

Summary of product characteristics for a biocidal product family

Family name: Calcium dihydroxide blends

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

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

Authorisation number: FR-2023-0079

R4BP 3 asset reference number: FR-0031594-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Calcium dihydroxide blends

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

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

1.3. 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

R4BP 3 asset reference
number

FR-0031594-0000

Date of the authorisation

26/12/2023

Expiry date of the
authorisation

25/12/2033

1.4. 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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

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	20 - 70

2.2. Type(s) of formulation

DP - Dustable powder
AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta-SPC 1: BIOCALCO SL

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

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

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

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	60 - 70

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

DP - Dustable powder

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

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

Wear protective clothing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

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.

Immediately call a POISON CENTER or doctor/physician.

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) of the meta SPC

4.1 Use description

Use 1 - Use #1.1 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: nematode eggs
Common name: worm 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 for bacteria to several weeks for endoparasites.
Application rate(s) and frequencies	Application Rate: Application rate: 0.3 – 3.4 kg product / kg dry weight of substrate; typical dry solids content - 12-25% in sewage sludge. Dilution (%): - Number and timing of application: -
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750 kg

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: 0.3 – 3.4 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.

4.1.2 Use-specific risk mitigation measures

- The loading of lime powder into the unit treatment must be done semi-automatically.
- Considering the use of big bags (750 kg), the loading into the treatment unit and the disposal of empty bags must be performed using a forklift or a tele handler (including a closed cabin).
 - During the loading of the product and the disposal of empty bags, wear :
 - 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);
 - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - 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.
 - 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

-

4.2 Use description

Use 2 - Use #1.2 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: Micro-organisms
Development stage: helminth 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 170 kg product /m3 of manure. After the necessary contact time, dispose of the lime treated manure according to local legislation.
Dilution (%): -
Number and timing of application:
-

Category(ies) of users

Professional

Pack sizes and packaging material

Bulk Big bags or sacks: 750 kg

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 170 kg product /m³ of manure,
 - 2. After the necessary contact time, dispose of the lime treated manure according to local legislation

4.2.2 Use-specific risk mitigation measures

- The loading of lime powder into the unit treatment must be done semi-automatically.
- Considering the use of big bags (750 kg), the loading into the treatment unit and the disposal of empty bags must be performed using a forklift or a tele handler (including a closed cabin).
- During the loading of the product and the disposal of empty bags, wear :
 - 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);
 - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (coverall material to be specified by the authorisation holder within the product information)
- During the treatment of manures, 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 manures.
- 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 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

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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

-

5. General directions for use of the meta SPC

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

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.
- 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 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

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 humidity.
- Keep away from acid

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	BIOCALCO SL70	Market area: FR
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	FR-0031594-0001 1-1	

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	70

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta-SPC 2: OPTILIT

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

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	20 - 30

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

DP - Dustable powder

3. Hazard and precautionary statements of the meta SPC

Hazard statements

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

Precautionary statements

Wear protective clothing.
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) of the meta SPC

4.1 Use description

Use 1 - Use #2.3 Disinfection of indoor floor surfaces of animal accommodations and transportation – 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: Yeasts Common name: Yeasts Development stage: All Scientific name: Fungi Common name: Fungi Development stage: All Scientific name: viruses Common name: Viruses Development stage: All
Field(s) of use	Indoor Indoor 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 method(s)	Method: Direct application Detailed description: Ready to use 800 g Ca(OH) ₂ / m ² Frequency in animal housing: Before each production cycle Frequency in animal transportation: After each animal transport Contact time: 48h
Application rate(s) and frequencies	Application Rate: - Dilution (%): - Number and timing of application: -
Category(ies) of users	Professional

Pack sizes and packaging material

Bulk Big bags or sacks: 750 kg
Paper sack: 25 kg

4.1.1 Use-specific instructions for use

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 installation with running water,
2. Sprinkle the product to cover the damp ground
3. Leave to act for at least 48 h.

B. On beaten-earth floors:

1. Brush and wet the floor,
2. Sprinkle the product on the damp ground
3. Leave to act for at least 48 h.

4.1.2 Use-specific risk mitigation measures

- During the loading, the application of the product and the disposal of empty bags and product after application, 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 a protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Considering the use of big bags (750 kg), the loading of the product and the disposal of empty bags must be performed automatically using a forklift or 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.
- Animals should not be present during all the treatment duration.
- Remove residues of the biocidal 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 other aquatic environment.

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

- 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, rinse and clean the vehicle.

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 - Use #2.4 Disinfection of floors of outdoor animal enclosures – 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: Yeasts Common name: Yeasts Development stage: All Scientific name: fungi Common name: Fungi Development stage: all Scientific name: viruses Common name: Viruses Development stage: all
Field(s) of use	Outdoor Outdoor. 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.
Application method(s)	Method: Direct application Detailed description: Ready to use 800 g Ca(OH) ₂ /m ²

	<p>Contact time 48 hours</p> <p>Frequency: maximum two applications per year</p>
<p>Application rate(s) and frequencies</p>	<p>Application Rate: Frequency: maximum two applications per year Dilution (%): - Number and timing of application: Leave to act for at least 48 hours before bringing in the animals.</p> <p>Frequency: maximum two applications per year</p>
<p>Category(ies) of users</p>	<p>Professional</p>
<p>Pack sizes and packaging material</p>	<p>Bulk Big bags or sacks: 1000 kg Paper sack: 25 kg</p>

4.2.1 Use-specific instructions for use

- Brush and wet the floor before the application of the product.
- At the beginning of a production cycle, spread the product onto the ground and then apply water.
- Leave to act for at least 48 hours before bringing in the animals.
- Do not apply in case of wind or rain

4.2.2 Use-specific risk mitigation measures

- During the loading, the application of the product and the disposal of empty bags and product after application, 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 a protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Considering the use of big bags (750 kg), the loading of the product and the disposal of empty bags must be performed automatically using a forklift or 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. Animals should not be present during all the treatment duration. Remove residues of the biocidal 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 exceed two applications per year.

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

-

4.2.5 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 of the meta SPC

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

- During the sweeping of the residues product on the soil before the re-entry of the animals, wear the same RPE and PPE as those required for the professional user.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal 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 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.

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 humidity.
- Keep away from acid.

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

OPTILIT 20

Market area: FR

Authorisation number

FR-0031594-0002 1-2

(R4BP 3 asset reference number - National Authorisation)

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	20

Trade name(s)

OPTILIT 30

Market area: FR

Authorisation number

FR-0031594-0003 1-2

(R4BP 3 asset reference number - National Authorisation)

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	30

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta-SPC 3: BIOCALCO M

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

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

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

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	20 - 50

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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

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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.

	<p>The dose must be sufficient to maintain a pH of > 12 during the contact time needed.</p> <p>Contact time: 72h (bacteria, virus) to 90 days (helminth eggs)</p>
<p>Application rate(s) and frequencies</p>	<p>Application Rate: Do not apply more than 500 kg product /m3 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.</p> <p>Contact time: 72h (bacteria, virus) to 90 days (helminth eggs)</p>
<p>Category(ies) of users</p>	<p>Professional</p>
<p>Pack sizes and packaging material</p>	<p>1000 kg IBC in HDPE.</p>

4.2.1 Use-specific instructions for use

<ul style="list-style-type: none"> - The dose must be sufficient to maintain a pH of > 12 during the contact time needed. - Remove the manure from the animal house. <p>Application rate:</p> <ol style="list-style-type: none"> 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

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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)	<p>Scientific name: bacteria Common name: Bacteria Development stage: All</p> <p>Scientific name: Fungi Common name: Fungi Development stage: All</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage: All</p> <p>Scientific name: Viruses Common name: Viruses Development stage: All</p>
Field(s) of use	<p>Indoor</p> <p>Indoor</p>
Application method(s)	<p>Method: Direct application with a brush. The product is painted onto the walls of animal accommodations Detailed description:</p> <p>Ready diluted products applied as sold by brushing on the walls</p> <p>800 g Ca(OH)₂ / m²</p> <p>Contact time 48 hours</p>

Application rate(s) and frequencies

Application Rate: 800 g Ca(OH)₂ / m² 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

Clean the surface with running water before the application of the product.

Needed volume of product depends on its concentration and on the porosity of the wall:

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 of the meta SPC

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

BIOCALCO M20

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0004 1-3

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	20

Trade name(s)

BIOCALCO M25

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0005 1-3

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	25

Trade name(s)

BIOCALCO M30

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0006 1-3

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	30

Trade name(s)

BIOCALCO M35

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0007 1-3

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

Trade name(s)

BIOCALCO M40

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0008 1-3

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	40

Trade name(s)

BIOCALCO M50

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0031594-0009 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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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	50
