container tightly closed.
Store locked up.

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 3.5 – Disinfection of sewage sludge – Indoor and Outdoor- Professional

Product type

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

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name: bacteria
Common name: Bacteria
Development stage: all stage

Scientific name: Endoparasites
Common name: helminth eggs
Development stage: Eggs

Field(s) of use

Indoor
Outdoor
Indoor outdoor
The product is dosed into the sewage sludge and mixed by means of a blender.

Application method(s)

Method: Automatic direct application
Detailed description:
Ready to use product

The dry product is mixed with the sewage sludge in an open mixer. The product should be loaded by fully automated processes.

The dose must be sufficient to maintain a pH of > 12 during the contact time needed.

Contact time: 24h to several weeks for endoparasites: helminth eggs

Application rate(s) and frequencies

Application Rate: Application rate: 1 – 10 kg product / kg dry weight of substrate; typical dry solids content - 12-25% in sewage sludge.
Dilution (%): -
Number and timing of application:
The dose must be sufficient to maintain a pH of > 12 during the contact time needed.

Contact time : 24h for bacteria to several weeks for endoparasites.

Category(ies) of users

Professional

Pack sizes and packaging material

1000 kg IBC in HDPE

4.1.1 Use-specific instructions for use

- The dose must be sufficient to maintain a pH of > 12 during the contact time needed.
- Application rate: 1 – 10 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 must ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case.
- For outdoor uses of the product, do not apply in case of wind or rain.

4.1.2 Use-specific risk mitigation measures

- During the loading of the product, wear :
 - o a face shield
 - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - o protective coverall (coverall material to be specified by the authorisation holder within the product information)
- During the cleaning of the unit treatment, wear :
 - o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
 - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - o protective coverall (coverall material to be specified by the authorisation holder within the product information)
- During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is required in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m³ for this gas.
- Wear protective gloves and protection coverall during the manual handling of treated sewage sludge.

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

Use 2 - 3.6 – Disinfection of manure – Indoor and Outdoor - Professional

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: All Scientific name: Viruses Common name: Viruses Development stage: All Scientific name: Endoparasites Common name: helminth eggs Development stage: Eggs
Field(s) of use	Indoor Outdoor Indoor, outdoor The product is dosed into the manure and mixed by means of a blender.
Application method(s)	Method: Automatic direct application Detailed description: Ready to use The product is mixed with the manure. The product should be loaded by fully automated processes. The dose must be sufficient to maintain a pH of > 12 during the contact time needed. Contact time: 72h (bacteria, virus) to 90 days (helminth eggs)
Application rate(s) and frequencies	Application Rate: Do not apply more than 500 kg product /m ³ of manure. After the necessary contact time, dispose of the lime treated manure according to local legislation. Dilution (%): - Number and timing of application: The dose must be sufficient to maintain a pH of > 12 during the contact time needed. Contact time: 72h (bacteria, virus) to 90 days (helminth eggs)

Category(ies) of users

Professional

Pack sizes and packaging material

1000 kg IBC in HDPE.

4.2.1 Use-specific instructions for use

- The dose must be sufficient to maintain a pH of > 12 during the contact time needed.

- Remove the manure from the animal house.

Application rate:

1. Do not apply more than 500 kg product /m³ of manure,

2. After the necessary contact time, dispose of the lime treated manure according to local legislation.

- For outdoor uses of the product, do not apply in case of wind or rain.

4.2.2 Use-specific risk mitigation measures

- During the loading of the product, wear :

o a face shield

o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);

o protective coverall (coverall material to be specified by the authorisation holder within the product information)

- During the cleaning of the unit treatment, wear :

o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);

o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);

o protective coverall (coverall material to be specified by the authorisation holder within the product information)

- During the treatment of manure, the wear of air fed or canister RPE specific for Ammonia gas, is required in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas.

- Wear protective gloves and protection coverall during the manual handling of treated manure.

Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or other aquatic environment.

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

Use 3 - Use # 3.7 – Disinfection of animal accommodations; limewashing of walls – Indoor – Professional

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name: bacteria
Common name: Bacteria
Development stage: All

Scientific name: Fungi
Common name: Fungi
Development stage: All

Scientific name: Yeasts
Common name: Yeasts
Development stage: All

Scientific name: Viruses
Common name: Viruses
Development stage: All

Field(s) of use	Indoor Indoor
Application method(s)	Method: Direct application with a brush. The product is painted onto the walls of animal accommodations Detailed description: Ready diluted products applied as sold by brushing on the walls 800 g Ca(OH) ₂ / m ² Contact time 48 hours
Application rate(s) and frequencies	Application Rate: 800 g Ca(OH) ₂ / m ² Contact time 48 hours Dilution (%): - Number and timing of application: -
Category(ies) of users	Professional
Pack sizes and packaging material	1000 kg IB in HDPE.

4.3.1 Use-specific instructions for use

<p>Clean the surface with running water before the application of the product.</p> <p>Needed volume of product depends on its concentration and on the porosity of the wall:</p> <ol style="list-style-type: none"> 1. Agitate before use to homogenize the suspension 2. Brush onto the wall uniformly

3. Let it dry before reintroducing cattle

4.3.2 Use-specific risk mitigation measures

- During the loading of the product, wear :
 - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
 - o a protective overall (overall material to be specified by the authorisation holder within the product information),
 - o a face shield.
 - During the application of the product on the walls, wear :
 - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
 - o protective overall (overall material to be specified by the authorisation holder within the product information),
 - o a respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter).
 - Minimization of splash and spills during application of water suspended lime.
 - Do not touch the treated surfaces until complete drying;
 - Animals should not be present during all the treatment duration;
- Do not let animal re-enter the accommodations before complete drying of surfaces.
- Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or other aquatic environment.

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

-

5. General directions for use

5.1. Instructions for use

- Comply with the instructions for use.
- Inform the registration holder if the treatment is ineffective.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc).
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.

5.2. Risk mitigation measures

Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration.

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

- 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 easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. 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.

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 (sink, toilets...) nor 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

- Shelf-life: 2 years.
- Protect from frost.
- Keep away from acid
- Dispose the packaging and any other waste in an appropriate collection circuit.

6. Other information

The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application.