Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Calcium dihydroxide blends

Product type 2 and 3

Calcium dihydroxide

Case Number in R4BP: BC-UA038817-35

Evaluating Competent Authority: FR

Date: [December 2023]

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1 CONCLUSION

The biocidal products family, CALCIUM DIHYDROXIDE BLENDS, is a calcium dihydroxyde based PT2 and 3 biocidal products family used as a disinfectant of sewage sludge, of manure and of indoor and outdoor floor surfaces of animal accommodations and transportation, for professional users only.

Conclusion on the physical, chemical and technical properties of the product

The products are a blend of the active substance and an inert filler (META 1 and 2) or a milk of lime (META SPC3). Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts.
The products are whitish to light grey homogeneous powder for META SPC 1&2. The solid are alkaline with a 1% diluted pH of 12.4 at 21°C and an alkalinity of 20 to 74% w/w as NaOH.
The products of META SPC 3 are milk of lime with a 0.2% to 0.7% diluted pH of 12.4 at 23°C and an alkalinity of 20.42% to 51.39% w/w as NaOH.
The products have been shown to be stable after 2 weeks at 54°C and with no significant changes in the appearance of the test item or the packaging after 20°C for 4 weeks.
No data relating to specification of active substance during storage is provided yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance.
Long-term storage stability is on-going and will be required in post-authorization (including specification of active substance). Based on the accelerated storage, a 2 years shelf life could be set.

Implication for labelling: For META SPC 1 & 2: Protect from humidity
For META SPC 3: Protect from frost

The BPF is not classified for physical hazard properties.

Validated analytical methods were provided for the active substance and are applicable to the product.

Conclusion on efficacy

The products of the family CALCIUM DIHYDROXIDE BLENDS have shown a sufficient efficacy:

- For the disinfection of sewage sludge (PT 2) against bacteria and endoparasites: helminth eggs.

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of sewage sludge.
Regarding virus, for the disinfection of sewage sludge, the efficacy data submitted were not sufficiently robust, due to the lack of negative control. Therefore this activity is not validated

- For the disinfection of manure (PT3), against bacteria, virus and endoparasite (helminth eggs).

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time.
The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of manure.

- For the disinfection of indoor floor surfaces of animal accommodations (including limewashing of walls) and transportation, floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus at the application rate of 800 g $Ca(OH)_2/m^2$.

The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the provisions in the SPC have to be implemented.

Nevertheless, the disinfection of bedding materials (PT3), against bacteria, yeast, fungi and virus, no specific study has been submitted by the applicant for this use. A read across with manure treatment studies, considered as a worst case, has been considered. However, in relation to the distribution properties, the content of organic material, the availability of water for the reaction of lime in the matrix that could differ from manure, read-accross is not acceptable[1]. The efficacy is therefore not supported by the data presented in the dossier.

Conclusion on the risk for human health

- **Disinfection of sewage sludge's and manures**

*__For Meta-SPC 1__

Acceptable risks are shown for human health **only by semi- automated process** (including loading and disposal of empty bags) considering the following PPE are worn:

- gloves;
- protective coverall;
- 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).

In addition to the above mentioned PPE, the following RMMs are required:

- 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).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.

*__For Meta-SPC 3__

Acceptable risks are shown for human health considering the following PPE are worn:

[1] Final minutes – WGI2022_EFF_7-2

During the loading into the unit treatment:
- gloves;
- protective coverall;
- face shield

During the cleaning of the unit treatment:
- gloves;
- protective coverall;
- 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).

Moreover, it is also likely that the addition of calcium hydroxide to sewage or manure leads to the production of ammonia gas, which may be of concern. During the treatment of sewage sludge and 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/m^3 for this gas.

Additional RMM for both meta-SPC are required:

- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge and 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 EU OEL of 14 mg/m^3 for this gas.

- **Disinfection of indoor floor surfaces of animal accommodations and transportation, bedding materials and outdoor floor surfaces**

***META SPC 2**

The risk for human health is considered acceptable for the loading, the application and the disposal of empty bags considering the following PPE:
- gloves;
- protective coverall;
- 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).

In addition to above-mentioned PPE, the following RMM are needed:
- 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).
- 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.
- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimize the remaining powder;

- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- 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 tele handler (including a closed cabin).
- Use in a well ventilated area.

- **Disinfection of animal accommodation walls by brush:**

***META SPC 3**

The risk for human health is considered acceptable for the loading considering the following PPE:

- gloves;
- protective coverall;
- face shield

During the application of water suspended lime on the walls, the risk is considered acceptable taking into account the following PPE:

- gloves;
- protective coverall;
- 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).

Moreover, the following RMM are needed:

- Minimization of splash and spills during application of water suspended lime.
- Do not touch the treated surfaces until complete drying.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration

Conclusion on the risk for animal health

The risk for animal health is considered acceptable if the following RMMs are applied:

- 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.
- Do not let animal re-enter the accommodations before complete drying of surfaces.

Conclusion on the risk for consumers via residues in food

Regarding the natural exposure and the toxicological properties of Ca^{2+}, the dietary risk from consumer related to the intended uses is negligible.

Conclusion on the risk for environment

Acceptable risks for the environment are foreseen for the uses:

META-SPC1 (dustable powder):

In PT2:

- ✓ disinfection of sewage sludge,

In PT3: and considering the following RMM: "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".

- ✓ disinfection of manure,

META-SPC2 (dustable powder):

In PT3, considering the following RMM "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.":

- ✓ disinfection of animal bedding material,
- ✓ disinfection of indoor floor of animal accommodations and transportation,

In PT3, and considering the following RMM "Do not exceed two applications per year."

- ✓ disinfection of floors of outdoor animal enclosures.

META-SPC3 (suspension):

In PT2:

- ✓ disinfection of sewage sludge,

In PT3: and considering the following RMM "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".

- ✓ disinfection of manure,
- ✓ disinfection of indoor walls of animal accommodations,

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	Country (if relevant)
Calcium dihydroxide blends	France Belgium Netherlands Romania

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Carmeuse Europe S.A.
	Address	Boulevard de Lauzell, 65 1348 Ottignies Louvain-La-Neuve Belgium
Authorisation number	**FR-2023-0079**	
Date of the authorisation	**26/12/2023**	
Expiry date of the authorisation	**25/12/2033**	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Carmeuse Chaux
Address of manufacturer	215 route d'Arras, 62320 Bois Bernard, France
Location of manufacturing sites	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, Czech Republic
Location of manufacturing sites	závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czech Republic

Name of manufacturer	Carmeuse Holding Srl
Address of manufacturer	Str.Carierei Nr.127A, 500047 Brasov, Romania
Location of manufacturing sites	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, 7827 Beremend, Hungary
Location of manufacturing sites	HRSZ 064/1, 7827 Beremend, Hungary

Name of manufacturer	Carmeuse Nederland BV
Address of manufacturer	Nijverheidsstraat 32, 2802 AL Gouda, The Netherlands
Location of manufacturing sites	Nijverheidsstraat 32, 2802 AL Gouda, The Netherlands

Name of manufacturer	Carmeuse SA
Address of manufacturer	Rue du Château 13a, 5300 Seilles, Belgium
Location of manufacturing sites	Rue du Val Notre Dame 300, 4520 Moha, Belgium. 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	závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia

2.1.1.4 Manufacturers of the active substance

Name of manufacturer	Carmeuse Chaux
Address of manufacturer	215 route d'Arras, 62320 Bois Bernard, France
Location of manufacturing sites	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, Czech Republic
Location of manufacturing sites	závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czech Republic

Name of manufacturer	Carmeuse Holding Srl
Address of manufacturer	Str.Carierei Nr.127A, 500047 Brasov, Romania
Location of manufacturing sites	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, 7827 Beremend, Hungary
Location of manufacturing sites	HRSZ 064/1, 7827 Beremend, Hungary

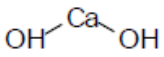
Name of manufacturer	Carmeuse Nederland BV
Address of manufacturer	Nijverheidsstraat 32, 2802 AL Gouda, The Netherlands
Location of manufacturing sites	Nijverheidsstraat 32, 2802 AL Gouda, The Netherlands

Name of manufacturer	Carmeuse SA
Address of manufacturer	Rue du Château 13a, 5300 Seilles, Belgium
Location of manufacturing sites	Rue du Val Notre Dame 300, 4520 Moha, Belgium. 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	závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia

2.1.2 Product family composition and formulation

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Calcium dihydroxide
IUPAC or EC name	Calcium dihydroxide
EC number	215-137-3
CAS number	1305-62-0
Index number in Annex VI of CLP	N/A
Minimum purity / content	800 g/kg (the value provides the content of Ca ex- pressed as Ca(OH)2)
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance contained in the biocidal products is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	20	70

2.1.2.4 Type of formulation

DP – Dustable powder (meta SPC 1 and 2) AL – Another Liquid (meta SPC 3)

PART II.- SECOND INFORMATION LEVEL - META SPC 1

1. Meta SPC 1 administrative information

1.1. Meta SPC identifier

BIOCALCO SL	

1.2. Suffix to the authorisation number

Number 1	

1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals PT03 – Veterinary hygiene

2. Meta SPC 1 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	60	70

2.2. Type(s) of formulation of the meta SPC 1

Formulation	DP – Dustable powder

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

Classification	
Hazard category	Skin irritation, category 2 Serious eye damage, category 1 STOT SE, category 3
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Labelling	
Signal words	GHS05, GHS07
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/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 CENTRE or doctor/physician. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTRE/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 in accordance with national regulation.
Note	

4. Authorised use(s) of the meta SPC 1

4.1. Use description

Table 1. Use # 1.1 – Disinfection of sewage sludge – Indoor and Outdoor- Professional

Product Type	2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Endoparasites: helminth eggs

Field of use	Indoor, outdoor The product is dosed into the sewage sludge and mixed by means of a blender.
Application method(s)	Automatic direct application
Application rate(s) and frequency	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: 24 h for bacteria to several weeks for endoparasites: helminth eggs
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750 kg big bag (closed with plastic foil)

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/m^3 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

See 5.4

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

Table 2. Use # 1.2 – Disinfection of manure – Indoor and Outdoor - Professional

Product Type	3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Viruses, Endoparasites: helminth eggs
Field of use	Indoor, outdoor The product is dosed into the manure and mixed by means of a blender.
Application method(s)	Automatic direct application.
Application rate(s) and frequency	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)
Category(ies) of users	Professional
Pack sizes and packaging material	750 kg big bag (closed with plastic foil)

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 /m^3 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/m^3 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

-

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

See 5.4

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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5. General directions for use of the meta SPC 1

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.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	BIOCALCO SL70				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	70

PART II. - SECOND INFORMATION LEVEL - META SPC 2

1. Meta SPC 2 administrative information

1.1. Meta SPC identifier

OPTILIT	

1.2. Suffix to the authorisation number

Number 2	

1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals PT03 – Veterinary hygiene

2. Meta SPC 2 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	20	30

2.2. Type(s) of formulation of the meta SPC 2

Formulation	
DP – Dustable powder	

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

Classification	
Hazard category	Skin irritation, category 2 Serious eye damage, category 1 STOT SE, category 3
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Labelling	
Signal words	GHS05, GHS07
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/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 CENTRE or doctor/physician. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTRE/doctorif you feel unwell. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of container in accordance with national regulation.
Note	

4. Authorised use(s) of the meta SPC 2

4.1. Use description

Table 3. Use # 2.3 – Disinfection of indoor floor surfaces of animal accommodations and transportation – Indoor – Professional

Product Type	3
Where relevant, an exact description of the authorised use	

Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	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)	Direct application
Application rate(s) and frequency	Ready to use 800 g $Ca(OH)_2$ / m² Frequency in animal housing: Before each production cycle Frequency in animal transportation: After each animal transport Contact time: 48h
Category(ies) of users	Professional
Pack sizes and packaging material	750 kg big bag (closed with plastic foil) 25 kg bag (closed with plastic foil)

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:
  - 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);
  - 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

-

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

Table 4. Use # 2.4 – Disinfection of floors of outdoor animal enclosures – Outdoor – Professional

Product Type	3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	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)	Direct application
Application rate(s) and frequency	Ready to use 800 g $Ca(OH)_2$ /m² Contact time 48 hours

	Frequency: maximum two applications per year
Category(ies) of users	Professional
Pack sizes and packaging material	750 kg big bag (closed with plastic foil) 25 kg bag (closed with plastic foil)

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:
    - 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);
    - 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

-

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

See 5.4

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 2

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.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	OPTILIT 20				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	20

Trade name(s)	OPTILIT 30				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	30

PART II. - SECOND INFORMATION LEVEL - META SPC 3

1. Meta SPC 3 administrative information

1.1. Meta SPC identifier

BIOCALCO M	

1.2. Suffix to the authorisation number

Number 3	

1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals PT03 – Veterinary hygiene

2. Meta SPC 3 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	20	50

2.2. Type(s) of formulation of the meta SPC 3

Formulation	
AL – Another liquid	

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

Classification	
Hazard category	Skin irritation, category 2 Serious eye damage, category 1 STOT SE, category 3
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Labelling	
Signal words	GHS05, GHS07
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/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 CENTRE or doctor/physician. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTRE/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 in accordance with national regulation.
Note	

4. Authorised use(s) of the meta SPC 3

4.1. Use description

Table 5. Use # 3.5 – Disinfection of sewage sludge – Indoor and Outdoor- Professional

Product Type	2
Where relevant, an exact description of the authorised use	

Target organism (including development stage)	Bacteria Endoparasites: helminth eggs
Field of use	Indoor outdoor The product is dosed into the sewage sludge and mixed by means of a blender.
Application method(s)	Automatic direct application
Application rate(s) and frequency	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: helminth eggs
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 :
    - a face shield
    - 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 cleaning of the unit treatment, 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/m^3 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

See 5.4

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

Table 6. Use # 3.6 – Disinfection of manure – Indoor and Outdoor - Professional

Product Type	3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Viruses, Endoparasites: helminth eggs
Field of use	Indoor, outdoor The product is dosed into the manure and mixed by means of a blender.
Application method(s)	Automatic direct application.
Application rate(s) and frequency	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)
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 /m^3 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 :
  - a face shield
  - 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 cleaning of the unit treatment, 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 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/m^3 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

Table 7. Use # 3.7 – Disinfection of animal accommodations; limewashing of walls – Indoor – Professional

Product Type	3

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor
Application method(s)	Direct application with a brush. The product is painted onto the walls of animal accommodations
Application rate(s) and frequency	Ready diluted products applied as sold by brushing on the walls 800 g $Ca(OH)_2$ / m² Contact time 48 hours
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 uniformally
3. Let it dry before reintroducing cattle

4.3.2 Use-specific risk mitigation measures

- During the loading of the product, wear :
  - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
  - a protective coverall (coverall material to be specified by the authorisation holder within the product information),
  - a face shield.

- During the application of the product on the walls, wear :
  - 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),
  - 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 3

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.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	BIOCALCO M 20				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	20

Trade name(s)	BIOCALCO M 25				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	25

Trade name(s)	BIOCALCO M 30
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	30

Trade name(s)	BIOCALCO M 35				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	35

Trade name(s)	BIOCALCO M 40				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	40

Trade name(s)	BIOCALCO M 50				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrated lime	Calcium dihydroxide	Substance active	1305-62-0	215-137-3	50

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
For META SPC 1 & 2					
Big bag/sack	750 kg	Paper	Plastic foil	Professional	Yes
Sack	25 kg	Paper	Plastic layer	Professional	Yes
For META SPC 3					

IBC	1000 kg	HDPE	Screw cap	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 3.1

2.1.8.2 Access to documentation

The applicant is a member of EuLA, the legal entity supporting the active substance. A letter of access to the active substance dossier and to the EuLa Hydra lime 23 PT2 and PT3 dossier has been supplied.

2.2 Assessment of the biocidal product (family)

2.2.1 Intended use(s) as applied for by the applicant

Meta-SPC 1

Table 4. Use # 1 – Disinfection of sewage sludge

Product Type	2
Where relevant, an exact description of the authorised use	The product is dosed into the sewage sludge and mixed by means of a blender. The treated sludge may have three destinations - agricultural use, incineration or landfill.
Target organism (including development stage)	Bacteria, yeast, fungi, viruses, nematode eggs
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	The dry product is mixed with the sewage sludge in a open mixer. The product can be loaded manually or using semi- or fully automated processes. 0.3 – 3.4 kg product/ kg dry weight of substrate; Typical dry solids content - 12-25% in sewage sludge and 1-6% in liquid manures The dose must be high enough to achieve a pH of > 12 for a minimum of 3 hours. Note; the rate may vary between application.
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750 kg Paper sack: 25 kg

Table 5. Use # 2 – Disinfection of manure

Product Type	3
Where relevant, an exact description of the authorised use	The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use.
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	Remove the manure or litter from the animal house. 1. For prevention: Add approximately 14-17 kg product/m3 of litter or manure. 2. For treatment: Add approx. 140-170 kg product/m3 of litter or manure 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water. 4. Stockpile the lime treated manure. 5. After at least 24h, dispose of the lime treated manure

	according to local legislation. Application of lime to litter or manure inside animal houses 1. For Prevention: Spread approx. 14-17 kg product/m3 (2.8-3.3 kg of product /m2 for 20 cm litter) on the litter or manure inside the poultry house 2. For treatment: Spread approx. 140-170 kg/m3 (28-33 kg of product /m2 of 20 cm litter) on the litter or manure inside the animal house 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water 4. Remove the lime/manure or lime/litter mixture from the animal house 5. Homogenise the lime/manure or litter mixture 6. Stockpile the lime treated manure 7. After at least 24 h, dispose the lime treated manure according to the local legislation
Category(ies) of users	Professional
Pack sizes and packaging material	Big bags : 1000kG Paper sack: 25 kg

Meta-SPC 2

Table 6. Use # 3 – Disinfection of indoor floor surfaces of animal accommodations and transportation

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto the floors of animal accommodations (poultry, cattle, sheep)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor
Application method(s)	Direct application
Application rate(s) and frequency	Disinfection of indoor floor surfaces of animal accommodations and transportation. The product is spread onto the floors of animal accommodations 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 sufficient product to cover the damp ground (e.g. 3.4-5 kg of product/m2) 3. Leave to act for at least 2 h B. On mud floors 1. Brush the floor 2. Sprinkle approx.2.7-4 kg of product per m2 on the damp ground 3. Leave to act for at least 24 h
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750 kg Paper sack: 25 kg

Table 7. Use # 4 – Disinfection of animal bedding materials

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto animal bedding materials (straw, sawdust, woodchip)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor
Application method(s)	Direct application
Application rate(s) and frequency	Cattle: Spread onto mulched or soiled bedding, do not apply alone to animal stalls. Use 5 to 7.5 kg product per livestock unit per week in straw area. 1 to 1.5 kg per stall once or twice a week Sheep/goats: 370 g to 1 kg/m2 per head/week Poultry: 340 g - 1 kg/m2 1-2 times per week
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 1000 kg Paper sack: 25 kg

Table 5. Use # 6 – Disinfection of floors of outdoor animal enclosures

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto the surface of animal enclosures (poultry)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Outdoor
Application method(s)	Direct application
Application rate(s) and frequency	At the beginning of a production cycle it is recommended to spread 2.7-4 kg product/m2 onto the ground and apply water to the soil. At the end of the production cycle it is recommended to remove any remaining material from the soil. Leave to act for at least 24 hours before bringing in poultry When the flock is in place, reapply if the ground becomes muddy or unstable.
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 1000 kg Paper sacks: 25 kg

Meta-SPC 3

Table 8. Use # 3.1 – Disinfection of sewage sludge

Product Type	2
Where relevant, an exact description of the authorised use	The product is dosed into the sewage sludge and mixed by means of a blender. The treated sludge may have three destinations - agricultural use, incineration or landfill.
Target organism (including development stage)	Bacteria, yeast, fungi, viruses, nematode eggs
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	The product is mixed with the sewage sludge in a open mixer. The product can be loaded manually or using semi- or fully automated processes. 0.4 – 10 kg product/ kg dry weight of substrate; Typical dry solids content - 12-25% in sewage sludge and 1-6% in liquid manures The dose must be high enough to achieve a pH of > 12 for a minimum of 3 hours. Note; the rate may vary between application..
Category(ies) of users	Professional
Pack sizes and packaging material	IBC: 1000 kg

Table 9. Use # 3.2 – Disinfection of manure

Product Type	3
Where relevant, an exact description of the authorised use	The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use.
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	Remove the manure or litter from the animal house. 1. For prevention: Add approximately 20-50 kg product/m3 of litter or manure. 2. For treatment: Add approx. 200-500 kg product/m3 of litter or manure 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water. 4. Stockpile the lime treated manure. 5. After at least 24h, dispose of the lime treated manure according to local legislation. Application of lime to litter or manure inside animal houses 1. For Prevention: Spread approx. 20-50 kg product/m3 (4-10 kg of product /m2 for 20 cm litter) on the litter or manure inside the poultry house 2. For treatment: Spread approx. 200-500 kg/m3 (40-100 kg of product /m2 of 20 cm litter) on the litter or manure inside the animal house

	3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water 4. Remove the lime/manure or lime/litter mixture from the animal house 5. Homogenise the lime/manure or litter mixture 6. Stockpile the lime treated manure 7. After at least 24 h, dispose the lime treated manure according to the local legislation
Category(ies) of users	Professional
Pack sizes and packaging material	IBC: 1000 kg

Table 8. Use # 5 – Disinfection of animal accommodations; limewashing of walls

Product Type	3
Where relevant, an exact description of the authorised use	The product is diluted in water and the mixture painted onto the walls of accommodations (poultry, cattle, sheep)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor
Application method(s)	Direct application
Application rate(s) and frequency	Ready diluted products should be applied as sold. Needed volume of product depends on its concentration: 20% : 0.55 to 0.75 l/m² 33% : 0.30 to 0.45 l/m² 50% : 0.15 to 0.25 l/m² Application method for 150 to 200 m2 of wall (depending on the porosity of the wall): Volume of product needed: 20% : 82.5 to 150 l 33% : 45 to 90 l 50% : 22.5 to 50 l 1. Agitate before use to homogenize the suspension 2. Brush onto the wall uniformly 3. Let it dry before reintroducing cattle
Category(ies) of users	Professional
Pack sizes and packaging material	IBC: 1000 kg

2.2.2 Physical, chemical and technical properties

META SPC 1 - BIOCALCO SL
The product does not contains H304 or hydrocarbons content >10%.
Products are ready-to-use.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical state at 20 °C and 101.3 kPa	Visual description	BIOCALCO SL70 Batch number 20190306_SL70	Solid homogeneous powder	Carmeuse 2019	Acceptable
Colour at 20 °C and 101.3 kPa	Visual description	BIOCALCO SL70 Batch number 20190306_SL70	Whitish to light grey		
Odour at 20 °C and 101.3 kPa	Not indicated	BIOCALCO SL70 Batch number 20190306_SL70	No odour testing was realized, as it is not compatible with QHSE procedures.		
pH Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	BIOCALCO SL70 Batch number 20190306_SL70	pH (1% diluted, at 21.4°C): 12.45 74.41 % m/m as NaOH	Carmeuse 2019	Acceptable
Relative density / bulk density	CIPAC MT 186 OECD 106 EC Method A3	≥ 97.0%	Relative density: 2.2 Pour density: 0.4 g/mL Tap density: 0.5 g/mL	AS dossier: A3.1.3/02 A3.1.3/03	Accepted in the CAR of active substance Based on the composition of the product, this test can be extrapolated from active substance to the biocidal product (see confidential annex).
	CIPAC MT 186	BIOCALCO SL70	Tap density : 0.57 g/mL.	Eurofins 2019	Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3</td>
<td>BIOCALCO SL70
Batch number 20190306_SL70</td>
<td>
<table>
<tr><th></th><th>Initial</th><th>After storage 2weeks at 54°C in paper bag (with plastic layer)</th></tr>
<tr><td>Alkalinity/pH</td><td>76.55 % w/w as NaOH

pH (1%): 12.77</td><td>74.76 % w/w as NaOH

(-1.79%)
pH (1%): 12.72</td></tr>
</table>
</td>
<td>Carmeuse 2019</td>
<td>Acceptable
No significant changes of the determined parameters were found after storage for 14 days at 54°C. No data about specification of active substance during storage is provided yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td></td>
<td>BIOCALCO SL70
Batch number 20190306_SL70</td>
<td>
<table>
<tr><th></th><th>Initial</th><th>After storage 4 weeks at 20°C in paper bag (with plastic layer)</th></tr>
<tr><td>Appearance</td><td colspan="2">Whitish to light grey homogeneous powder.</td></tr>
<tr><td>Packaging stability</td><td colspan="2">No difference</td></tr>
<tr><td>Alkalinity/pH</td><td>74.41 % w/w as NaOH</td><td>72.82 % w/w as NaOH (-1.59%)</td></tr>
</table>
</td>
<td>[redacted]</td>
<td>Product is stable after 1 month at 20°C.
Based on accelerated storage, the shelf-life can be extrapolated to 24months.

Determination of active part of the lime mixture can be assessed using</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>pH (1%): 12.45 (21.4°C)</td><td>pH (1%): 12.27 (21.3°C)</td></tr>
<tr><td>Dry sieve</td><td>% residue at:
- 45 µm = 9.20 %
- 63 µm = 3.48 %
- 90 µm = 1.20 %
- 125 µm = 0.48 %
- 1 mm = 0 %</td><td>% residue at:
- 45 µm = 9.60 %
- 63 µm = 4.04 %
- 90 µm = 1.60 %
- 125 µm = 0.68 %
- 1 mm = 0 %</td></tr>
<tr><td>Particle size</td><td>D(0.1) = 1.11 µm
D(0.5) = 5.01 µm
D(0.9) = 31.34 µm</td><td>D(0.1) = 1.09 µm
D(0.5) = 4.88 µm
D(0.9) = 30.87 µm</td></tr>
</table>
</td><td></td><td>alkalinity before and after storage. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance</td></tr>
<tr><td></td><td>Norm EN 459-2

CIPAC MT31</td><td>WKH, 100% $Ca(OH)_2$</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 15months in big-bags</td></tr>
<tr><td>Mean content (%w/w)</td><td></td><td></td></tr>
<tr><td>$Ca(OH)_2$</td><td>93.2</td><td>91.6 (-1.6)</td></tr>
<tr><td>$CaCO_3$</td><td>3.3</td><td>6.5</td></tr>
<tr><td>CO2</td><td>1.42</td><td>2.81</td></tr>
<tr><td>MgO</td><td>0.5</td><td>0.5</td></tr>
<tr><td>pH</td><td>12.6</td><td>12.5</td></tr>
<tr><td>Alkalinity</td><td>0.26% NaOH</td><td>0.25% NaOH</td></tr>
<tr><td>Particle size</td><td>D10: 1.5µm
D50: 8.6µm
D90: 26µm
D100: 86µm</td><td>D10: 1.6µm
D50: 9.1µm
D90: 29µm
D100: 86µm</td></tr>
</table>
</td><td>[redacted]</td><td>Results of long term storage of HYDRALIME product (100% active substance) is added here for information. A LoA to EULA products is provided by the applicant.
The specifications of active substance are considered stable after 15months in big bag.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
					The data can be extrapolated to the meta SPC 1, 2 and 3 (see PAR conf)
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Waiver		Active substance is not light sensitive.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver		As the substance is hygroscopic, the product should be protect from humidity. Therefore, a note should be added on the label.		Acceptable **Protect from humidity**
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver		Experience indicates that paper bags lined with plastic (to prevent contact with moisture) do not react significantly with dry lime and so can be used as container material for this product.		See storage study. Technical tests are remained unchanged after storage, indicates that packaging (paper bag) is suitable for the biocidal product.
Wettability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Suspensibility, spontaneity and dispersion stability	Waiver		Not relevant		
Wet sieve analysis and dry sieve test	CIPAC MT 59.1	BIOCALCO SL70 Batch number 20190306_SL70	Dry sieve Percentage residue at: - 45 µm = 9.20 % - 63 µm = 3.48 % - 90 µm = 1.20 % - 125 µm = 0.48 % - 1 mm = 0 % - 1.4 mm = 0 % D(0.1) = 1.11 µm D(0.5) = 5.01 µm D(0.9) = 31.34 µm	Carmeuse 2019	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		Not relevant		
Disintegration time			Not applicable		
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	BIOCALCO SL70 Batch number 20190306_SL70	D(0.1) = 1.11 µm D(0.5) = 5.01 µm D(0.9) = 31.34 µm	Carmeuse 2019	Acceptable Inhalation fraction (content of particle size under 10µm) is above 1%. See HH section.
Flowability/Pourability/Dustability	CIPAC MT 59.1 CIPAC MT 187	BIOCALCO SL70 Batch number 20190306_SL70	Not performed – the product is a dusty solid as indicated by the dry sieve and PSD test.	Carmeuse 2019	Acceptable
Burning rate — smoke generators			Not relevant for DP products		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Burning completeness — smoke generators			Not relevant for DP products		
Composition of smoke — smoke generators			Not relevant for DP products		
Spraying pattern — aerosols			Not relevant for DP products		
Physical compatibility			According to storage study, Hydrated lime (and consequently the Hydrated lime products) can be stored without any problems in paper and plastic materials/ bags and in silos.		Acceptable
Chemical compatibility			Keep away from acids and nitro compounds. Aluminium should not be used for transport and storage.		Acceptable
Degree of dissolution and dilution stability			The test is not appropriate for the use of lime products diluted in water for paints for walls		Acceptable
Surface tension	Waiver		Not applicable to solids		
Viscosity	Waiver		Not applicable to solids		

Conclusion on the physical, chemical and technical properties of the product
Tested product is representative of META SPC1. Moreover, viewing the composition of the META SPC1 (see confidential annex), density test performed in CAR of active substance can be extrapolated to the META SPC 1. Therefore, META SPC is cover by physico-chemical tests. The product is a Whitish to light grey homogeneous powder. The solid is alkaline with a 1% diluted pH of 12.45 at 21°C and an alkalinity of 74.41% w/w as NaOH. The product has been shown to be stable with no significant changes in the appearance of the test item or the packaging at 20°C for 4 weeks. The product has been shown to be stable with no significant change of the test item or the packaging at 20°C for 4 weeks and 2weeks at 54°C. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance

. Long-term storage stability is on-going and will be required in post-authorization (including specification of active substance). Base on the accelerated storage, a 2 years shelf life could be set.

Implication for labelling: Shelf-life: 2 years
Protect from humidity
Keep away from acid

META SPC 2 – OPTILIT

The product does not contains H304 or hydrocarbons content >10%.
Products are ready-to-use.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical state at 20 °C and 101.3 kPa	Visual description	OPTILIT 20 Batch number 20190306_O20	Solid homogeneous powder	Carmeuse 2019	Acceptable
Colour at 20 °C and 101.3 kPa	Visual description	OPTILIT 20 Batch number 20190306_O20	Grey with a few white grains.		
Odour at 20 °C and 101.3 kPa	Not indicated	OPTILIT 20 Batch number 20190306_O20	No odour testing was realized, as it is not compatible with QHSE procedures.		
pH Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	OPTILIT 20 Batch number 20190306_O20	pH (1% diluted, at 20.6°C): 12.48 20.42 % m/m as NaOH	Carmeuse 2019	Acceptable
Relative density / bulk density	CIPAC MT 186 OECD 106 EC Method A3	≥ 97.0%	Relative density: 2.2 Pour density: 0.4 g/mL Tap density: 0.5 g/mL	AS dossier: A3.1.3/02 A3.1.3/03	Accepted in the CAR of active substance Based on the composition of the product, this test can be extrapolated from active

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>substance to the biocidal product (see confidential annex).</td></tr>
<tr><td></td><td>CIPAC MT 186</td><td>Optilit 20: 20% calcium dihydroxide</td><td>Tap density : 0.88 g/mL.</td><td>Eurofins 2019</td><td>Acceptable</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3</td><td>OPTILIT 20
Batch number 20190306_O20</td><td><table><tr><th></th><th>Initial</th><th>After storage 2weeks at 54°C in paper bag (with plastic layer)</th></tr><tr><td>Alkalinity/pH</td><td>24.67 % w/w as NaOH

pH (1%): 12.72</td><td>22.75 % w/w as NaOH (-1.92%)
pH (1%): 12.68</td></tr></table></td><td>Carmeuse 2019</td><td>Acceptable
No significant changes of the determined parameters were found after storage for 14 days at 54°C. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>In progress</td><td></td><td><table><tr><th></th><th>Initial</th><th>After storage 4 weeks at 20°C in paper bag (with plastic layer)</th></tr></table></td><td>Carmeuse 2019</td><td>Product is stable after 1 month at 20°C.
Based on accelerated storage, the shelf-life can be</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><td>Appearance</td><td colspan="2">Grey powder with a few white grains.</td></tr>
<tr><td>Packaging stability</td><td colspan="2">No difference</td></tr>
<tr><td>Alkalinity/pH</td><td>20.42 % w/w as NaOH

pH (1%): 12.48 (20.6°C)</td><td>20.74 % w/w as NaOH (+0.32%)

pH (1%): 85.64 (21.9°C)</td></tr>
<tr><td>Dry sieve</td><td>% residue at:
- 45 µm = 15.56 %
- 63 µm = 7.04 %
- 90 µm = 2.68 %
- 125 µm = 0.92 %
- 1 mm = 0 %</td><td>% residue at:
- 45 µm = 15.6 %
- 63 µm = 7.32 %
- 90 µm = 2.12 %
- 125 µm = 1.32 %
- 1 mm = 0 %</td></tr>
<tr><td>Particle size</td><td>D(0.1) = 1.14 µm
D(0.5) = 5.94 µm
D(0.9) = 46.47 µm</td><td>D(0.1) = 1.13 µm
D(0.5) = 5.57 µm
D(0.9) = 44.87 µm</td></tr>
</table>
</td>
<td></td>
<td>extrapolated to 24months.

Determination of active part of the lime mixture can be assessed using alkalinity before and after storage. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Opilit 20
Batch n° : 20201217</td>
<td>
<table>
<tr><td></td><td>Initial</td><td>After storage 4 weeks at 20°C in paper bag</td></tr>
<tr><td>Appearance</td><td colspan="2">The test item was found as a fine off-white powder</td></tr>
<tr><td>Packaging stability</td><td colspan="2">10 kg white, non transparent paper sack shut tightly. No</td></tr>
</table>
</td>
<td>[redacted]</td>
<td>The dry sieve test and the particle size are missing after storage.

The pH and alkalinity are stable.</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td colspan="2">damage to the shape or size was observed
Weight change : <0.59%</td></tr>
<tr><td>Alkalinity/pH</td><td>27.05 % w/w as NaOH

pH (1%): 12.61 (20.8 – 21.5°C)</td><td>25.36 % w/w as NaOH (-1.69%)

pH (1%): 12.46 (20.4-20.6°C)</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td></td><td>Norm EN 459-2

CIPAC MT31</td><td>WKH, 100% $Ca(OH)_2$</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 15months in big-bags</td></tr>
<tr><td>Mean content (%w/w)</td><td></td><td></td></tr>
<tr><td>$Ca(OH)_2$</td><td>93.2</td><td>91.6 (-1.6)</td></tr>
<tr><td>$CaCO_3$</td><td>3.3</td><td>6.5</td></tr>
<tr><td>CO2</td><td>1.42</td><td>2.81</td></tr>
<tr><td>MgO</td><td>0.5</td><td>0.5</td></tr>
<tr><td>pH</td><td>12.6</td><td>12.5</td></tr>
<tr><td>Alkalinity</td><td>0.26% NaOH</td><td>0.25% NaOH</td></tr>
<tr><td>Particle size</td><td>D10: 1.5µm
D50: 8.6µm
D90: 26µm
D100: 86µm</td><td>D10: 1.6µm
D50: 9.1µm
D90: 29µm
D100: 86µm</td></tr>
</table>
</td><td>[redacted]</td><td>Results of long term storage of HYDRALIME product (100% active substance) is added here for information. A LoA to EULA products is provided by the applicant.
The specifications of active substance are considered stable after 15months in big bag. The data can be extrapolated to the meta SPC 1, 2 and 3 (see PAR conf)</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td></td><td></td><td>Waiver</td><td></td><td>Active substance is not light sensitive.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver		Lime products are not degradable. As the substance is hygroscopic, the product should be protect from humidity. Therefore, a note should be added on the label.		Acceptable **Protect from humidity**
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver		Experience indicates that paper bags lined with plastic (to prevent contact with moisture) do not react significantly with dry lime and so can be used as container material for this product.		See storage study. Technical tests are remained unchanged after storage, indicates that packaging (paper bag) is suitable for the biocidal product.
Wettability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls.		Acceptable
Suspensibility, spontaneity and dispersion stability	Waiver		Not relevant		
Wet sieve analysis and dry sieve test	CIPAC MT 59.1	OPTILIT 20 Batch number 20190306_O20	Dry sieve Percentage residue at: - 45 µm = 15.56 % - 63 µm = 7.04 % - 90 µm = 2.68 % - 125 µm = 0.92 % - 1 mm = 0 % - 1.4 mm = 0 %	Carmeuse 2019	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			D(0.1) = 1.14 µm D(0.5) = 5.94 µm D(0.9) = 46.47 µm		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls.		Acceptable
Disintegration time			Not applicable		
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	OPTILIT 20 Batch number 20190306_O20	D(0.1) = 1.14 µm D(0.5) = 5.94 µm D(0.9) = 46.47 µm	Carmeuse 2019	Acceptable Inhalation fraction (content of particle size under 10µm) is above 1%. See HH section.
Flowability/Pourability/Dustability	CIPAC MT 59.1 CIPAC MT 187	OPTILIT 20 Batch number 20190306_O20	Not performed – the product is a dusty solid as indicated by the dry sieve and PSD test,	Carmeuse 2019	Acceptable
Burning rate — smoke generators			Not relevant for DP products		
Burning completeness — smoke generators			Not relevant for DP products		
Composition of smoke — smoke generators			Not relevant for DP products		
Spraying pattern — aerosols			Not relevant for DP products		
Physical compatibility			According to storage study, Hydrated lime (and consequently the Hydrated lime products) can be stored without any		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			problems in paper and plastic materials/ bags and in silos.		
Chemical compatibility			Keep away from acids and nitro compounds. Aluminium should not be used for transport and storage		Acceptable
Degree of dissolution and dilution stability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls		Acceptable
Surface tension	Waiver		Not applicable to solids		
Viscosity	Waiver		Not applicable to solids		

Conclusion on the physical, chemical and technical properties of the product

Tested product is representative of the lower content of active substance in META SPC2. Moreover, the composition of the META SPC1 and the composition of the active substance reported in the CAR, they can be considered as similar to the highest content of the meta SPC 2 (see confidential annex). In consequence tests from META SPC 1 and in the CAR of active substance can be extrapolated to the META SPC 2. Therefore, META SPC 2 is covered by physico-chemical tests of tested product and META SPC 1 tests.
The product is a grey powder with a few white grains. The solid is alkaline with a 1% diluted pH of 12.48 at 21°C and an alkalinity of 20.42% w/w as NaOH.
The product has been shown to be stable with no significant changes in the appearance of the test item or the packaging at 20°C for 4 weeks and 2weeks at 54°C. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages and stored away from humidity, based on pH data and data on active substance . Long-term storage stability is on-going and will be required in post-authorization (including specification of active substance). Base on the accelerated storage, a 2 years shelf life could be set.

Implication for labelling:

Shelf-life: 2 years
Protect from humidity.
Keep away from acid

META SPC 3 - BIOCALCO M

The product does not contains H304 or hydrocarbons content >10%.
Products are ready-to-use.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical state at 20 °C and 101.3 kPa	Visual description	BIOCALCO M 20 Batch number 20190311_M20 BIOCALCO M 50 Batch number 20190311_M50	Milk of lime (liquid)	Carmeuse 2019	Acceptable
Colour at 20 °C and 101.3 kPa	Visual description	BIOCALCO M 20 Batch number 20190311_M20 BIOCALCO M 50 Batch number 20190311_M50	White		
Odour at 20 °C and 101.3 kPa	Not indicated	BIOCALCO M 20 Batch number 20190311_M20 BIOCALCO M 50 Batch number 20190311_M50	No odour testing was realized, as it is not compatible with QHSE procedures.		
pH Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	BIOCALCO M 20 Batch number 20190311_M20	pH (0.23% diluted, at 22.6°C): 12.38 19.07 % m/m as NaOH	Carmeuse 2019	Acceptable
	CIPAC MT 75.3 CIPAC MT 191	BIOCALCO M 50 Batch number 20190311_M50	pH (0.69% diluted, at 22.7°C): 12.42 51.39 % m/m as NaOH	Carmeuse 2019	Acceptable
Relative density / bulk density	CIPAC MT 186 OECD 106 EC Method A3	Milk of lime	BIOCALCO M 20 1.204 BIOCALCO M 50 1.394	[redacted]	Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3</td><td>BIOCALCO M 20
Batch number M-00023145</td><td>
<table>
<tr><th></th><th>Initial</th><th>After storage 2weeks at 54°C in paper bag (with plastic layer)</th></tr>
<tr><td>Alkalinity/pH</td><td>21.85 % w/w as NaOH

pH (1%): 12.72</td><td>20.86 % w/w as NaOH (-0.99%)

pH (1%): 12.67</td></tr>
</table>
BIOCALCO M 50
Batch number M-00023141
<table>
<tr><th></th><th>Initial</th><th>After storage 2weeks at 54°C in paper bag (with plastic layer)</th></tr>
<tr><td>Alkalinity/pH</td><td>52.41 % w/w as NaOH

pH (1%): 12.77</td><td>50.36 % w/w as NaOH (-2.05%)

pH (1%): 12.69</td></tr>
</table>
</td><td>Carmeuse 2019</td><td>Acceptable
No significant changes of the determined parameters were found after storage for 14 days at 54°C. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages, based on pH data and data on active substance</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>In progress</td><td>BIOCALCO M 20
Batch number 20190311_M20</td><td>
<table>
<tr><th></th><th>Initial</th><th>After storage 4 weeks at 20°C in paper bag (with plastic layer)</th></tr>
<tr><td>Appearance</td><td colspan="2">White milk of lime.</td></tr>
<tr><td>Packaging stability</td><td colspan="2">No difference</td></tr>
<tr><td>Alkalinity/pH</td><td>20.42 % w/w as NaOH

pH (0.23%w/v):</td><td>21.22 % w/w as NaOH (+0.8%)</td></tr>
</table>
</td><td>Carmeuse 2019</td><td>Product is stable after 1 month at 20°C.
Based on accelerated storage, the shelf-life can be extrapolated to 24months.

Determination of active part of the lime mixture can be assessed using alkalinity before and</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results			Reference	Comment
				12.38 (22.6°C)	pH (0.31%w/v): 12.28 (23.3°C)		after storage. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages, based on pH data and data on active substance Pourability results are very high. A note on the label should be added: Dispose the packaging and any other waste in an appropriate collection circuit.
			Wet sieve	% residue at: - 45 µm = 1.41 % - 63 µm = 0.66 % - 90 µm = 0.14 % - 125 µm = 0.04 %	% residue at: - 45 µm = 1.45 % - 63 µm = 0.59 % - 90 µm = 0.08 % - 125 µm = 0.02 %		
			Particle size	D(0.1) = 1.02 µm D(0.5) = 4.09 µm D(0.9) = 21.65 µm	D(0.1) = 0.93 µm D(0.5) = 3.20 µm D(0.9) = 11.43 µm		
			Gravimetric suspensibility (at concentration of use)	80%	95%		
			Pourability	26.86% Rinsed residue : 24.68%	22.41% Rinsed residue : 4.28%		
			Persistent foaming (at concentration of use)	No foam was observed after 1 minute.			

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr>
<td></td>
<td>Norm EN 459-2

CIPAC MT31</td>
<td>WKH, 100% $Ca(OH)_2$</td>
<td>
<table>
<tr><td></td><td>Initial</td><td>After 15months in big-bags</td></tr>
<tr><td>Mean content (%w/w)</td><td></td><td></td></tr>
<tr><td>$Ca(OH)_2$</td><td>93.2</td><td>91.6 (-1.6)</td></tr>
<tr><td>$CaCO_3$</td><td>3.3</td><td>6.5</td></tr>
<tr><td>CO2</td><td>1.42</td><td>2.81</td></tr>
<tr><td>MgO</td><td>0.5</td><td>0.5</td></tr>
<tr><td>pH</td><td>12.6</td><td>12.5</td></tr>
<tr><td>Alkalinity</td><td>0.26% NaOH</td><td>0.25% NaOH</td></tr>
<tr><td>Particle size</td><td>D10: 1.5µm
D50: 8.6µm
D90: 26µm
D100: 86µm</td><td>D10: 1.6µm
D50: 9.1µm
D90: 29µm
D100: 86µm</td></tr>
</table>
</td>
<td>[redacted]</td>
<td>Results of long term storage of HYDRALIME product (100% active substance) is added here for information.
A LoA to EULA products is provided by the applicant.
The specifications of active substance are considered stable after 15months in big bag. The data can be extrapolated to the meta SPC 1, 2 and 3 (see PAR conf)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BIOCALCO M 50
Batch number 20190311_M50</td>
<td>
<table>
<tr><td></td><td>Initial</td><td>After storage 4 weeks at 20°C in paper bag (with plastic layer)</td></tr>
<tr><td>Appearance</td><td colspan="2">White milk of lime.</td></tr>
<tr><td>Packaging stability</td><td colspan="2">No difference</td></tr>
<tr><td>Alkalinity/pH</td><td>51.39 % w/w as NaOH

pH (0.69%w/v): 12.42 (22.7°C)</td><td>53.84 % w/w as NaOH (+2.45%)

pH (0.74%w/v): 12.28 (25°C)</td></tr>
<tr><td>Wet sieve</td><td>% residue at:</td><td>% residue at:
- 45 µm = 3.80 %</td></tr>
</table>
</td>
<td>Carmeuse 2019</td>
<td>Based on accelerated storage, the shelf-life can be extrapolated to 24months.

Determination of active part of the lime mixture can be assessed using alkalinity before and after storage
Pourability results are very high.
A note on the label should be added: Dispose the</td>
</tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results			Reference	Comment
				- 45 µm = 4.40 % - 63 µm = 2.26% - 90 µm = 0.35 % - 125 µm = 0.13 %	- 63 µm = 1.53 % - 90 µm = 0.32 % - 125 µm = 0.09 %		packaging and any other waste in an appropriate collection circuit. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages, based on pH data and data on active substance
			Particle size	D(0.1) = 0.97 µm D(0.5) = 3.76 µm D(0.9) = 24.86 µm	D(0.1) = 0.96 µm D(0.5) = 3.65 µm D(0.9) = 23.56 µm		
			Gravimetric suspensibility (at concentration of use)	100%	100%		
			Pourability	5.37% Rinsed residue : 2.54%	2.67% Rinsed residue : 0.67%		
			Persistent foaming (at concentration of use)	No foam was observed after 1 minute.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Waiver				Active substance is not light sensitive.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Storage stability test – **low temperature storage**	waiver		Waiver		Lime products are not degradable. Milk of lime is not sensitive to temperature out of freezing (0°C) and boiling conditions (100°C). **the product should be protect from frost.**
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver		Lime products are not degradable. Milk of lime is not sensitive to temperature out of freezing (0°C) and boiling conditions (100°C). It needs to be kept in this range to keep its properties. It is not recommended to reuse a frozen milk of lime.		
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3	BIOCALCO M20 20% calcium dihydroxide BIOCALCO M50: 50% calcium dihydroxide	There was no significant change in the product or the packaging after 4 weeks at 20°C.	Carmeuse 2019	See storage study. Technical tests are remained unchanged after storage, indicates that packaging (paper bag) is suitable for the biocidal product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Wettability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls.		Acceptable
Persistent foaming	MT 47.3	BIOCALCO M 20 Batch number 20190311_M20 BIOCALCO M 50 Batch number 20190311_M50	At concentration of use, no foam (0mL) is observed after 1minute for both products. 34mL of foam directly after stirring for BIOCALCO M 20. 4mL of foam directly after stirring for BIOCALCO M 50.		Acceptable
Suspensibility, spontaneity and dispersion stability	CIPAC MT 184.1	BIOCALCO M20: 20% calcium dihydroxide	83.7% of the product remains suspended after 30 minutes of standing at 30°C.	Eurofins 2019	Acceptable
		BIOCALCO M50: 50% calcium dihydroxide	100.4% The product is completely suspensible after 30 minutes standing at 30°C	Eurofins 2019	
Wet sieve analysis and dry sieve test	CIPAC MT 59.1	BIOCALCO M 20 Batch number 20190311_M20	Wet sieve Percentage residue at: - 45 µm = 1.41 % - 63 µm = 0.66 % - 90 µm = 0.14 % - 125 µm = 0.04 %	Carmeuse 2019	Acceptable
		BIOCALCO M 50 Batch number 20190311_M50	Wet sieve Percentage residue at: - 45 µm = 4.40 % - 63 µm = 2.26% - 90 µm = 0.35 % - 125 µm = 0.13 %		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Disintegration time			Not applicable		
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	BIOCALCO M 20 Batch number 20190311_M20	D(0.1) = 1.02 µm D(0.5) = 4.09 µm D(0.9) = 21.65 µm	Carmeuse 2019	Acceptable Inhalation fraction (content of particle size under 10µm) is above 1%. Nevertheless, as the product is viscous liquid (sludge), no other data is required.
		BIOCALCO M 50 Batch number 20190311_M50	D(0.1) = 0.97 µm D(0.5) = 3.76 µm D(0.9) = 24.86 µm		
Flowability/Pourability/Dustability	CIPAC MT 148	BIOCALCO M 20 Batch number 20190311_M20	Pour residue : 26.86% Rinsed residue : 24.68%	Carmeuse 2019	Pourability results are above usual limits (5%). A note on the label should be added: Dispose the packaging and any other waste in an appropriate collection circuit.
		BIOCALCO M 50 Batch number 20190311_M50	Pour residue : 5.37% Rinsed residue : 2.54%		
Burning rate — smoke generators			Not relevant for DP or AL products		
Burning completeness — smoke generators			Not relevant for DP or AL products		
Composition of smoke — smoke generators			Not relevant for DP or AL products		
Spraying pattern — aerosols			Not relevant for DP or AL products		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical compatibility			According to storage study, Hydrated lime (and consequently the Hydrated lime products) can be stored without any problems in paper and plastic materials/ bags and in silos.		Acceptable
Chemical compatibility			Keep away from acids and nitro compounds. Aluminium should not be used for transport and storage.		Acceptable
Degree of dissolution and dilution stability	Waiver		The test is not appropriate for the use of lime products diluted in water for paints for walls		Acceptable
Surface tension	Waiver		Not applicable		
Viscosity	Not precise (viscosimeter /rheometer	Milk of lime	At speed of $5s^{-1}$, viscosity depend of concentration: <100cP at 20% 400cP at 30% 1000cP around 36%	[redacted]	Composition of tested product is not available. As it is not used for risk assessment, no further data is required. acceptable

Conclusion on the physical, chemical and technical properties of the product
Two products were tested corresponding to maximum and minimum content of active substance of the meta SPC 3. Therefore, the provided tests cover the META SPC 3.The product is a white milk of lime with a 0.2% to 0.7% diluted pH of 12.4 at 23°C and an alkalinity of 20.42% to 51.39% w/w as NaOH. The product is not foaming and has acceptable technical properties (wet sieve, suspensibility, particle size). Pourability is high, therefore, a note on label should be added: Dispose the packaging and any other waste in an appropriate collection circuit. The product has been shown to be stable with no significant changes in the appearance of the test item or the packaging at 20°C for 4 weeks and 2weeks at 54°C. No data about specification of active substance during storage is provide yet. Nevertheless, the test item is expected to be stable in its original test item packages, based on pH data and data on active substance. Long-term storage

stability is on-going and will be required in post-authorization (including specification of active substance). Based on the accelerated storage, a 2 years shelf life could be set.

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

2.2.3 Physical hazards and respective characteristics

Physical hazards tests are for the family products

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Explosives	Waiver		Not explosive According to the TNsG on data requirements, the test can be exempted when [...] absence of certain reactive groups in the structural formula or its "oxygen balance" establishes beyond reasonable doubt that the substance is incapable of decomposing, forming gases or releasing heat very rapidly." These criteria fully apply to $Ca(OH)_2$.	/	Acceptable Not explosive product
	Waiver based on composition	Calcium dihydroxide Ca(OH)2 (Eula hydralime product) Batch BE1110.144.3	There are no chemical groups within the structure that would imply explosive properties according to the manual of recommendation on Transport of dangerous goods.	[redacted]	
Flammable solids	Waiver		In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded.	AS dossier IIIA 3.11	Acceptable Not flammable Based on the composition of BPF
	EEC A10 (Test N.1)	Calcium dihydroxide	The substance does not ignite within the 2min screening test.	[redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
		Ca(OH)2 of Eula hydralime product) Batch BE1110.144.3		[redacted]	and the test on the active substance.
Self-reactive substances and mixtures	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that $Ca(OH)_2$ is instable at high temperatures. $Ca(OH)_2$ is produced from CaO, itself produced from limestone (CaCO3) at 900 – 1300 °C. It can be concluded that $Ca(OH)_2$ is stable at least at this temperature range and that SADT test would not show an exothermic peak. Therefore, the substance is not considered having self-reactive nor self-heating properties. Moreover, for the META SPC 3 (sludge) there are no chemical groups within the structure that would imply self-reactive properties according to the manual of recommendation on Transport of dangerous goods.	/	Acceptable Not self-reactive according to CLP regulation
Pyrophoric liquids	Waiver		Not relevant		
Pyrophoric solids	Waiver		In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. The active substance and hence the products are not pyrophoric	/	Acceptable
Self-heating substances and mixtures	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that $Ca(OH)_2$ is instable at high temperatures. $Ca(OH)_2$ is produced from CaO, itself produced from limestone (CaCO3) at 900 – 1300 °C. It can be concluded that $Ca(OH)_2$ is	/	Acceptable Not self-heating according to CLP regulation

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			stable at least at this temperature range and that SADT test would not show an exothermic peak. Therefore, the substance is not considered having self-reactive nor self-heating properties.		
	UN Test N.4	Calcium Dihydroxide Hydra Lime 23 Batch number BE1121.6.1	After 24h in an "Fan Assisted" oven at an isothermical temperature of 140°C, the sample does not self-heat more than 140°C. Basket Size (mm cube): 100 Test Temperature (°C): 140 Test System: 9 Test Item Weight (g): 501.2 Ignition Yes / No: No	[redacted]	
Substances and mixtures which in contact with water emit flammable gases	Waiver		In contact with water, the active substance and hence the products will not emit flammable gases. $Ca(OH)_2$ is made from oxide calcium and is already hydrated.	/	Acceptable
Oxidising solids	Waiver		Not oxidising According to the CLP regulation, " *Before submitting a substance or a mixture to the full test procedure, an evaluation of its chemical structure may be very useful as it may prevent unnecessary testing. The following text provides a guideline for the theoretical evaluation of potential oxidising properties on the basis of its composition and chemical structure."*	/	Acceptable according to CLP regulation

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			Moreover, "in cases where an examination of structural formula establishes beyond reasonable doubt that the active ingredient is incapable of reacting exothermically with combustible material, it is acceptable to provide such information as justification for the non-determining of oxidising properties. "There is no chemical evidence to assume oxidising properties for $Ca(OH)_2$ because in $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state and $Ca(OH)_2$ is an inert material.		
	Waiver based on composition	Calcium dihydroxide Ca(OH)2 (EULA hrydralime product) Batch BE1110.144.3	The substance is inorganic and does not contain halogens or oxygen bond directly to another oxygen. This waiver can be extrapolated to the BPF.	[redacted]	
Organic peroxides			Not applicable		
Corrosive to metals	OSHA Regulations CFR 1910.1200 Appendix B: B.16 (=UN Manual of Tests and Criteria, Section 37)	30% wt Hydrated Lime solution (Calcium dihydroxide powder suspended in water)	After 7days at 55°C, corrosion rate < 1 mm/year for carbon steel and aluminium for headspace, half-immersed and fully immersed samples. Tested product is not corrosive to metal For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk transportation of wet lime products.	[redacted]	The content of active ingredient in the tested product is 30% instead of a range of 20% to 50% for the META SPC 3 of CALCIUM DIHYDROXYDE BLENDS (test is not required for META SPC 1 and META SPC 2 as it is solid

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
					product). No information was specify about uniform or pitting corrosion. Nevertheless, as the tested product is diluted in water, pH>12 and the solubility in water is limited (1.26g/L at 20°C according to the CAR) and the supernatant at 30% will be the same at the 50% as the saturation concentration is reached. Therefore, the meta SPC 3 is not classified as H290.
Auto-ignition temperatures of products (liquids and gases)	Waiver		For META SPC 3 : In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability and auto-ignition can be excluded.	/	Acceptable
Relative self-ignition temperature for solids	Waiver		The melting point of $Ca(OH)_2$ is > 2500 °C. Therefore it can be excluded that $Ca(OH)_2$ is instable at high temperatures. $Ca(OH)_2$ is produced from CaO, itself produced from limestone (CaCO3) at 900 –	/	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			1300 °C. It can be concluded that $Ca(OH)_2$ is stable at least at this temperature range and that SADT test would not show an exothermic peak. Therefore, the substance is not considered having self-ignition properties. Moreover, the substance/product is not flammable.		
	EEC A16	Calcium dihydroxide Ca(OH)2 (Eula hydralime product) Batch BE1110.144.3	No self-ignition point below 400°C	[redacted]	
Dust explosion hazard	Waiver		In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state and is not explosive as the substance is not combustible or flammable. In addition, the absence of a dust explosion hazard is supported by the use of inert limestone dust to prevent dust explosions in coal mining.	AS dossier	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
For META SPC 1&2, based on the composition, these meta SPC are not classified for physical hazard properties. For meta SPC 3, based on the acceptable waiver and tests provided, the meta SPC 3 is not classified for physical hazard properties.

2.2.4 Methods for detection and identification

The products are the same as the active substance. Analytical methods employed for the active substance are applicable. Justifications for non-submission of data for the active substance are appropriate for products.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance (CaO, MgO)	Gravimetric, Volumetric, EDTA, Pyrophosphate, Insoluble matter	N/A	N/A	N/A	See Table below			N/A	ASTM C25-99 (1999)
Active substance (Na, Mg)	X-ray spectrometric analysis Ca as % CaO Mg as % MgO	5			53,347 53,683 54,304 55,599 55,837 0,176 0,216 0,637 0,919 1,406		0,28 % 0,30 % 0,23 % 0,20 % 0,26 % 8,52 % 2,78 % 1,10 % 1,09 % 3,49 %		ASTM C1271-99 (1999)

Active substance (calcium, magnesium, oxide and hydroxide.	ICP AA	Duplicate							ASTM CC 1301 – 95 (1995) (Reapproved 2001)
Active substance	Titration		N/A	Reproducibility: 12.64%			*2.30*		EN12945
Active substance	AA (Mg)			Reproducibility: 0.25%			*0.21*		DIN EN 12946 DIN EN 12947 DIN EN 12048 DIN EN 14397-2

Analytical methods for monitoring
Relevant residues of Lime variants may be calcium, magnesium and hydroxide-ions. The determination of calcium and magnesium may be done e.g. with a complexometric method with EDTA or an Atomic Absorption method as described for the analysis of the active. Hydroxide-ions can be determined by acid-base titration or the measurement of pH-values.

Analytical methods for soil
Relevant residues of Lime variants may be calcium, magnesium and hydroxide-ions. The determination of calcium and magnesium may be done e.g. with a complexometric method with EDTA or an Atomic Absorption method as described for the analysis of the active. Hydroxide-ions can be determined by acid-base titration or the measurement of pH-values. The main influences of Lime variants on soil are the change of the pH-value and the change of Ca^{2+} and Mg^{2+} contents. The applicant has provided details of the following standards to measure these changes; NF ISO 10390: "French standard: Soil quality – determination of pH". Doc. No. 492-020.

NF X 31-108: "Soil quality – Determination of ammonium acetate extractable Ca++, Mg++, K+ and Na+ cations – Agitaion method"".

However, given that these ions will occur naturally in soil and hydrated lime is commonly used for agricultural liming it would not be possible to determine the source of these ions as being from biocidal use. In addition, the biocidal use of hydrated lime allows for application of the treated sewage or manure to agricultural land (as a replacement for agricultural liming). Given this, the normal requirement for more detailed analysis of the active/residues in soil would seem unnecessary.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	Ion chromatography	0.01 mg to 5 mg		No differentiation between the hydroxides and salts detectable by this method.					ISO 17091:2013

Analytical methods for water
Specific methods for analysis of the active/residues in water have not been provided as the applicant states methods for the analysis of the active can be used as these require initial dissolution in water. However, given the nature of the active/residues these or any other methods would not be able to determine whether the source was natural or from biocidal use.

Analytical methods for animal and human body fluids and tisues
The determination of analytical methods for human body fluids and tissues is not justified as hydrated lime products are not classified as toxic or highly toxic. Nevertheless, it should be referred to medical standard procedures for the determination of calcium and magnesium in blood.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Any analysis for the active/residues in food/feedstuffs would not be able to establish the origin of the ions as being naturally occurring, from liming or following use as a biocide. Established standard methods for the determination of Hydrated lime components (Mg^{2+} and Ca^{2+}) in animal feeding stuffs are described in the following standards; DIN EN (Deutsche Norm; Entwurf) 15505 "Foodstuffs – Determination of trace elements – Determination of sodium, magnesium and calcium by flame atomic absorption spectrometry (AAS) after microwave digestion; German version prEN 15505:2006", DIN EN (Deutsche Norm; Entwurf) 15510 "Animal feeding stuffs – Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES; German version prEN 15510:2006", Given the uses of hydrated lime on agricultural land & the nature of the active/residues the requirement for more detailed analysis of the active/residues in food or feedstuffs would seem unnecessary.

Conclusion on the methods for detection and identification of the product
The analytical methods for the active substance are applicable to the products. The ISO method for detection of the substance in air is applicable to monitor workplace exposures.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals
PT3: Veterinary hygiene

The biocidal product family CALCIUM DIHYDROXIDE BLENDS includes several products, and related uses, which were separated in 3 Meta SPCs:
- Meta SPC 1 includes dustable powders at 60 to 70 % w/w calcium dihydroxide.
- Meta SPC 2 includes dustable powders at 20 to 30 % w/w calcium dihydroxide.
- Meta SPC 3 includes suspensions at 20 to 50 % w/w calcium dihydroxide.

The products of the family are intended for:
- Use #1.1 and use #3.1: Disinfection of sewage sludge (PT 2) – Meta SPC 1 and Meta SPC 3.
- Use #1.2 and use #3.2: Disinfection of manure (PT3) – Meta SPC 1 and Meta SPC 3
- Use #2.3 – Disinfection of indoor floor surfaces of animal accommodations and transportation (PT3) – Meta SPC 2.
- Use # 3.5 - Disinfection of animal accommodations; limewashing of walls (PT 3) – Meta SPC 3
- Use # 2.4 - Disinfection of animal bedding materials (PT3) – Meta SPC 2
- Use # 2.6: Disinfection of floors of outdoor animal enclosures (PT 3) – Meta SPC 2

It is not intended to be used for direct contact with food or feeding stuffs.
It is intended to be applied directly on surfaces beforehand wet for powders or directly on surfaces for suspensions.
In the case of bedding materials, manure and sewage sludge, this will likely be directly into the substrate.
The product is for professional users only.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Disinfectant product intended to control bacteria, yeast, fungi, viruses and endoparasites: helminth eggs.
The product is used for the purpose of the protection of human and animal health.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is able to produce a reduction of relevant test organisms in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), of moulds spores (fungicidal activity), of infectious virus particles (virucidal activity), and a developmental inhibition of nematode eggs under defined conditions.

2.2.5.4 Mode of action, including time delay

Several effects of Calcium dihydroxide are known:

1) Increased alkalinity - Addition of sufficient quantities of Lime to organic waste brings about a rapid and sustained increase in pH, to a level > 12. The high concentration of free OH^- ions results in the denaturation of protein structures of microorganisms such as cell walls, capsid structures, enzymes and organelles.

2) Increase in free / non-ionised ammonia (NH_3) - Proteolytic activity in biodegrading organic matter results in high concentrations of nitrogenous compounds. The high pH associated with lime activity is sufficient to convert any ammonium ions (NH^{4+}) into free / non-ionised ammonia gas (NH_3). Ammonia gas diffuses into bacterial cells, altering chemical equilibrium between intra-and extra-cellular environments, and impeding essential enzymatic function to bring about cell death. Free non-ionised ammonia has also been shown to be destructive to viruses. However, only in closed systems, in which loss of gaseous ammonia is prevented, can concentrations relevant for a synergistic effect with high pH be reached.

The time delay depends on the type of pathogen to be inactivated. It varies from a few minutes for pH sensitive viruses, to several hours for the most resistant bacteria and up to several weeks for the most pH resistant parasites.

2.2.5.5 Efficacy data

Efficacy tests have been performed with Calcium oxide and/or Calcium dihydroxide based-products.

Both active substance and products may be referred to as "Lime". Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime ($Ca(OH)_2$). The raw material for all lime-based products is limestone, which is composed almost exclusively of calcium carbonate ($CaCO_3$).

- Calcium oxide (CaO) is also known as burnt lime or quicklime, obtained from the calcination (removal of CO2) above 900°C of limestone.
- Calcium dihydroxide ($Ca(OH)_2$) is also known as hydrated lime or slaked lime, obtained from the hydration (addition of water) of quick lime.

Calcium oxide produces calcium dihydroxide in contact with water.

The results are summarised in the section 6.7 of the Iuclid file and the main points are summarised below.

- **Uses # 1.1 and 3.1 – Disinfection of sewage sludge (PT2)**

In terms of microbiological pollution, sludge frequently contains various pathogenic agents introduced by wastewater such as bacteria, viruses and parasites.
Simulated-use tests has been performed in order to demonstrate efficacy of lime to disinfect sewage sludge.

First, sewage substrate was combined, with a range of inocula (Salmonella, Streptococci, *E.coli*, *Clostridium perfringens*, Bovine parvovirus, ECBO and *Ascaris suum*) and the biocidal product (study 6.7-11). The product test tested is Burnt lime but as low temperatures are also involved in this study, efficacy results can be used for Hydrated lime.
Temperature and pH were measured over time, the amount of lime required was calculated as a percentage of the dry content of the sewage sludge.

=>A range of application rates from 0.7 kg/kg sludge to 1.2 kg of CaO/kg dry sludge, with a range of contact times (1hr-24hrs, until 4-8 weeks for worm eggs) were shown to be effective at controlling all target organisms. Greater than 5 log reduction in bacteria, greater than 4 log reduction in viruses and a 3 log reduction for Ascaris eggs were observed, depending on the temperature and pH.
=>pH above 12 is needed and contact time needed to obtain a sufficient efficacy decreased with a rise in temperature.

In a second study (6.7.12), inactivation kinetics of Ascaris eggs were established in different situations (contaminated sludge with milk of lime and heat, naturally contaminated sludge treated with slaked lime and heat, naturally contaminated sludge treated with quick lime, and sludge treated at full scale with quick lime). Indeed, Ascaris eggs are the most resistant to liming, and hence, may serve as indicators of hygienic quality of biosolids.
=> Depending on the experimental situation, the inactivation threshold period was found to fluctuate between 5 and 75 min at 55°C, and between 1 and 8 min at 60°C, pH should be maintained at 12 or more.

In the third study (6.7.13), the disinfectant effect of hydrated lime added to raw sewage sludge was investigated with special consideration of the influence on the following digestion process. In preliminary investigations in laboratory scale, the necessary pH-value and contact time of the sludge/lime mixture for a safe inactivation of salmonellas as test microorganisms were determined. In a further laboratory experiment, the effect of the high alkalinity of the limed raw sludge on the following digestion process was investigated for a mean hydraulic retention time of 20 days. No adverse effects could be recorded.
The level of contamination in the digester where no treatment was applied was the same than the raw sludge used to feed it during the 20 days.

In comparison, the second digester fed for the raw sludge and milk of lime at 10%, at D21, 3 log reduction. *Salmonella senftenberg* as test microorganism was inactivated by a pH of 12.8 within 3 hours (4 log reduction) in the preliminary laboratory experiments and in the large-scale experiment in the sewage treatment plant as well. No adverse effects on the digestion process nor the gas quality were observed.

Based on these efficacy data, the efficacy of calcium dihydroxide is demonstrated for the disinfection of sewage sludge, against bacteria and endoparasites: helminth eggs. Effective treatment is due to raised pH (>12), that should be maintained during the contact time needed (until several weeks). It should be noticed that as no effect of temperature is expected for calcium hydroxide, contact time is longer than the one with calcium oxide.
No data has been provided for yeast and fungi.

Conclusion: Efficacy of calcium hydroxide is demonstrate against bacteria and endoparasites: helminth eggs.

Regarding virus, for the disinfection of sewage sludge, the efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study.
This target organism is therefore not proposed for authorisation for this use.

- **<u>Uses # 1.2 and 3.2– Disinfection of manure (PT3)</u>**

According to the intended use, based-lime products are dosed directly into the manure or litter and mixed by means of a blender. The type of manures to be disinfected is defined by

the content of water (qualified as liquid or solid manure). The quantity of lime depends on the quantity of dry matter.

To demonstrate the efficacy, a first simulated-use study (6.7-13) has been performed to assess the effect of calcium oxide in solid manure and calcium hydroxide in liquid manure, against bacteria (Salmonella and Enterococci), virus (parvovirus bovine) and eggs of *Ascaris suum*.
Solid manure (pig and poultry) was treated with calcium oxide (pH= 12.01) and liquid manure (pig and cattle) was treated with calcium dihydroxide (pH=12.59). For calcium oxide, temperature measured is 60° and 70°C, and for calcium hydroxide, the liquid manure is heated at 60°C for the *Ascaris suum* testing.

For calcium hydroxide, in liquid pig and cattle manure:
- For bacteria, more than 7 log reduction are observed for a contact time of 72H;
- For virus, more than 5 log reduction are observed for a contact time of 72H;
- For *Ascaris suum* eggs, 100 % inhibition of development are obtained for a contact time of 60 minutes, at the temperature of 60 °C.

A second simulated-use test (6.7-15) has been carried out only on liquid manure (pig and cattle manure), treated with calcium dihydroxide against *Ascaris suum* eggs (pH obtained is higher than 12, no heating applied). For endoparasites: helminth eggs (*Ascaris suum)*, respectively 100 % inhibition of development are obtained for pig manure and 98% for cattle manure, with a contact time of 90 days (pH measured is higher than 12, liquid manure not heated)

Based on these studies, it can be concluded, that:
- Calcium dihydroxide, at a pH> 12, is efficient against bacteria and virus, for a contact time of 72 hours and against endoparasites: helminth eggs (*Ascaris suum)* after 90 days in liquid pig and cattle manures.

Since liquid manure differs only from solid manure with the content of water, similar efficacy of calcium hydroxide is expected in solid manure.
Based on these efficacy data, the efficacy of calcium dihydroxide is demonstrated for the disinfection of manure, against bacteria, virus, and helminth eggs. Effective treatment is due to the raised pH (>12), that should be maintained during the contact time needed with regard to the situation.
It should be noticed that as no effect of temperature is expected for Calcium dihydroxide, contact time is longer than the one with calcium oxide.
No data has been provided for yeast and fungi.

From the efficacy study, the quantity of lime to be applied should be enough to reach a pH>12 in all the cases. Two recommendations are presented by the applicant, one for routine application (10 kg lime/m3 of manure) and one in case of outbreak (100 kg lime/m3 of manure). Since application rate should be adapted to the type of manure in order to achieve a pH>12, the SPC should only specify that 100 kg lime/m3 of manure should not be exceeded whatever the circumstances of manure treatment.

- **Use # 2.4 – Disinfection of bedding materials (PT3)**

For the disinfection of bedding materials (PT3), against bacteria, yeast, fungi and virus, no specific study has been submitted by the applicant for this use. A read across with manure treatment studies, considered as a worst case, has been considered. However, in relation to

the distribution properties, the content of organic material, the availability of water for the reaction of lime in the matrix that could differ from manure, read-across is not acceptable. The efficacy is therefore not supported by the data presented in the dossier.

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Disinfectant for sewage sludge	PT2 – Uses # 1.1 and 3.1	Burnt Lime specified according to the "Building Lime Standard" EN 459-1 as "CL 90". Calcium Oxide content was 93.7%. The reactivity was defined as T60 =2.5 minutes and Tmax =73C. Mean density was 0.95kg/L.	Bacteria (2,3.10^3 – 23.10^6 CFU/g) *Salmonella senftenberg, Streptococci, Clostridium perfringens, E.coli* Virus (2,3.10^5-6,16.10^6 TID50 / ml) *Bovine parvovirus, ECBO* Nematodes *Ascaris suum eggs* Culture collection, except Ascaris eggs source unknown	Simulated study Direct mixing of sewage sludge with the biocidal product The test was applied on two different scales: one to simulate small scale use (mixers of 130 L and 145 L) and the second to simulate industrial scale treatment (cavity mixer-unknown volume). For the small scale tests, burnt lime was homogeneously mixed into the substrates. The mixture was sampled at intervals to determine the numbers of viable bacteria, viruses or Ascaris eggs. For the industrial scale test, the mix was pumped and piled for storage. Samples were taken from the stored material at intervals, to determine the numbers of viable bacteria, viruses or Ascaris eggs.	0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solids Contact time: 1-24 hours, until 8 weeks for *Ascaris suum* temperatures and pH values were recorded over the time	0.7 – 1.2 kg burnt lime / kg dried sludge Small scale test : pH>12.9 <table><tr><th>Substrate</th><th colspan="2">Virus</th><th colspan="2">Bacteria</th><th colspan="2">Worm eggs</th></tr><tr><td>Sewage sludge (22% dry matter)</td><td colspan="2">not tested</td><td>pH > 12.9 T_{max}: 26°C</td><td>24 hours</td><td>pH > 12.9 T_{max}: 17°C</td><td>4-8 weeks</td></tr><tr><td></td><td>AR: 0.9 T_{max}: 57°C</td><td>> 10 hours</td><td>pH > 12.9 T_{max}: 57°C</td><td>0.5 hours</td><td>pH > 12.9 T_{max}: 57°C</td><td>5-10 hours</td></tr><tr><td></td><td>AR: 1.1 T_{max}: 71°C</td><td>2 hours</td><td>pH > 12.9 T_{max}: 71°C</td><td>0.5 hours</td><td>pH > 12.9 T_{max}: 71°C</td><td>2-5 hours</td></tr><tr><td colspan="7"></td></tr><tr><td>Paunch contents (16% or 28% dry matter)</td><td>AR: 1.25 T_{max}: 35°C</td><td>>24 hours</td><td>AR: 0.2 T_{max}: 22°C</td><td>24 hours</td><td>AR: 1.25 T_{max}: 35°C</td><td>< 4 weeks</td></tr><tr><td></td><td>AR: 1.56 T_{max}: 55°C</td><td>> 24 hours</td><td>AR: 0.3 T_{max}: 22°C</td><td>1 hour</td><td>AR: 1.56 T_{max}: 55°C</td><td>5-10 hours</td></tr><tr><td></td><td>AR: 0.7 T_{max}: 64°C</td><td>> 10 hours</td><td>AR: 0.6 T_{max}: 22°C</td><td>1 hour</td><td>AR: 0.7 T_{max}: 64°C</td><td>3-5 hours</td></tr><tr><td></td><td>AR: 0.9 T_{max}: 74°C</td><td>5 hours</td><td>AR 1.25 T_{max}: 35°C</td><td>< 1 hour</td><td>AR: 0.9 T_{max}: 74°C</td><td>0.5-2 hours</td></tr></table> Industrial scale test: <table><tr><th>Application rate (kg Lime / kg dry matter in substrate)</th><th>Temperature (°C)</th><th>Ascaris eggs</th><th>BPV</th><th>Salmonella senftenberg</th><th>Streptococci</th></tr><tr><td>0.9</td><td>50-55</td><td>0.5 hours</td><td>24 hours</td><td>0.25 hours</td><td>0.5 hours</td></tr><tr><td>1.0-1.1</td><td>65-75</td><td>0.25 hours</td><td>0.5-2 hours</td><td>0.25 hours</td><td>0.25 hours</td></tr></table> Efficacy criteria achieved: 5 log reduction bacteria 4 log reduction viruses 3 log reduction nematode eggs	[redacted] 6.7-11 R.I=2
Disinfectant for sewage sludge	PT2 – Uses #1.1 and 3.1	Milk of lime ($Ca(OH)_2$ suspension in water Dry hydrated lime ($Ca(OH)_2$ Burnt lime (CaO)	Nematodes *Ascaris suum* eggs (Sludge from pig slaughter houses) Sludge A: 924 ± 295 eggs per 10 g solid Total solids: 33% Sludge B 132 ± 108 eggs per 10 g solid Total solids: 15%	Simulated-use tests: 1), Artificially contaminated milk of lime was heated to 50°C, 55°C and 60°C. 2) Naturally contaminated sewage sludges were treated with slaked lime (40% weight slaked lime per weight of sludge dry solids) and afterwards heated to either 50°C or 60°C. 3) Naturally contaminated sewage sludge was treated with quick lime at a predetermined dose in	Contact time : 5-160 minutes pH ≥12	Inactivation threshold: duration required to reach a level of inactivation at which no viable egg was detected per g of solid sludge (TS) Inactivation threshold is: - in milk of lime and heat, is equal to 70, 5 and 2 min, respectively at 50°C, 55°C and 60°C - with quick lime, is equal to 120 min at 50°C, to 45 min at 55°C, and 5 min at around 60°C - with slaked lime and heat, is higher than 128 min at 50°C, and ranges between 4 and 8 min at 60°C - is equal to 75 min at 55°C and 5 min at 60°C in the industrial situation (quicklime) => This study has demonstrated that in the four investigated situations, either 75 min at 55°C or 8	Capizzi-Banas (2004) Literature Publication in Water Research 28, 3251-3258, Doc No 392-024 6.7-12 RI=2

				order to reach 50°C, 55°C and 60°C. 4) Sewage sludge was treated at full scale with a predetermined dose of quick lime in order to reach temperatures ranging from 50°C to 60°C and stockpiled. When the stockpile target temperature was reached, bags containing Ascaris eggs were inserted in it.		min at 60°C will lead to a negligible level of viable Ascaris eggs	
Disinfectant for sewage sludge	PT2 – uses # 1.1 and 3.1	Calcium dihydroxide (10% Ca(OH)2 in water: milk of lime)	Bacteria *Salmonella senftenberg (*10^8 CFU/mL) Coliforms (10^6 CFU/mL)	Simulated tests Direct mixing of sewage sludge with the biocidal product	Two laboratory scale pilot-plant tests were used for the trial proper (Digester 1 and Digester 2), that were fed with dry sludge (the sludge had a mean hydraulic retention time of 20 days). Step 1: The sludge was fed through the digesters for 20 days. Step 2: Days 21-39 Digester 1 was fed with 10% milk of lime to pH=12.8 and given 3 hours agitation. Step 3: From day 30 to day 50, raw sludge was inoculated with Salmonella and only Digester 1 was treated with lime. Raw sludge from both digesters inoculated with Salmonella. Digester 1 is treated with decreasing amounts of Lime (pH is reduced from 12.9 from 11.6), Digester 2 is also treated with Lime.	Step 1: The total bacterial and coliform counts of raw sludge and digested sludge are in the same order. No impact of the digestion on the level of contamination. Step 2: in Digester 1, after 3 hours contact time, 3 to 4 log reduction is obtained for bacteria (no coliforms isolated). Step 3: Salmonellas and coliforms were never isolated and total germ count were reduced by 6 logs Step 4: in Digester 1, Salmonella and coliforms are detected, while in Digested 2 (treated for the first time), total germs decreased of 3 log.	Pfuderer (1985) Literature Publication Doc No 392-035 6.7-13 RI=2
Disinfectant for manure and litter,	PT 3 – Uses #1.2, #2.4 and #3.2	Calcium dihydroxide (liquid manure)	Bacteria (lab collection)	Simulated test Direct mixing of manure with the biocidal product	Liquid manure: Bacteria and viruses: 72H and 96 hours contact	Liquid pig and cattle manure (Ca(OH)2) at 72H and 96H contact time:	A. Daugshies (2008)

bedding materials		Calcium oxide (solid manure) (EuLA specifications)	*Salmonella senftenberg* *Enteroococcus faecium* For each bacteria: 5.10^8 CFU/ml, <u>Virus</u> *Bovine Parvovirus* The virus host cells were MDCK cells <u>Nematodes</u> *Ascaris suum* eggs (recovered from adult female worms) 2 ml egg suspension in gaze-bags (200000 eggs)	Suspension of bacteria was added to liquid manure (100 ml) and filled into the steel pipe, or added to 500 g lime-treated solid manure Virus: Sandwich-germ-carrier technique was used (viral suspension was given on an electropositive charged membrane, and exposed to liquid or solid waste) Nematodes: Stockpiled lime treated manure and contaminated with gaze-bags of eggs At the end of the trial the treated aliquots were compared to untreated (unlimed) controls and log reduction calculated.	time (except for A. suum eggs – 60 min with heated manure at 60°C) Solid manure 60 and 120 min contact time Temperature : 60 and 70°C pH >12	Virus: > 5 log reduction Bacteria: > 7 log reduction *Ascaris suum* eggs: 100% development inhibition at 60 min exposure time (manure heated à 60°C) Solid pig manure and poultry manure (CaO), at 60° C (CT of 60 and 120 min) and at 70°C (CT of 30 and 60 min) : Virus: > 5 log reduction Bacteria: > 7 log reduction *Ascaris suum* eggs: 100% development inhibition	6.7-14 RI=2
Disinfectant for manure and litter, bedding materials	PT 3 – Uses #1.2, #2.4 and #3.2	Calcium dihydroxide (EuLA specification)	Nematodes *Ascaris suum* eggs (recovered from adult female worms) 2 ml egg suspension in gaze-bags (200000 eggs)	Simulated test Direct mixing of manure with the biocidal product Stockpiled lime treated manure and contaminated with gaze-bags of eggs At the end of the trial the treated aliquots were compared to untreated (unlimed) controls and log reduction calculated	Liquid manure: Contact time: 30/60/90 days	Contact time: 90 days liquid pig manure: 100 % development inhibition liquid cattle manure: 98 % development inhibition	6.7-15 RI = 2

- **Uses # 2.3/ 2.6 / 3.5 surface disinfection (PT3)**

For PT3 uses (disinfection of indoor floor surfaces of animal accommodations and transportation, animal accommodations (limewashing of walls), and of floors of outdoor animal enclosures), both phase 2 steps 1 and 2 tests should be normally submitted according to Vol II part B/C efficacy guidance.
Nevertheless, for efficacy testing of veterinary hard surfaces, the tiered approach was not suitable for lime and should be adapted in order to demonstrate the efficacy of the products used in the form of a powder or a thick milk applied to a surface.

Therefore the following approach was agreed to demonstrate the efficacy of lime:

- Laboratory suspension tests (phase 2, step 1 tests) have been withdrawn, as not relevant for an insoluble active substance applied as a dried powder or as a thick slurry.

- Laboratory surface tests (phase 2, step 2 tests) according to EN 14349 have been provided with some deviations from the standard methodology (test coupons are larger, test procedure adapted). Efficacy criteria and experimental conditions (temperature, contact time, interfering substances and test organisms) met the requirements of the norms. No laboratory efficacy trial on porous surfaces was provided.
    - Bactericidal activity is demonstrated on non-porous surfaces, according to EN 14349, at 10°C, with a contact time of 60 min, in clean (3 g/L BSA), with Calcium dihydroxide-based product (Optilit C+, 20 % w/w Calcium hydroxide at the application rate of 600 g $Ca(OH)_2$/m² (3000 g Optilit C+/m²).
    - Bactericidal activity is demonstrated on non-porous surfaces, according to EN 14349, at 10°C, with a contact time of 60 min, in clean (3 g/L BSA), with Calcium dihydroxide-based product (Biocalco M, 20 % w/w Calcium hydroxide at the application rate of 600 g $Ca(OH)_2$/m² (3000 g Biocalco M /m²).
    - Bactericidal activity is demonstrated on non-porous surfaces, according to EN 14349, at 10°C, with a contact time of 30 min, in clean (3 g/L BSA) and dirty conditions (10 g/L BSA and 10 g/L yeast extract), with Calcium dihydroxide-based product at the application rate of 800 g $Ca(OH)_2$/m²
    - Bactericidal activity is not demonstrated on porous surfaces, according to EN 16437, at 10 °C, with a contact time of 60 min, in clean conditions (3 g/L BSA), with Calcium dihydroxide-based product at the application rate of 800 g $Ca(OH)_2$/m².

Under EN standard conditions, the product shows only limited performance at the application ratios tested, due to the small surface area treated and the large amount of product and water to be applied. It has been agreed that the EN tests protocols are not valid for this type of product due to the application method, the insolubility of the product and the mode of action.
In order to confim the efficacy of lime products for all the activities claimed, the applicant performed both simulated-use tests and field tests:

- Simulated-use tests on a larger scale have been carried out, following a methodology inspired from the French norm NF T 72 281 (for the test procedure and validation parameters) to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice (mosaic tile as stone carriers is then used). Efficacy criteria and experimental conditions (temperature, contact

time, interfering substances and test organisms) met the requirements of the surface norms for vet areas.

- ⇨ Bactericidal activity (4 Log reduction according to EN 14349) and yeasticidal activity (3 Log reduction according to EN 16438) are demonstrated, at 15-22°C, with a contact time of 48 hours, in dirty conditions (10 g/L BSA and 10 g/L yeast extract), at the application rate of 1 Kg Optilit20/m².
  In these conditions, fungicidal activity is not proven (< 3 log reduction).
- ⇨ Bactericidal activity (4 log reduction according to EN 14349 except for *P. hauserii* where 3.75 log reduction due to the sensitivity of the strain to desiccation) and yeasticidal activity (3 Log reduction according to EN 16438) are demonstrated, at 15-22 °C, with a contact time of 24 hours, in dirty conditions (10 g/L BSA and 10 g/L yeast extract), at the application rate of 0.66 L Biocalco M20/m² (META SPC 3).
  In these conditions, fungicidal activity is not proven.

To complete results from laboratory and simulated-use tests, three field studies have been performed.

Two tests have been performed in poultry farms during 2 years (in France), in 2018 (summer season) and 2019 (in March), in order to study the biocidal efficacy of lime for ground disinfection during crawl space.
The quicklime used was provided at the dose of 800 g CaO / m² of floor (2018) and 600 gCaO /m² (2019).
Both studies were conducted into two phases:

The first phase consisted in identifying and quantifying the pathogens present in the breeding with the current practices of vacuum-sanitary, in order to evaluate existing pathogenic pressure.
The second phase consisted in evaluating the effectiveness of CaO under real conditions of disinfectant treatment. The building is cleaned beforehand with a water pressure washer. The product is then applied directly to wet soil in the area.

Microorganisms monitored during these studies are: aerobic microorganisms at 30°C, *Escherichia coli* B glucuronidase positive at 44 °C, spores of *Clostridium perfringens*, intestinal enterococci, enterobacteria presumed at 30 °C, *Pseudomonas spp*., yeasts and moulds, Aspergillus, Salmonella and *Staphylococci*.
=> Salmonella and staphylococci are not detected on the floor, either before or after the technical operations (washing, biocidal treatment or not) of the crawl space. Indeed, many precautions are implemented in poultry farms to avoid the presence of salmonella on these sites.

=> In 2018 study, between the initial and the final state, the whole zone is cleaned with a water pressure washer. This practice allows a significant reduction in the levels of pathogens. This concerns in particular enterobacteria, *Escherichia coli*, *Pseudomonas spp*. and intestinal enterococci (4 Log reduction). The other microorganisms are very little impacted by the cleaning with water, which does not allow to control the recontamination. The quicklime intake increases strongly the abatement of aerobic microorganisms, yeasts and moulds, and optimizes the reduction of Enterobacteria, *Pseudomonas sp*., *Aspergillus sp.* and intestinal Enterococci.

=> In 2019 study, the initial microbial load was lower than in 2018. The results obtained with quicklime treatment at 600 g/m² show significantly higher reductions than those measured on the control. Indeed, no reduction exceeding 2 Log is observed for the control while for the majority of pathogens followed in the quicklime modality, the measured

contents are below the detection limit of the laboratory. The levels of inoculum after treatment for aerobic microorganisms, yeasts and moulds are similar to those of 2018.

A third trial has been carried out in order to study the efficacy of lime products in pig farm (France) in real conditions of crawlspace. The treatment was carried out in the feeder building, specifically in the pig room at the end of the fattening. The quicklime used in these tests was provided in the form (100% CaO) at the dose of 600 g and 800 g CaO / m² of floor. The floor is moistened with a water pressure washer before treatment. For the sake of similarity between "control" and "treated" housing, the "witness" housing were also sprayed with a water pressure washer.
Microorganisms monitored during these studies are: aerobic microorganisms at 30°C, *Escherichia coli* B glucuronidase positive at 44 °C, spores of *Clostridium perfringens*, intestinal enterococci, enterobacteria presumed at 30 ° C, *Pseudomonas sp*., yeasts and moulds, and *Aspergillus sp*.
=>As a result, a slight mortality of microorganisms in untreated area due to the cleaning the water pressure washer was noticed. In the treated surfaces, a reduction of the order or more than 2/3 logs is obtained for aerobic microorganisms, *Pseudomonas sp*., yeast and moulds. Abatement is less for other microorganisms since populations in untreated areas are present in small quantities (*E. coli*, *Clostridium perfringens*, intestinal enterococci). The applied dose of 600 g/m² gives similar results to 800 g/m².

Since in the field trials, calcium oxide in contact with the wetted floors turned into calcium dihydroxide and considering that during the test only a slight increase of temperature was observed (from 1.1 to 3°C), the efficacy results obtained with calcium oxide can be extrapolated to calcium hydroxide, as only a pH effect was noticed (the temperature effect is negligible).

These field studies have been conducted on concrete floors. Treatment of beaten-earth floors have been also claimed and the applicant points out that both types of surface are in effect largely semi-porous structures and arguable very similar. This one is shown in a thesis of the Sheffield Hallam University[2] which identified rammed earth as having the same porosity and a moisture ingress typical equal or lower than concrete.
Then lime efficacy demonstrated on concrete floors can be extrapolated to beaten-earth floors.

[2] http://shura.shu.ac.uk/id/eprint/19744

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Optilit C+ Calcium hydroxide 20 % w/w Meta SPC 2	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349:2013	3000g product/m^2 product 60 minutes 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >4 Log reduction	Eise, 2018 DLG Test Service Test No 201800315 6.7-01 IC2
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Optilit C+ Calcium hydroxide 20 % w/w Meta SPC 2	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349:2013	4000g product/m^2 product 60 minutes, 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >4 Log reduction	Eise, 2018 DLG Test Service Test No 201800315 6.7-02 IC2
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Optilit C+ Calcium hydroxide 20 % w/w Meta SPC 2	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349:2013	5000g product/m^2 product 60 minutes, 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >4 Log reduction	Eise, 2018 DLG Test Service Test No 201800315 6.7-03 IC2
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Biocalco M Calcium hydroxide	*Pseudomonas aeruginosa* ATCC 15442,	EN 14349:2013	3000 g product/m^2 product 60 minutes, 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >4 Log reduction	Eise, 2018 DLG Test Service

		(Milk of Lime 20% w/w) Meta SPC 3	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569				Test No 201800315 6.7-05 IC2
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Biocalco M Calcium hydroxide (Milk of Lime 20% w/w) Meta SPC 3	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349:2013	4000g/m^2 product 60 minutes, 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >4 Log reduction	Eise, 2018 DLG Test Service Test No 201800315 6.7-06 IC 2
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Biocalco M Calcium hydroxide (Milk of Lime 20% w/w) Meta SPC 3	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349:2013	5000g/m^2 product 60 minutes, 3g/L BSA - clean conditions, 10 °C Non porous surface	PASS Bactericidal >45 Log reduction	Eise, 2018 DLG Test Service Test No 201800315 6.7-07 IC2
Surface disinfectant	PT3– Uses 3/4/5	Calcium dihydroxide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349 modified Test coupons: 3.14 cm² with 251 mg of powder applied to obtain an application rate: equivalent to 800 g/m^2 product mixed with 2000 ml/m^2 water	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 10°C TC : 30 min 800 g/m²	Fail >4 log reduction sur *P.aeruginosa*, *E.hirae* and *P.vulgaris* <4 log reduction sur *S.aureus*	Crane et al 2016 J000714-1 RI = 3
Surface disinfectant	PT3– Uses 3/4/5	Calcium dihydroxide	*Pseudomonas aeruginosa* ATCC 15442,	EN 16437 modified Test coupons: 2 cm² with 160 mg of powder applied to obtain	3 g/L BSA) T°C : 10°C TC : 60 min	FAIL *P.aeruginosa* and *P.vulgaris*	Crane et al 2016 J000714-2 RI = 3

			Staphylococcus aureus ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	an application rate: equivalent to 800 g/m^2 product mixed with 2000 ml/m^2 water	800 g/m²	=>4log reduction *S.aureus* and *E. hirae* <4log reduction	
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Biocalco M20 Calcium hydroxide 20 w/w Calcium carbonate 80 % v/v Meta SPC 3	*Pseudomonas aeruginosa* DSM 939, *Staphylococcus aureus* DSM 799 *Enterococcus hirae* CIP 58.35 *Proteus hauserii* DSM 30118 *Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404 Strains have been chosen in accordance with those used in the standard EN tests: EN16437, EN16438 Test suspensions prepared in accordance with NF T 72-281	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried. Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers Efficacy criteria: Bacteria 3 log reduction Yeasts/fungi: 3 log reduction	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 15-22°C Contact time: 24h Test material: 0.66 L / m² (in two steps of 0.33L product / m^2)	Biocalco M20 PASS Bactericidal (> 4 log reduction): For P. hauserii, only 3.75 log reduction was shown due to the sensitivity of the strain to desiccation. PASS yeasticidal (>3 log reduction) Fail Fungicidal 0.98 log reduction 24 hours contact time	Carre (2020_ IRM Study No. RE-1101/0220 6.7-08 IC 2
Disinfectant	PT3	Biocalco SL60 (Calcium hydroxide 60% w/w, 40 % w/w calcium carbonate) Meta SPC 1	*Escherichia coli* DSM 682 *Streptococcus uberis* DSM 20569 *Staphylococcus aureus* DSM 799 *Proteus hauserii* DSM 30118	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried.	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 15-22°C Contact time: 24h *S. aureus* Contact time: 2h Remaining organisms Test material: Biocalco SL 60: 1Kg/m^2	Biocalco SL60 PASS Bactericidal (> 4 log reduction) For P. hauserii, only 3.75 log reduction was shown due to the sensitivity	Carre (2020_ IRM Study No. RE-1104/0220 6.7-09 IC2

				The tiles are placed in the test room and 0.45 L/m^2 water added (no pressure); The test material was applied and another aliquot of water as above to give total water of 0.9L/m^2 Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers Efficacy criteria: Bacteria 4 log reduction		of the strain to desiccation.	
Disinfectant	PT3	Biocalco SL60 (Calcium hydroxide 60% w/w Calcium carbonate 40% w/w Meta SPC 1	*Pseudomonas aeruginosa* DSM 939, *Enterococcus hirae* CIP 58.35 *Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried. The tiles are placed in the test room and 0.45 L/m^2 water added (no pressure); The test material was applied and another aliquot of water as above to give total water of 0.9L/m^2 Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 15-22°C Contact time: 48h Bacteria and yeast Contact time: 72h A. brasiliensis Test material: Biocalco SL 60: 1Kg/m^2	Biocalco SL60 PASS Bactericidal (> 4 log reduction): On P. aeruginosa and E. hirae PASS yeasticidal (>3 log reduction) Fail Fungicidal 2.18 log reduction	Carre (2020_ IRM Study No. RE-1441/1119 6.7-09A IC2

				Efficacy criteria: Bacteria 4 log reduction Yeasts/fungi: 3 log reduction			
Disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Optilit 20 (Calcium di hydroxide 20%, calcium carbonate 80%) Meta SPC 2	*Pseudomonas aeruginosa* DSM 939, *Enterococcus hirae* CIP 58.35 *Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried. The tiles are placed in the test room and 0.45 L/m^2 water added (no pressure); The test material was applied and another aliquot of water as above to give total water of 0.9L/m^2 Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers Efficacy criteria: Bacteria 4 log reduction Yeasts/fungi: 3 log reduction	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 15-22°C Contact time: 48h *P. aeruginosa, E. hirae and C. albicans* Contact time 72h A. brasiliensis Test material: Optilit 20: 1Kg/m^2	Optilit 20 PASS Bactericidal (> 4 log reduction): On P. aeruginosa and E. hirae PASS yeasticidal (>3 log reduction) Fail Fungicidal 2.07 log reduction	Carre (2020_ IRM Study No. RE-1439/1119/A 6.7-10A IC 2
Surface disinfectant	PT3 - Uses # 2.3/ 2.6 / 3.5	Calcium oxide	Organisms monitored: Aerobic microorganisms at 30°C Escherichia coli B glucuronidase positive at 44 °C Clostridium Perfringens	Field Trial (poultry farm in France) The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in poultry farming (indoor floor disinfection).	Phase 1 control Standard treatment Phase 2: 800 g of CaO / m² of soil Contact time: 48 h Temp: ambient (max 31.4 deg C)	100% CaO at 800 g/m^2 (48h contact time): > Log 4 reduction for all organisms analysed Reduction greater than 4	RITTMO 18-445R RI = 2

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>intestinal enterococci
enterobacteria at 30°C
Pseudomonas spp
Aspergillus
Salmonella
Staphylococci
Coagulase
Yeasts
Moulds

Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods</td>
<td>Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.

Samples are taken on delimited areas of 1x1 m. Each modality is represented by 6 repetitions, ie 6 zones of 1x1 m
For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.
2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored</td>
<td>
<table>
<tr><th></th><th>INITIAL STATE /m²</th><th>FINAL STATE WITHOUT TREATEMENT /m²</th><th>ABATTEMENT WITHOU TREATEMENT Log10</th></tr>
<tr><td>Number of aerobic microorganisms 30 ° C</td><td>> 9,0E+09</td><td>8,5E+07</td><td>2,0</td></tr>
<tr><td>Number of presumed enterobacteria</td><td>1,9E+09</td><td>7,1E+04</td><td>4,4</td></tr>
<tr><td>Search Positive Coagulase Staphylococci</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
<tr><td>Enumeration of Escherichia coli</td><td>1,6E+08</td><td>4,5E+03</td><td>4,6</td></tr>
<tr><td>Spores de Clostridium perfringens</td><td>< 1,1E+04</td><td>< 4,5E+03</td><td>0,4</td></tr>
<tr><td>Enumeration of Pseudomonas spp.</td><td>> 4,5E+09</td><td>< 1,9E+05</td><td>4,4</td></tr>
<tr><td>Enumeration of Yeasts and Molds</td><td>5,7E+07</td><td>1,7E+05</td><td>2,5</td></tr>
<tr><td>Enumeration of intestinal enterococci</td><td>5,4E+08</td><td>8,6E+04</td><td>3,8</td></tr>
<tr><td>Enumeration of Aspergillus</td><td>< 3,0E+03</td><td>< 6,3E+04</td><td>-1,3</td></tr>
<tr><td>Search for Salmonella spp</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
</table>
<table>
<tr><th></th><th>INITIAL STATE /m²</th><th>FINAL STATE WITH TREATEMENT /m²</th><th>ABATTEMENT WITH TREATEMENT Log10</th></tr>
<tr><td>Number of aerobic microorganisms 30 ° C</td><td>> 9,0E+09</td><td>< 7,5E+03</td><td>6,1</td></tr>
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<tr><td>Search Positive Coagulase Staphylococci</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
<tr><td>Enumeration of Escherichia coli</td><td>1,6E+08</td><td>< 3,0E+03</td><td>4,7</td></tr>
<tr><td>Spores de Clostridium perfringens</td><td>< 1,1E+04</td><td>< 3,0E+03</td><td>0,6</td></tr>
<tr><td>Enumeration of Pseudomonas spp.</td><td>> 4,5E+09</td><td>< 3,0E+03</td><td>6,2</td></tr>
<tr><td>Enumeration of Yeasts and Molds</td><td>5,7E+07</td><td>< 3,0E+03</td><td>4,3</td></tr>
<tr><td>Enumeration of intestinal enterococci</td><td>5,4E+08</td><td>< 3,0E+03</td><td>5,3</td></tr>
<tr><td>Enumeration of Aspergillus</td><td>< 3,0E+03</td><td>< 3,0E+03</td><td>0,0</td></tr>
<tr><td>Search for Salmonella spp</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
</table>
</td>
<td>Log for microorganisms monitored with high initial concentrations (greater than 4 Log10).</td>
<td></td>
</tr>
<tr>
<td>Surface disinfectant</td>
<td>PT3 - Uses # 2.3/ 2.6 / 3.5</td>
<td>Calcium oxide</td>
<td>Organisms monitored:

Escherichia coli B glucuronidase at 44 °C
Clostridium Perfringens
intestinal enterococci
enterobacteria at 30°C
Pseudomonas spp
Aspergillus
Salmonella
Staphylococci
Coagulase
Yeasts
Moulds

Analysis performed by Laon Analysis and Research Laboratory</td>
<td>Field Trial (Poultry farm in France)

The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in poultry farming (indoor floor disinfection)

Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.</td>
<td>600 g of CaO / m² of soil
Contact time: 48 h
Temp: ambient (Feb 2019: max 7.6 deg C). The increase of the soil temperature is + 3.1 ° between the start of the test and the end of the quicklime intake

pH = 11 after 48H exposure and after hydration.

The soil temperature is increased by 3.1 °C between the start of the test and the end of the quicklime intake.

traces of ammonium (NH3) were measured in the breeding room (between 2 and 6ppm) during product treatment</td>
<td>100% CaO at 600 g/m² (48h contact time):

Pathogen concentration has declined sharply to reach values close to the detection limit for these pathogens (< 10 cfu/m²).

Populations of aerobic microorganisms, intestinal enterococci</td>
<td>RITTMO 19415R
RI = 2</td>
</tr>
</table>

<table>
<tr>
<td></td><td></td><td></td>
<td>(LDAR) using validated standard methods</td>
<td>Samples are taken on delimited areas of 1x1 m. Each modality is represented by 6 repetitions, i.e. 6 zones of 1x1 m
For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.
2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored</td>
<td>
<table>
<tr><th>Elevage Avicole mars 2019</th><th>Initial state
/m²</th><th>FINAL state without treatment
/m²</th><th>Reduction without treatment
Log10</th><th>Reduction without treatment
%</th></tr>
<tr><td>Dénombr. microorganismes aérobies 30°C</td><td>1,9E+08</td><td>4,5E+07</td><td>0,6</td><td>75,8</td></tr>
<tr><td>Dénombr. des entérobactéries présumées</td><td>1,0E+04</td><td>2,2E+03</td><td>0,7</td><td>78,5</td></tr>
<tr><td>Dénombrement d'Escherichia coli</td><td>2,7E+03</td><td>1,3E+02</td><td>1,3</td><td>95,2</td></tr>
<tr><td>Dénombrement de Pseudomonas spp</td><td>5,5E+04</td><td>3,7E+04</td><td>0,2</td><td>31,9</td></tr>
<tr><td>Spores de Clostridium perfringens</td><td>9,8E+02</td><td>4,7E+01</td><td>1,3</td><td>95,2</td></tr>
<tr><td>Dénombrement de levures et moisissures</td><td>3,2E+05</td><td>3,8E+04</td><td>0,9</td><td>87,8</td></tr>
<tr><td>Dénombrement d'Aspergillus</td><td>6,8E+04</td><td>1,0E+03</td><td>1,8</td><td>98,5</td></tr>
<tr><td>Dénombrement d'entérocoques intestinaux</td><td>1,8E+04</td><td>3,0E+04</td><td>-0,2</td><td>-68,7</td></tr>
<tr><td>Rech. de Staphylocoques à coagulase positive</td><td>Absent</td><td>Absent</td><td>Absent</td><td>Absent</td></tr>
</table>
<table>
<tr><th>Elevage Avicole mars 2019</th><th>INITIAL state
/m²</th><th>FINAL state D600
/m²</th><th>reduction D600
Log10</th><th>reduction D600
%</th></tr>
<tr><td>Dénombr. microorganismes aérobies 30°C</td><td>1,9E+08</td><td>6,8E+04</td><td>3,4</td><td>99,96</td></tr>
<tr><td>Dénombr. des entérobactéries présumées</td><td>1,0E+04</td><td>< 10</td><td>3,0</td><td>99,90</td></tr>
<tr><td>Dénombrement d'Escherichia coli</td><td>2,7E+03</td><td>< 10</td><td>2,4</td><td>99,63</td></tr>
<tr><td>Dénombrement de Pseudomonas spp</td><td>5,5E+04</td><td>< 10</td><td>3,7</td><td>99,98</td></tr>
<tr><td>Spores de Clostridium perfringens</td><td>9,8E+02</td><td>< 10</td><td>2,0</td><td>98,98</td></tr>
<tr><td>Dénombrement de levures et moisissures</td><td>3,2E+05</td><td>6,5E+03</td><td>1,7</td><td>97,94</td></tr>
<tr><td>Dénombrement d'Aspergillus</td><td>6,8E+04</td><td>< 100</td><td>2,8</td><td>99,85</td></tr>
<tr><td>Dénombrement d'entérocoques intestinaux</td><td>1,8E+04</td><td>< 10</td><td>3,2</td><td>99,94</td></tr>
<tr><td>Rech. de Staphylocoques à coagulase positive</td><td>Absent</td><td>Absent</td><td>Absent</td><td>Absent</td></tr>
</table>
</td>
<td>and Pseudomonas have a reduction of more than 3 Log.

Staphylococci are not detected

Initial level s of organisms low with some less than Log3.</td>
<td></td>
</tr>
<tr>
<td></td><td></td><td></td>
<td>Organisms monitored:

Escherichia coli B glucuronidase
Clostridium Perfringens
intestinal enterococci
enterobacteria
Pseudomonas spp
Aspergillus
Salmonella
Staphylococci Coagulase
Yeasts
Moulds

Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods</td>
<td>Field Trial (pig farm in France)

The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in pig farms (indoor floor disinfection)

Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.
Three treatments were studied: an untreated housing unit, a housing unit treated with 600 g / m² of product, and a last housing unit treated with 800 g / m² of product.
Concrete floor and/or gratings
12 housing of equivalent sizes (4, 5x2 m) – 3 per treatment</td>
<td>600 or 800 g of CaO / m² of soil
Contact time: 40 h
Temp: ambient (ave 8.5 deg C), the temperature rise associated with the hydration of quicklime is limited (max 1.1 °C)

pH = 11 after 40H exposure and after hydration

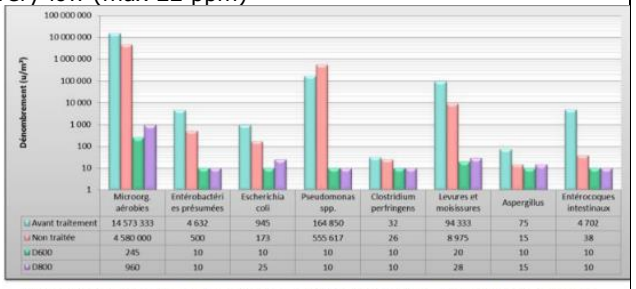
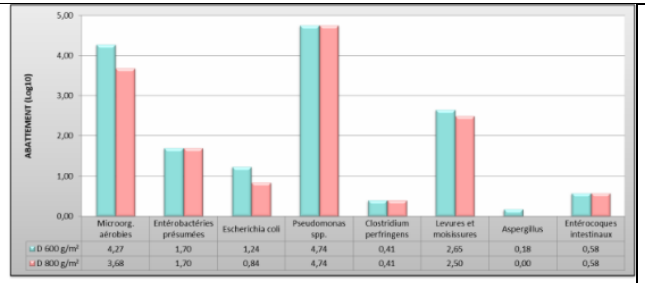
Follow up of the emissions of ammoniac (NH3): increase emissions of NH3 in the box treated, even they remain very low (max 22 ppm)


Figure 5 : Population count of different microorganismes before traitement and after treatement in treated and non-treated areas.</td>
<td>100% CaO at 600 g/m² (40h contact time):

>2/3 Log for aerobic microorganisms, Pseudomonas spp, yeast and moulds

Less reduction for the other microorganisms (small level of initial population)

No significant difference between 600 and 800 g/m² application in terms of reduction.</td>
<td>RITTMO 19-431R
RI = 2</td>
</tr>
</table>

				Samples are taken on delimited areas of 1x1 m. For an area of 1x1 m zone, the microorganisms are removed using sampling cloths 4 per zone (1/4 surface/wipe). The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried. 2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored	 *Figure 6 : Reduction (log_{10}) of microbe populations between treated and non-treated zones 40h after treatment*		

Conclusion on the efficacy of the product

The products of the family CALCIUM DIHYDROXIDE BLENDS have shown a sufficient efficacy:

- For the disinfection of sewage sludge (PT 2) against bacteria and endoparasites: helminth eggs.

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of sewage sludge.
Regarding virus, for the disinfection of sewage sludge, the efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study. Therefore this activity is not validated

- For the disinfection of manure (PT3), against bacteria, virus and endoparasite (helminth eggs).

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time.
The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

No data has been provided for yeast and fungi for the disinfection of manure.

- For the disinfection of indoor floor surfaces of animal accommodations (including limewashing of walls) and transportation, floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus at the application rate of 800 g $Ca(OH)_2/m^2$.

The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the provisions in the SPC have to be implemented.

For the disinfection of bedding materials (PT3), against bacteria, yeast, fungi and virus, no specific study has been submitted by the applicant for this use. A read across with manure treatment studies, considered as a worst case, has been considered. However, in relation to the distribution properties, the content of organic material, the availability of water for the reaction of lime in the matrix that could differ from manure, read-across is not acceptable. The efficacy is therefore not supported by the data presented in the dossier.

2.2.5.6 Occurrence of resistance and resistance management

Development of resistance of pathogens against Lime treatment has not been observed. For all lime variants a pH > 12 can be reached upon treatment of substrates such as sewage sludge and manure. The extreme alkaline environment leads to denaturation of protein structures of microorganisms (e.g. cell walls) present in the substrate and results in cell death. It is difficult to envisage the development of resistance of microorganisms against a non-specific effect such as denaturation of cellular proteins; the damage is irreversible and adaptation can be excluded.

Also the other effects described:
- Increase in free / non-ionised ammonia (NH_3)
- Increased temperature
- Decreased water availability and increased osmotic pressure are also non-specific effects and development of resistance against these can be excluded.

Literature searches have not revealed literature indicating that resistance to Lime has been reported.

2.2.5.7 Known limitations

There is no known limitation for the biocidal products.

2.2.5.8 Evaluation of the label claims

Please refer to the SPC

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

2.2.6 Risk assessment for human health

In order to avoid unnecessary animal experiment, no study was conducted. Classification is determined following the CAR and by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

META SPC 1, 2, 3

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The META SPC 1, 2 and 3 are considered irritant to the skin.
Justification for the value/conclusion	Considering the products active substance content (20 to 70 %), a classification Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is needed.
Classification of the product according to CLP	Skin irritation, category 2 - H315: Causes skin irritation

Eye irritation

META SPC 1, 2, 3

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The META SPC 1, 2 and 3 are considered to cause serious eyes damage.
Justification for the value/conclusion	No new data on eye irritation was performed. Considering the products active substance content (20 to 70%), a classification Eye Dam.1 H318 is needed.
Classification of the product according to CLP	Serious eye damage cat. 1, H318: Causes serious eye damage

Respiratory tract irritation

META SPC 1, 2, 3

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No data on irritation in the respiratory tract is available. Considering the products active substance content (20 to 70%), a classification STOT SE 3 H335 is needed for all the META SPC.
Classification of the product according to CLP	Classification STOT SE 3 H335: May cause respiratory irritation is required.

Skin sensitization

META SPC 1, 2, 3

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin
Justification for the value/conclusion	No data on skin sensitisation was generated. Considering the content of active substance and co-formulant in the meta-SPCs, no classification for skinsensitisation is required.
Classification of the product according to CLP	Not classified for skin sensitisation

Respiratory sensitization (ADS)

META SPC 1, 2, 3

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory system.
Justification for the value/conclusion	According to the composition, none of the component is classified for respiratory sensitisation.
Classification of the product according to CLP	Not classified for respiratory sensitisation is required

Acute toxicity

Acute toxicity by oral route

META SPC 1, 2, 3

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic *via* oral route
Justification for the selected value	According to the composition, none of the components is classified for acute oral toxicity.
Classification of the product according to CLP	No classified for acute oral toxicity.

Acute toxicity by inhalation

META SPC 1, 2, 3

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic *via* inhalation.
Justification for the selected value	According to the composition, none of the components is classified for acute inhalation toxicity.
Classification of the product according to CLP	Not classified for acute inhalation toxicity.

Acute toxicity by dermal route

META SPC 1, 2, 3

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic *via* dermal route
Justification for the selected value	According to the composition, none of the components is classified for acute dermal toxicity.
Classification of the product according to CLP	Not classified for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Calcium dihydroxide
Value(s)*	100%
Justification for the selected value(s)	According to the CAR of calcium dihydroxide, a dermal absorption value of 100 % of the applied dose of calcium is a reasonable worst-case assumption at irritant concentrations

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, there is no substance of concern in the family product.

2.2.6.2 Exposure assessment

CALCIUM DIHYDROXIDE BLENDS is a family of hydrated lime products containing three META SPCs used by professionals for:

- disinfection of sewage sludge (PT2) and manures (PT3) for the META SPC 1 and 3;
- disinfection of floors surfaces (animal accommodation and transportation, animal beddings materials) (PT3) for the META SPC 2;
- disinfection of floors of outdoor animal enclosures for the META SPC 2;
- disinfection of walls animal accommodation using a brush (PT3) for the META SPC 3.

The products from META SPC 1 and 2 are supplied as dustable powder whereas the products from META SPC 3 are a suspension of milk of lime (liquid form).

The lime powder products are available in bulk or packed in small bags of 25 kg and big bags of 750 kg. Considering the products in the form of suspension, they are packed in IBC containing up to 1000 kg milk of lime.

Considering the different modes of application and the available packaging sizes, exposure is expected to occur during the following tasks:

- The loading phase (manual, semi-automated);

- The application phase (manual, semi-automated);
- The cleaning task (including disposal of empty bags).

Inhalation and dermal exposure during these different operations are considered.

Adverse effects

The mode of action of lime leads to an increase of the alkalinity of the treated substrates (manures, litter).Naturally, these substrates are involved in the release of ammonia gas due to their content in nitrogen compounds. Adding lime on these substrates may lead to an increase of the level of ammonia gas released in the air. This effect that may be of concern has been taken into account in the assessment.

Calcium and magnesium contents

The main contents of the lime variants are calcium, magnesium and their oxides and hydroxides. According to the CAR, the assessments of calcium hydroxide, **calcium and magnesium** exposure are proposed.

The following contents are considered for exposure:

META SPC 1

Calcium and magnesium contents	
$Ca(OH)_2$ (max.)	70%
Ca (equivalent) (max.)	**59.85%**
Mg (equivalent) (max.)	**1.59%**

META SPC 2

Calcium and magnesium contents	
$Ca(OH)_2$ (max.)	30%
Ca (equivalent) (max.)	**44.21%**
Mg (equivalent) (max.)	**0.68%**

META SPC 3

Calcium and magnesium contents	
$Ca(OH)_2$ (max.)	50%
Ca (equivalent) (max.)	**27.18%**
Mg (equivalent) (max.)	**1.13%**

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	No	n.a.	No	No	No
Dermal	n.a.	Yes	No	n.a.	Yes	Yes	No
Oral	n.a.	No	No	n.a.	No	Yes	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Disinfection of sewage sludge and manures			
META SPC 1			
1.	**Loading (manual)**	**Primary exposure** – Manual loading of hydrated lime powder to sewage sludge and manures. This scenario takes into account opening of bags.	Professionals
META SPC 1 & 3			
2.	**Loading (semi-automatic)**	**Primary exposure** – Semi-automated loading of lime to sewage sludge and manures	Professionals
3.	**Cleaning**	**Primary exposure** - Cleaning of the unit treatment	Professionals
4.	**Disposal**	**Primary exposure** - Disposal of empty bags	Professionals
5.	**Disposal**	**Primary exposure** - Disposal of treated waste	Professionals
Disinfection of indoor floor of animal accommodations, transportation and bedding materials			
META SPC 2			
6.	**Loading (Manual)**	**Primary exposure** - Manual loading of the products to a wheelbarrow This scenario takes into account the opening of bags	Professionals
7.	**Application (Manual)**	**Primary exposure** - Manual spreading of dry product using a shovel- indoor	Professionals
8.	**Loading (Semi-automatic)**	**Primary exposure** - Semi-automated loading of the product to the tank of a tractor. This scenario takes into account the opening of bags.	Professionals

Summary table: scenarios			
9.	**Application (semi-automatic)**	**Primary exposure** - Semi- automatic application of dry product using a tractor-drawn spreader - indoor	Professionals
10.	**Disposal**	**Primary exposure** - Disposal of empty bags	Professionals
11.	**Disposal**	**Primary exposure** - Disposal of lime product after application	Professionals
Disinfection of floors of outdoor animal enclosures			
META SPC 2			
12.	**Application (Manual)**	**Primary exposure** - Manual spreading of dry product onto floors of animal enclosure (poultry) using a shovel - outdoor	Professionals
13.	**Loading (Semi-automatic)**	**Primary exposure** - Semi-automated loading of the product to the tank of tractor in outdoor conditions. This scenario takes into account the opening of bags.	Professionals
14.	**Application (Semi-automated)**	**Primary exposure** - Semi- automatic application of dry product onto animal enclosure (poultry) - outdoor	Professionals
15.	**Disposal**	**Primary exposure** - Disposal of empty bags	Professionals
16.	**Disposal**	**Primary exposure** - Disposal of lime product after application	Professionals
Disinfection of animal accommodations walls using a brush			
META SPC 3			
17.	**Loading**	**Primary exposure** - Semi-automated loading of the products from packaging (IBC 1m^3) to buckets	Professionals
18.	**Application (walls)**	**Primary exposure** – Manual application by brush	Professionals
19.	**Cleaning equipment**	**Primary exposure** - Cleaning of the brush equipment	Professionals
20.	**Exposure to treated surfaces- Adults**	**Secondary exposure** – Dermal exposure After brush on surfaces, secondary dermal exposure may occur during the contact with wet surfaces	Professionals and general public
21.	**Contact with treated surfaces**	**Secondary exposure** – Dermal exposure After brush on surfaces, secondary dermal exposure may occur during the contact with dried surfaces	Professionals and general public
22.	**Contact with treated surfaces**	**Secondary exposure** – Dermal and oral exposure After brush on surfaces, secondary dermal and oral toddler's exposure may occur during the contact with wet surfaces	General public

Summary table: scenarios			
23.	**Contact with treated surfaces**	**Secondary exposure** – Dermal and oral exposure After brush on surfaces, secondary dermal and oral toddler's exposure may occur during the contact with dried surfaces	General public

Industrial exposure

No industrial use intended for these products.

Professional exposure

Disinfection of sewage sludge and manures (Meta SPCs 1 & 3)

Scenario [1]: Mixing and loading – Manual loading to sewage sludge and manures (Meta SPC 1)

Description of Scenario [1]
Products from meta-SPC 1 are available in small bags of 25 kg for manual loading to sewage sludge and manures. The bags are manually opened (thanks to a knife) and emptied in the storage container (hopper) of the unit of treatment. Workers are not protected by any cab. The lime is then transferred to the sludge mixer through a screw conveyor (closed system). The actual mixing can occurs before or after dewatering. The same assumption is made for the treatment of manures where bags of 25 kg calcium hydroxide are opened and emptied manually in an open area. Dermal exposure is assessed using RISKOFDERM Dermal Exposure Model and by taking into account an application rate of 25 kg/min and a task duration of 10 min (for details, please refer to output tables in Annexe 3.2). A dermal exposure of **56.9 mg bp/min** (75th percentile) is calculated. It has to be noted that exposure value for body is not available with this model (only hand exposure value). Gloves are taken into consideration in Tier 2. A field study for the measurement of potential inhalation exposure has been submitted in the CAR on the active substance[3]. The objective of the study was to measure the inhalation exposure of two operators opening and emptying lime sacks containing 100 % of calcium oxide into sludge treatment units at three different sites in France. The results of this study are as follows: When normalised over 8 hours, a daily exposure of 0.27 to **2.58** mg of bp/m^3 was measured, with an average of 1.07 mg/m^3. During the task only, an inhalation exposure of 23.2 mg bp/m^3 was measured. Thus, the following exposure values have been retained for the product assessment : - 2.58 mg of bp/m^3 for systemic exposure; - 23.2 mg bp/m^3 for local exposure.

[3] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014.

Description of Scenario [1]			
Regarding the local exposure, the concentration in active substance (70% $CaOH_2$) has been used to estimate the inhalation exposure of the professional during the loading task for products pertaining to meta-SPC 1For Tier 2, a respiratory mask (APF 40) is taken into account.			
	Parameters[1]	**Value**	**References**
Tier 1	$Ca(OH)_2$ concentration	70%	Applicant's data
	Assumed calcium fraction	59.9%	Applicant's data
	Assumed magnesium fraction	1.6%	Applicant's data
	Duration (min)	10	General time duration for a M&L scenario in accordance with the CAR on active substance PT 2
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m3) – full shift	2.58	Field study from the CAR PT 2
	Inhalation exposure (mg/m3) – task only	23.2	Field study from the CAR PT 2
	Dermal absorption value	100%	Active substance data
	Inhalation rate (m3/hour)	1.25	HEAd hoc Recommendation no. 14 , 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14 , 2017
Tier 2a	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF=40	BHEEM

Calculations for Scenario [1]

Systemic effect - Calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	Tier 1/no PPE	2.57E-01	5.68E+00	5.93E+00
Scenario [1]	Tier 2a/gloves	2.57E-01	2.84E-01	5.41E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	Tier 1/no PPE	6.84E-03	1.51E-01	1.58E-01
Scenario [1]	Tier 2a/gloves	6.84E-03	7.54E-03	1.44E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [1]	Tier 1/no PPE	1.62E+01
Scenario [1]	Tier 2b/ respiratory mask (RPE APF 40)	4.06E-01

Scenario [2]: Mixing and loading – Semi-automated loading to sewage sludge and manures (Meta SPC 1 & 3)

As described above, the uses Disinfection of sewage sludge (PT 2) and Disinfection of manures (PT3) are claimed for the products pertaining to META SPC 1 and META SPC3.

Since the formulation of the products has an impact on the operator's exposure estimation, the scenario [2] has been split into 2 sub-scenario taking into account the formulation of the products. The different sub-scenarios developed are as follows:

- Scenario [2a]: Semi automated loading to sewage sludge and manures**- powder products- META SPC1**
- Scenario [2b]: Semi automated loading to system of sewage sludge and manures- **liquid products- META SPC 3**

Description of Scenario [2a] : Semi automated application to sewage sludge and manures- powder products (Meta SPC 1)

The products from META SPC1 are available in big bags of 750 kg for semi-automated loading to sewage sludge and manures.
The big bags are lifted onto the hopper/discharger and automatically cut at the bottom to discharge the product.
The worker remains in the cabin of the **tele handler (enclosed cab) or in forklift (no cabin)** during the discharge. Alternatively, the bag can be placed at the top of the hopper and is not removed until it is empty (cf. CAR on active substance PT 2).

The same assumption is made for the use on manures.
Exposure is principally limited to the loading of lime before contact with sludge or manure.

For dermal exposure, the indicative value of **56.9 mg/min** for manual loading is taken into account with an application rate of 25 kg/min (worst-case assumption as the product is lifted and not handled by the worker) and a task duration of 10 min.
For Tier 2, gloves are taken into consideration.

Potential inhalation exposure of the product is estimated using ART (Advanced Reach Tool) taking into account 100% active substance and a transfer of 100 to 1000 kg of active substance/min.
Then, the concentration in active substance in the product (= 70% a.s) is considered to estimate the inhalation exposure of the professional during the task.
A task duration of 120 min is taken into account.

The predicted 75th percentile is equal to (see Annex 3.2 for reports):
For full shift:

- **0.27 mg/m^3 and 1.8 mg/m^3 for tele handler** for outdoor and indoor activities, respectively.
- **0.62 mg/m^3 and 4.3 mg/m^3 for forklift** for outdoor and indoor activities, respectively.

For task only:

- **1.1 mg/m^3 and 7.3 mg/m^3 for tele handler** for outdoor and indoor activities, respectively.
- **2.5 mg/m^3 and 17 mg/m^3 for forklift** for outdoor and indoor activities, respectively

The value for forklift indoor activities is chosen for inhalation exposure as a worst-case.			
	Parameters	**Value**	**References**
	$Ca(OH)_2$ concentration	70%	Applicant's data
	Assumed calcium fraction	59.9%	Applicant's data
	Assumed magnesium fraction	1.6%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure – forklift indoors (mg/m^3) full shift	4.3	ART model
	Inhalation exposure – forklift indoors (mg/m^3) task only	17	ART model
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	BHEEM

Calculations for Scenario [2a]

Systemic effect - Calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2a]	Tier 1/no PPE	4.19E-01	5.68E+00	6.09E+00
Scenario [2a]	Tier 2a/gloves	4.19E-01	2.84E-01	7.03E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2a]	Tier 1/no PPE	1.11E-02	1.51E-01	1.62E-01
Scenario [2a]	Tier 2a/gloves	1.11E-02	7.54E-03	1.87E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m³)**
Scenario [2a]	Tier 1/no PPE	1.19E+01
Scenario [2a]	Tier 2b/ respiratory mask (RPE APF 40)	2.98E-01

Description of Scenario [2b] : Semi automated application to system of sewage sludge and manures- liquid products (Meta SPC 3)			
The products of the META SPC 3 are a suspension of hydrated lime packed in containers up to 1000 kg (IBC). Considering the high volume of the packaging, it is assumed that the loading will be performed by (semi-)automated transfer/pumping. During this step, the worker has to connect the container to the system. The product is then transferred to the sewage sludge through a closed system. Calcium hydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected during the task. To determine dermal exposure, RISKOFDERM Toolkit Connecting lines Model is used (HEEG opinion 1). A duration of 10 minutes is taken into consideration (cf CAR).			
	Parameters	**Value**	**References**
	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2%	Applicant's data
	Assumed magnesium fraction	1.1%	Applicant's data
	Dermal exposure – Hand only (mg/min)	0.92	RISKOFDERM Toolkit (HEEG Opinion 1)
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017

Systemic effect - Calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2b]	Tier 1/no PPE	-	4.17E-02	4.17E-02

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2b]	Tier 1/no PPE	-	1.73E-03	1.73E-03

Scenario [3]: Cleaning and maintenance – Cleaning of the treatment unit

As performed for the scenario 2, the scenario [3] has been split into two sub-scenario taking into account the formulation of the products. The different scenarios developed below are as follows:

- Scenario [3a]: Cleaning of the treatment unit**- powder products- META SPC1;**
- Scenario [3b]:Cleaning of the treatment unit - **liquid products- META SPC 3.**

Description of Scenario [3a] : Cleaning of unit treatment - Powder products (Meta SPC 1)

According to the information presented in the CAR (PT2) on calcium dihydroxide, cleaning of equipment is required for PT3.
The cleaning of equipment (dry process) is reported to be done very carefully to reduce dust in suspension with vacuum cleaners or exhaust ventilation used during the cleaning process.
For PT3, cleaning activities are considered covered by exposure of PT2.

There is no specific model to estimate exposure during this task. The closest model found in the BEAT database (2008) is the 'Cleaning of spray equipment' model, which includes rinsing and rubbing) tasks.
The indicative exposure values for dermal exposure are as follows:
- 35.8 µL/min for hands;
- 19.2 µL/min for body.

It is assumed that the air concentration during the cleaning task would be no higher than predicted for manual loading in the field study presented in the CAR (see above scenario [1]).
Therefore, during the task, an inhalation exposure value of **23.2 mg/m³** is taken into account.

A task duration of 30 min is considered.

As no information has been provided by the applicant regarding this process, it has been considered, as a worst case, that the operator can be exposed to wet residues of product. Indeed, it cannot be sure that after the cleaning task, only dry matter remains in the unit. As a consequence, the protection factor of 90% has been used in the exposure calculations

	Parameters	**Value**	**References**
Tier 1	$Ca(OH)_2$ concentration-	70%	Applicant's data
	Assumed calcium fraction-	59.9%	Applicant's data
	Assumed magnesium fraction	1.6%	Applicant's data
	Duration (min)	30	Default value for this task
	Product density (tap density)	0.5 g/mL	Applicant's data
	Inhalation exposure (mg/m^3)	23.2	Field study from CAR PT2
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017

Tier 2a	Gloves	PF = 90%	HEEG Opinion 9, 2010
Tier 2b	Respiratory Protection	PF=40	BHEEM

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3a]	Tier 1/no PPE	1.45E-01	8.25E+00	8.40E+00
Scenario [3a]	Tier 2a/gloves	1.45E-01	3.42E+00	3.57E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3a]	Tier 1/no PPE	3.84E-03	2.19E-01	2.23E-01
Scenario [3a]	Tier 2a/gloves	3.84E-03	9.09E-02	9.47E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [3a]	Tier 1/no PPE	1.62E+01
Scenario [3a]	Tier 2b/ RPE (APF 40)	4.06E-01

Description of Scenario [3b] : Cleaning of the treatment unit - liquid products (Meta SPC 3)			
As the products of the META SPC 3 are in liquid form, it's assumed that the exposure during the cleaning of the equipment will be equal or inferior to the cleaning of the equipment after treatment with a product in powder. Therefore, the same approach than the approach proposed in the scenario [3a] is applied. The BEAT model "Cleaning of spray equipment" is used to determine the dermal exposure. For inhalation exposure, it is assumed that the air concentrations would not be higher than the maximal predicted air concentration for manual loading of bags of powder of 23.2 mg/m^3 (as in the scenario 3a). The task duration is 30 min according to the CAR.			
	Parameters	**Value**	**References**
Tier 1	$CaOH_2$ concentration-	50%	Applicant's data
	Assumed calcium fraction-	27.2%	Applicant's data
	Assumed magnesium fraction	1.1%	Applicant's data
	Duration (min)	30	Default value for this task
	Product density	1.394	Applicant's data
	Inhalation exposure (mg/m^3)	23.2	Field study from CAR PT2
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 90%	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF=40	BHEEM

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3b]	Tier 1/no PPE	6.57E-02	1.05E+01	1.05E+01

Summary table: systemic exposure from professional uses				
	Tier 2a/gloves	6.57E-02	4.34E+00	4.40E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3b]	Tier 1/no PPE	2.73E-03	4.34E-01	4.37E-01
Scenario [3b]	Tier 2a/gloves	2.73E-03	1.80E-01	1.83E-01

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [3b]	Tier 1/no PPE	1.16E+01
	Tier 2b/ RPE (APF 40)	2.90E-01

Scenario [4]: Cleaning- Disposal of empty bags (Meta SPC 1 only)

Description of Scenario [4]
After loading the lime powder from the big bags into the treatment unit using a forklift or a tele handler (closed cabin), the bags are disposed of still using the same type of device. No dermal exposure is expected during this task that is performed using a vehicle. Potential inhalation exposure is estimated using ART taking into account 100% of the active substance and a task duration of 10 min. Then the concentrations in active substance in the meta-SPC 1 (70%) is taken into account to estimate the inhalation exposure of the professional during the task. As a worst-case situation the "Handling of substantially and visibly contaminated objects (layer of more than 0.5 kg)" has been chosen. The model has been run for outdoor and indoor simulations. The predicted 75th percentile is equal to (see Annex 3.2 for reports): For full shift: - 0.019 mg/m^3 (outdoor); - 0.12 mg/m^3 (indoor). For task only: - 0.91mg/m^3 (outdoor); - 5.7 mg/m^3 (indoor). As a worst-case approach, only indoor value with a forklift is retained for the risk assessment.

	Parameters	**Value**	**References**
	$CaOH_2$ concentration	70%	Applicant's data
	Assumed calcium fraction	59.9%	Applicant's data
	Assumed magnesium fraction	1.59%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	0.019 (out) 0.12 (in)	ART model
	Inhalation exposure (mg/m^3)- task only	0.91 (out) 5.7 (in)	ART model
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAD hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [4]

Systemic exposure – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	Tier 1/no PPE	1.20E-02	-	1.20E-02

Systemic exposure – magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	Tier 1/no PPE	3.18E-04	-	3.18E-04

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [4]	Tier 1/no PPE	3.99E+00
Scenario [4]	Tier 2b/ RPE (APF 20)	2.00E-01

Combined exposure

Meta SPC 1: scenario [1 +3a] and scenario [2a + 3a]

Regarding the very low systemic exposure during the disposal phase (please refer to the systemic calculations), the scenarios 4 has not been taken into account in the combined exposure.

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1+3a	Tier 1/no PPE	4.02E-01	1.39E+01	1.43E+01
	Tier 2a/ gloves	4.02E-01	3.71E+00	4.11E+00
Scenario 2a+3a	Tier 1/no PPE	5.64E-01	1.39E+01	1.45E+01
	Tier 2a/gloves	5.64E-01	3.71E+00	4.27E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1+3a	Tier 1/no PPE	3.84E-03	3.70E-01	3.81E-01
	Tier 2a/ gloves	3.84E-03	9.84E-02	1.09E-01
Scenario 2a+3a	Tier 1/no PPE	1.50E-02	3.70E-01	3.85E-01
	Tier 2a/ gloves	1.50E-02	1.82E-01	1.97E-01

Meta SPC 3: scenario [2b + 3b]

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 2b+3b	Tier 1/no PPE	6.57E-02	1.05E+01	1.06E+01
	Tier 2a/gloves	6.57E-02	4.38E+00	4.44E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 2b+3b	Tier 1/no PPE	2.73E-03	4.36E-01	4.39E-01

Scenario [5]: Disposal of treated sludge and manures

Description of Scenario [5]
According to the information reported in the CAR (PT3), the oxide component would be transformed to hydroxide and a significant degree of further chemical reaction would take place with components of the treated substrate producing a non-dusty product. Workers have to wear personal protective equipment during the disposal phase and any residual contamination effectively minimised.

Disinfection of floor surfaces of animal accommodations (indoor), animal transportation and animal bedding materials

Scenario [6]: Manual loading into a wheelbarrow for disinfection of floor and bedding materials (Meta SPC 2 only).

Description of Scenario [6]

The products from META SPC 2 are available in small bags of 25kg, which can be manually opened thanks to a knife and then emptied in a wheelbarrow or a low-impact spreader for application of the product onto floor surfaces of animal accommodation and bedding materials.

During this task, professionals are not enclosed into a cabin, therefore dermal and inhalation exposure can occurred.

RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model). An application rate of 25 kg/min and a task duration of 10 min are taken into consideration. The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2).
For Tier 2, gloves are taken into account.

Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s.and a transfer of 10 – 100 kg of bp/min. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.

A task duration of 10 min is considered.

The predicted 75th percentile obtained is equal to (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours), **2** mg bp/m^3
- For task only (10min), **110** mg/ m^3.

For Tier 2, a respiratory protection (mask with APF 40) is taken into account.

	Parameters	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	2	ART Model
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010

Tier 2b	Respiratory protection	PF = 40	BHEEM

Calculations for Scenario [6]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6]	Tier 1/no PPE	1.47E-01	4.19E+00	4.34E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6]	Tier 1/no PPE	2.27E-03	6.45E-02	6.68E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [6]	Tier 1/no PPE	3.30E+01
Scenario [6]	Tier 2b/ RPE (APF 40)	8.25E-01

Scenario [7]: Application– Manual spreading of dry product onto floor surfaces and bedding materials using a shovel- indoor (Meta SPC 2 only)

After the transfer of the lime powder from bags to a wheelbarrow (scenario [6]), the lime is manually spread using a spade or shovel over the area to be treated.
During this task, professionals are not enclosed into a cabin therefore dermal and inhalation exposure can occurred.
Indoor application are taken into account for the disinfection of poultry, cattle and sheep floor surfaces (as intended by the applicant) with only good natural ventilation.

For poultry and cattle, the default values for surfaces to be treated have been taken from the PT 3 ESD, 2011.
In the ESD, no surface value is available for sheep (due to lack of data); therefore, no assessment can be developed for this animal category. Nevertheless, it has been considered that the risk assessment for the disinfection of sheep housing can be considered in the frame of the risk assessment for poultry and cattle floor surfaces.

The applicant did not submit any information regarding time duration for the treatment of floor surfaces. Therefore, application time durations (manually or semi-automatic) have been calculated based on several assumptions.
For manual application of lime on floor surfaces a walking speed value of 2.5 km/h and a spreading width of 50 cm have been considered.

Based on the following equation: T = d/v

Where T = task time duration;
d = distance travelled by the operator,
v = speed of the operator

it can be possible to calculate a task time duration.

According to the information presented in the ESD PT 3, a surface value of 3330 m^2 is proposed for turkey's litter floor. This is the highest default surface value proposed in the document.
Based on this surface data, the following reasoning is made in order to calculate the distance travelled by the operator during the task (parameter "d" in the equation presented above).

It is assumed that the turkey's litter floor is a squared surface with a total surface area of 3330 m^2. This means that the side of the squared surface is of 57.7 m rounded to **58 m**.
In order to treat all the surface, the operator must go back and forth with his wheelbarrow or spreader. Considering that the operator has a spreading width of 50 cm, a number of round trips can be calculated as follows:

Round trips = 58 m / 0.5 m = 116.

Considering this data, the distance travelled by the operator during the treatment of turkey's litter floor is calculated as follows:

d = √surface area x round trips
d = √3330 m^2 x 116
d = 6 693.9 m (rounded to **6.7 km**).

Considering a walking speed of 2.5 km/h for an operator, a task time duration of 2.7h eq. to **160 min** is calculated (6.7 km/2.5km/h).
In conclusion, to manually treat with lime a surface of 3330 m^2, a task time duration of 160 min is taken into account. This leads to a surface/time ratio of 20.8 m^2/min (3330 m^2 / 160 min), that can be applied to every surface area value presented in the ESD PT 3 to derive a task time duration (please refer to excel data sheet presented in Annexe 3.2).

Since the estimation of potential exposure, especially inhalation exposure, is dependent to the treated surface area, the scenario [7] has been split into 4 sub-scenario taking into account the minimum and the maximum default surface values defined for poultry and cattle. The different scenarios developed below are as follows:

- Scenario [7a]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**;
- Scenario [7b]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**;
- Scenario [7c]: Application– Manual spreading of dry product onto floor surfaces of **cattle _ Minimum surface area**;
- Scenario [7d]: Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**.

Description of Scenario [7a] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**

According to the ESD PT3, a poultry covers different subcategories of housing (batteries, free range, etc) with different floor surfaces ranging from 390 to 3330 m^2.
Taking into account the surface/time ratio calculated above, a task time duration of 18.74 min (rounded to 19 min) is calculated for the lowest default surface value of 390 m^2 for poultry. (see Annex 3.2 for the detailed calculations).

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 104 kg/min is calculated based on the intended dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **668** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of product/min is retained as it corresponds to the dose range of the model proposed for a manual task.

A minimal room volume of 1000 m^3 has been taken account in the model. This volume corresponds approximately to the surface of 390 m^2 multiplied by a height of 2.7 m calculated from the ESD PT 3 data[4].

[4] Based on the data on floor surface area presented in the ESD PT 3 it is possible to calculate a default value for height.
A wall and roof area of 600 m^2 is presented in the ESD associated to a floor area of 390 m^2. Making the worst-case assumption that the floor surface area is equal to the ceiling surface area, this leads to a total wall surface area of 210 m^2 meaning that a single wall is of 52.5 m^2 surface area. Making

Description of Scenario [7a] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **4.3** mg bp/m^3
- For task only (19 min): **110** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	19	see calculation above
	Dermal exposure – Hand only (mg/min)	668	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	4.3	ART Model
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [7a]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7a]	Tier 1/no PPE	3.17E-01	9.35E+01	9.38E+01
Scenario [7a]	Tier 2a/gloves	3.17E-01	4.67E+00	4.99E+00

the assumption that the floor is a squared surface with a 24 m length side, a maximal wall height of 2.7 m is obtained.

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7a]	Tier 1/no PPE	5.02E-03	1.48E+00	1.49E+00
Scenario [7a]	Tier 2a/gloves	5.02E-03	7.40E-02	7.91E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [7a]	Tier 1/no PPE	3.30E+01
Scenario [7a]	Tier 2b/ RPE (APF 40)	8.25E-01

Description of Scenario [7b] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**

Taking into account the surface/time ratio calculated above, a task time duration of 160 min is calculated for the highest default surface value of 3330 m^2 for poultry. (see Annex 3.2 for the detailed calculations).

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 104 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **668** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of bp/min is retained as it corresponds to the dose range of the model proposed for a manual task.

A maximal room volume of 3000 m^3 has been taken account in the model.
It has to be noted that this volume corresponds to the maximal volume which can be selected in ART. This value is conservative since a maximal volume of 19 314 m^3 is calculated taking into account a maximal floor surface area of 3330 m^2 and a height of 5.8 m calculated from the ESD PT 3 data[5].

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **32** mg bp/m^3
- For task only (160 min): **97** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	160	see calculation above
	Dermal exposure – Hand only (mg/min)	668	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	32	ART Model

[5] Based on the data on floor surface area presented in the ESD PT 3 it is possible to calculate a default value for height.
A wall and roof area of 4650 m^2 is presented in the ESD associated to a floor area of 3330 m^2. Making the assumption that the floor surface area is equal to the ceiling surface area, this leads to a total wall surface area of 1320 m^2 meaning that a single wall is of 330 m^2 surface area. Making the assumption that the floor is a squared surface with a 58 m length side, a maximal wall height of 5.8 m is obtained.

Description of Scenario [7b] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**			
	Inhalation exposure (mg/m^3)- task only	97	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [7b]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7b]	Tier 1/no PPE	2.36E+00	7.87E+02	7.90E+02
Scenario [7b]	Tier 2 /gloves + RPE (APF 40)	5.89E-02	3.94E+01	3.94E+01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7b]	Tier 1/no PPE	3.73E-02	1.25E+01	1.25E+01
Scenario [7b]	Tier 2a/gloves	3.73E-02	6.23E-01	6.61E-01

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [7b]	Tier 1/no PPE	2.91E+01
Scenario [7b]	Tier 2b/ RPE (APF 40)	7.28E-01

Description of Scenario [7c] : Application– Manual spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**

According to the ESD PT 3, the cattle covers several categories of animals (dairy and beef cattle, veal calves) with different floor surface areas ranging from 160 to 1170 m^2.

Taking into account the surface/time ratio of 20.8 m^2/min calculated above, a task time duration of 7.69 min (rounded to 8 min) is calculated for the lowest default surface value of 160 m^2 for cattle (see Annex 3.2 for the detailed calculations).

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 104 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **668** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of bp/min is retained as it corresponds to the dose range of the model proposed for a manual task.

A minimal room volume of 300 m^3 has been taken account in the modelling. This volume corresponds approximately to the mean surface of 160 m^2 multiplied by a height of 3.3 m calculated from the ESD PT 3 data[6].

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **2.4** mg bp/m^3
- For task only (8 min): **140** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	8	see calculation above
	Dermal exposure – Hand only (mg/min)	668	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	2.4	ART Model
	Inhalation exposure (mg/m^3)- task only	140	ART Model

6 Based on the data on floor surface area presented in the ESD PT 3 it is possible to calculate a default value for height.
A wall and roof area of 330 $m^2$is presented in the ESD associated to a floor area of 160 m2. Making the worst-case assumption that the floor surface area is equal to the ceiling surface area, this leads to a total wall surface area of 170 m^2 meaning that a single wall is of 42.5 m^2 surface area. Making the assumption that the floor is a squared surface with a 12.7 m length side, a maximal wall height of 3.3 m is obtained.

Description of Scenario [7c] : Application– Manual spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**			
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [7c]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7c]	Tier 1/no PPE	1.77E-01	3.94E+01	3.95E+01
Scenario [7c]	Tier 2/agloves	1.77E-01	1.97E+00	2.15E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7c]	Tier 1/no PPE	2.80E-03	6.23E-01	6.26E-01
Scenario [7c]	Tier 2a/gloves	2.80E-03	3.12E-02	3.40E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [7c]	Tier 1/no PPE	4.20E+01
Scenario [7c]	Tier 2b/ RPE (APF 40)	1.05E+00

Description of Scenario [7d] : Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**

Taking into account the surface/time ratio calculated above, a task time duration of 56 min is calculated for the highest default surface value of 1170 m^2 for cattle. (see Annex 3.2 for the detailed calculations)

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 104 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above. .
A dermal exposure (75th percentile) of **668** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of bp/min is retained as it corresponds to the dose range of the model proposed for a manual task.
A maximal room volume of 3000 m^3 has been selected in the ART model. This volume corresponds approximately to the maximum surface of 1170 m^2 multiplied by a height of 3.7 m calculated from the ESD PT 3 data[7].

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **11** mg bp/m^3
- For task only (56 min): **97** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	56	see calculation above
	Dermal exposure – Hand only (mg/min)	668	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	11	ART Model
	Inhalation exposure (mg/m^3)- task only	97	ART Model

[7] Based on the data on floor surface area presented in the ESD PT 3 it is possible to calculate a default value for height.
A wall and roof area of 1670 m^2 is presented in the ESD associated to a floor area of 1170 m^2. Making the worst-case assumption that the floor surface area is equal to the ceiling surface area, this leads to a total wall surface area of 500 m^2 meaning that a single wall is of 125 m^2 surface area. Making the assumption that the floor is a squared surface with a 34 m length side, a maximal wall height of 3.7 m is obtained.

Description of Scenario [7d] : Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**			
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [7d]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7d]	Tier 1/no PPE	8.10E-01	2.76E+02	2.76E+02
Scenario [7d]	Tier 2a/gloves	8.10E-01	1.38E+01	1.46E+01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7d]	Tier 1/no PPE	1.28E-02	4.36E+00	4.38E+00
Scenario [7d]	Tier 2a/gloves	1.28E-02	2.18E-01	2.31E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [7d]	Tier 1/no PPE	2.91E+01
Scenario [7d]	Tier 2b/ RPE (APF 40)	7.28E-01

Measured inhalation exposure from the field study- disinfection of indoor floor surfaces

The Applicant is a member of the Eula consortium and a letter of access to the EuLA dossier has been supplied. In this PAR, a field study with measured exposure data has been provided in order to refine inhalation exposure that is overestimated when using exposure models. Thanks to the LoA, the exposure data from the field study can be applied to this dossier.

In the study, professional inhalation exposure has been measured during the manual application of lime powder products on floor of animal accommodations using a shovel. These measured exposure data include the opening and the loading of the bags into the wheelbarrow before the application onto the floor surfaces.

For more details on the field study, please refer to the part paragraph "*Monitoring data*" of the PAR.

The results for inhalation exposures (95th percentile) from the study are as follow:

- For full shift (normalised over 8 hours): 0.37 mg /m^3;
- For task only: 9.58 mg/ m^3.

In Tier 3, the local exposures have been calculated integrating the inhalation exposure values from the study.

For Tiers 3b, a respiratory protection (APF 10) is taken into account.

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	2.87E+00
	Tier 3b/ RPE (APF 10)	2.87E-01

Scenario [8]: Loading – Semi automated loading into the tank of a tractor for disinfection of floor surfaces and bedding materials (Meta SPC 2 only)

Description of Scenario [8]

The products from META SPC 2 are available in big bags of 750 kg, which are mechanically raised and emptied into the tank of a tractor for application of the product onto animal accommodation floor surfaces and bedding materials (straw, sawdust, woodchip).

During this task, it's considered that the worker remains in the cabin of the tractor (partial enclosure) during the full discharge of the bag.

RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model).
An application rate of 25 kg/min and a task duration of 10 min are taken into consideration by making the worst case hypothesis that worker holds the bag during the unloading.
The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2).
For Tier 2, gloves are taken into account.

Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of bp/min corresponding to the dose range proposed by the model for an automatic process is considered.

The predicted 75th percentile obtained is equal to (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours), **0.94** mg bp/m^3
- For task only (10min), **45** mg/ m^3.

For Tier 2, a respiratory protection (mask with APF 40) is taken into account.

	Parameters	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.94	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	BHEEM

Calculations for Scenario [8]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8]	Tier 1/no PPE	6.92E-02	4.19E+00	4.26E+00
Scenario [8]	Tier 2a/gloves	6.92E-02	2.10E-01	2.79E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8]	Tier 1/no PPE	1.10E-03	6.64E-02	6.75E-02
Scenario [8]	Tier 2a/gloves	1.10E-03	3.32E-03	4.42E-03

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [8]	Tier 1/no PPE	1.35E+01
Scenario [8]	Tier 2b/ RPE (APF 40)	3.38E-01

Scenario [9]: Application– Semi-automated spreading of dry product using a tractor – indoor (Meta SPC 2 only)

The same approach that the one developed for manual application has been applied for semi-automatic application. The applicant did not submit any information regarding time duration for the treatment of floor surfaces. Therefore, application time durations (manually or semi-automatic) have been calculated based on several assumptions.
For semi-automatic application of lime on floor surfaces, a speed value of 5 km/h and a spreading width of 1 m have been considered for the tractor.

Based on the following equation: T = d/v

Where T = task time duration;
d = distance travelled by the operator,
v = speed of the operator

it can be possible to calculate a task time duration.

According to the information presented in the ESD PT 3, a surface value of 3330 m^2 is proposed for turkey's litter floor. This is the highest default surface value proposed in the document.
Based on this surface data, the following reasoning is made in order to calculate the distance travelled by the operator during the task (parameter "d" in the equation presented above).

It is assumed that the turkey's litter floor is a squared surface with a total surface area of 3330 m^2. This means that the side of the squared surface is of 57.7 m rounded to **58 m**.
In order to treat all the surface, the operator must go back and forth with his low impact spreader. Considering that the operator has a spreading width of 1 m, a number of round trips can be calculated as follows:

Round trips = 58 m / 1 m = 58.

Considering this data, the distance travelled by the operator during the treatment of turkey's litter floor is calculated as follows:

d = √surface area x round trips
d = √3330 m^2 x 58
d = 3347 m (rounded to **3.35 km**).

Considering a speed of 5 km/h for a tractor, a task time duration of 0.67h eq. to **40 min** is calculated (3.35 km/5km/h).
In conclusion, to semi-automatically treat with lime a surface of 3330 m^2, a task time duration of 40 min is taken into account. This leads to a surface/time ratio of **83.25** m^2/min (3330 m^2 / 40 min), that can be applied to every surface area value presented in the ESD PT 3 to derive a task time duration (please refer to excel data sheet presented in Annexe 3.2).

Since the estimation of potential exposure, especially inhalation exposure, is dependent to the treated surface area, the scenario [9] has been split into 4 sub-scenario taking into account the minimum and the maximum default surface values defined for poultry and cattle. The different scenarios developed below are as follows:

- Scenario [9a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**;
- Scenario [9b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**;
- Scenario [9c]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Minimum surface area**;
- Scenario [9d]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**

Description of Scenario [9a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**

The lime powder contained in big sacks could be loaded into the tank of a tractor/ low impact spreader for a semi-automated application of burnt lime powder onto animal floor surfaces and bedding materials.
Taking into account the surface/time ratio of 83.25 m^2/min calculated above, a task time duration of 4.68 min (rounded to 5 min) is calculated for the lowest default surface value of 390 m^2 for poultry. (see Annex 3.2 for the detailed calculations).

During this task, professionals are enclosed in a partial cab without ventilation therefore dermal and inhalation exposure can potentially occurred during the application of the product.

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 416 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
As the model does not allow entering a dose value up to 225 kg/min this does has been selected.
A dermal exposure (75th percentile) of **24.9** mg of bp/min is obtained.
For Tier 2, gloves are taken into account

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of bp/min is retained as it corresponds to the dose range of the model proposed for an automatic task.

In this scenario, the emission source is considered to be far from the worker's breast.
A minimal room volume of 1000 m^3 has been taken account in the model. This volume corresponds approximately to the real surface of 390 m^2 multiplied by a height of 2.7 m calculated from the ESD PT 3 data.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **1.1** mg bp/m^3
- For task only (5 min): **110** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model

Description of Scenario [9a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**			
	Inhalation exposure (mg/m^3)- full shift	1.1	ART Model
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF=40	BHEEM

Calculations for Scenario [9a]

Systemic exposure – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9a]	Tier 1/no PPE	8.10E-02	9.17E-01	9.98E-01

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9a]	Tier 1/no PPE	1.28E-03	1.45E-02	1.58E-02

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [9a]	Tier 1/no PPE	3.30E+01
Scenario [9a]	Tier 2b/ RPE (APF 40)	8.25E-01

Description of Scenario [9b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**

Taking into account the surface/time ratio calculated above, a task time duration of 40 min is calculated for the highest default surface value of 3330 m^2 for poultry. (see Annex 3.2 for the detailed calculations).

During this task, professionals are enclosed in a partial cab without mechanic ventilation so dermal and inhalation exposure can potentially occurred during the application of the product. RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 416 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
As the model does not allow entering a dose value up to 225kg/min this does has been selected.
A dermal exposure (75th percentile) of **24.9** mg of bp/min is obtained.

For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of active substance/min is retained as it corresponds to the dose range of the model proposed for an automatic task.
In this scenario, the emission source is considered to be far from the worker's breast.

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **3.8** mg bp/m^3
- For task only (40 min): **45** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	3.8	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF=40	BHEEM

Calculations for Scenario [9b]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9b]	Tier 1/no PPE	2.80E-01	7.34E+00	7.62E+00
Scenario [9b]	Tier 2a/gloves	2.80E-01	3.67E-01	6.47E-01

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9b]	Tier 1/no PPE	4.43E-03	1.16E-01	1.21E-01
Scenario [9b]	Tier 2a/gloves	4.43E-03	5.81E-03	1.02E-02

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m³)**
Scenario [9b]	Tier 1/no PPE	1.35E+01
Scenario [9b]	Tier 2b/ RPE (APF 40)	3.38E-01

Description of Scenario [9c]: Application– Semi-automatic spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**

According to the ESD PT 3, the cattle covers several categories of animals (dairy and beef cattle, veal calves) with different floor surface areas ranging from 160 to 1170 m^2.
Taking into account the surface/time ratio of 66.6 m^2/min calculated above, a task time duration of 1.92 min (rounded to 2 min) is calculated for the lowest default surface value of 160 m^2 for cattle (see Annex 3.2 for the detailed calculations).

During this task, professionals are enclosed in a partial cab without ventilation so dermal and inhalation exposure can potentially occurred during the application of the product.

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 416 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
As the model does not allow entering a dose value up to 225kg/min this does has been selected.
A dermal exposure (75th percentile) of **24.9** mg of bp/min is obtained.
For Tier 2, gloves are taken into account

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of active substance/min is retained as it corresponds to the dose range of the model proposed for an automatic task.
In this scenario, the emission source is considered to be far from the worker's breast.
A minimal room volume of 300 m^3 has been selected in the ART modelling. This volume corresponds approximately to the minimal surface of 160 m^2 multiplied by a height of 3.3 m calculated from the ESD PT 3 data.

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **1.5** mg bp/m^3
- For task only (2 min): **360** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	2	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.5	ART Model
	Inhalation exposure (mg/m^3)- task only	360	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017

Description of Scenario [9c]: Application– Semi-automatic spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**			
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF=40	BHEEM

Calculations for Scenario [9c]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9c]	Tier 1/no PPE	1.11E-01	3.67E-01	4.77E-01

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9c]	Tier 1/no PPE	1.75E-03	5.81E-03	7.56E-03

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [9c]	Tier 1/no PPE	1.08E+02
Scenario [9c]	Tier 2b/ RPE (APF 40)	2.70E+00

Description of Scenario [9d]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**

Taking into account the surface/time ratio of 66.6 m^2/min calculated above, a task time duration of 14 min is calculated for the highest default surface value of 1170 m^2 for cattle. (see Annex 3.2 for the detailed calculations)

During this task, professionals are enclosed in a partial cab without ventilation so dermal and inhalation exposure can potentially occurred during the application of the product.

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 416 kg/min is calculated based on the dose of 5 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
As the model does not allow entering an application rate up to 225kg/min, this dose of 225 kg/min has been selected.
A dermal exposure (75th percentile) of **24.9** mg of bp/min is obtained.

For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of bp/min is retained.
In this scenario, the emission source is considered to be far from the worker's breast.
A minimal room volume of 3000 m^3 has been selected in the ART modelling. This volume corresponds approximately to the mean surface of 1170 m^2 multiplied by a height of 3.7 m calculated from the ESD PT 3 data.

The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **1.3** mg bp/m^3
- For task only (14 min): **45** mg/ m^3.

For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	14	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.3	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017

Description of Scenario [9d]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**			
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [9d]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9d]	Tier 1/no PPE	9.58E-02	2.57E+00	2.66E+00

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9d]	Tier 1/no PPE	1.52E-03	4.07E-02	4.22E-02

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [9d]	Tier 1/no PPE	1.35E+01
Scenario [9d]	Tier 2b/ RPE (APF 40)	3.38E-01

Measured inhalation exposure from the field study- disinfection of indoor floor surfaces

In the field study, inhalation exposure of professionals has been measured during the application of lime powder products on floor of animal accommodations using a low impact spreader. These data include the loading task before the application.

It is assumed that inhalation exposure of professional will be greater using a low impact spreader rather than a tractor for the application.
Indeed, with a tractor, professionals are enclosed in a partial cab and so more protected from particles emissions than during manual application with a low impact spreader.
Thus, measured data obtained for manual application with a low impact spreader can be used as refinement of the scenario corresponding to semi-automated application of lime products with a tractor.

In Tier 3, the local exposures have been calculated integrating the inhalation exposure values from the study.

For Tiers 3b, a respiratory protection (APF 10) is taken into account.

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	1.68E+00
	Tier 3b/ RPE (APF 10)	1.68E-01

Scenario [10]: Cleaning - Disposal of empty bags (Meta SPC 2 only)

Description of Scenario [10]
After loading the lime powder from the big bags into the emptying device using a forklift or a tele handler (with a closed cabin), the bags are disposed of still using the same apparatus. No dermal exposure is expected during this task that is performed using a vehicle. Potential inhalation exposure is estimated using ART taking into account 100% of the active substance and a task duration of 10 min. Then the concentration in active substance in the Meta SPC 2 is taken into account to estimate the inhalation exposure of the professional during the task As a worst-case situation the "Handling of substantially and visibly contaminated objects (layer of more than 0.5 kg)" has been chosen. The model has been run for outdoor and indoor simulations. The predicted 75th percentile is equal to (see Annex 3.2 for reports): For full shift: - **0.019** mg/m^3 (outdoor); - **0.12** mg/m^3 (indoor). For task only: - **0.91** mg/m^3 (outdoor); - **5.7** mg/m^3 (indoor). As a worst-case approach, only indoor value with a forklift is retained for the risk assessment. For the disposal of small bags (25 kg), the potential exposure during this task is considered covered by the assessment performed for the manual application on the floor (using a shovel). Indeed, the potential exposure during this task is deemed to be of a lower extend compared to the application.

	Parameters	**Value**	**References**
	$Ca(OH)_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	0.019 (out) 0.12 (in)	ART model
	Inhalation exposure (mg/m^3)- task only	0.91 (out) 5.7 (in)	ART model
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAD hoc Recommendation no. 14, 2017
Tier 2b	Respiratory protection	APF = 10	BHEEM

Calculations for Scenario [10]

Systemic exposure – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10]	Tier 1/no PPE	8.84E-03	-	8.84E-03

Systemic exposure – magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10]	Tier 1/no PPE	1.40E-04	-	1.40E-04

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [10]	Tier 1/no PPE	1.71E+00
Scenario [10]	Tier 2b/ RPE (APF 10)	1.71E-01

Combined exposure (M&L + application)

Regarding the very low systemic exposure during the disposal phase (please refer to the systemic calculations), the scenario [10] has not been taken into account in the combined exposure.

- ***Manual process (M&L and application)***

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 6+7a	Tier 1/no PPE	4.64E-01	9.77E+01	9.82E+01
	Tier 2a/gloves	4.64E-01	4.88E+00	5.35E+00
Scenario 6+7b	Tier 1/no PPE	2.50E+00	7.92E+02	7.94E+02
	Tier 2/gloves for loading and gloves + RPE APF 40 for application	2.06E-01	3.96E+01	3.98E+01
Scenario 6+7c	Tier 1/no PPE	3.24E-01	4.36E+01	4.39E+01
	Tier 2a/gloves	3.24E-01	2.18E+00	2.50E+00
Scenario 6+7d	Tier 1/no PPE	9.58E-01	2.80E+02	2.81E+02
	Tier 2a/gloves	9.58E-01	1.40E+01	1.49E+01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 6+7a	Tier 1/no PPE	7.28E-03	1.55E+00	1.55E+00
	Tier 2a/gloves	7.28E-03	7.73E-02	8.45E-02
Scenario 6+7b	Tier 1/no PPE	3.96E-02	1.25E+01	1.26E+01
	Tier 2a/gloves	3.96E-02	6.27E-01	1.30E+00
Scenario 6+7c	Tier 1/no PPE	5.07E-03	6.88E-01	6.93E-01
	Tier 2a/gloves	5.07E-03	3.44E-02	3.95E-02
Scenario 6+7d	Tier 1/no PPE	5.07E-03	6.88E-01	6.93E-01
	Tier 2a/gloves	5.07E-03	3.44E-02	3.95E-02

- ***Semi-automated process (loading and application)***

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8+9a	Tier 1/no PPE	1.50E-01	5.11E+00	5.26E+00
	Tier 2a/gloves	1.50E-01	2.55E-01	4.06E-01
Scenario 8+9b	Tier 1/no PPE	3.49E-01	1.15E+01	1.19E+01
	Tier 2a/gloves	3.49E-01	5.76E-01	9.26E-01
Scenario 8+9c	Tier 1/no PPE	1.80E-01	4.56E+00	4.74E+00
	Tier 2a/gloves	1.80E-01	2.28E-01	4.08E-01
Scenario 8+9d	Tier 1/no PPE	1.65E-01	6.76E+00	6.92E+00
	Tier 2a/gloves	1.65E-01	3.38E-01	5.03E-01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8+9a	Tier 1/no PPE	2.38E-03	8.09E-02	8.33E-02
	Tier 2a/gloves	2.38E-03	4.05E-03	6.43E-03
Scenario 8+9b	Tier 1/no PPE	5.53E-03	5.53E-03	1.88E-01
	Tier 2a/gloves	5.53E-03	9.13E-03	1.47E-02
Scenario 8+9c	Tier 1/no PPE	2.85E-03	7.22E-02	7.50E-02
	Tier 2a/gloves	2.85E-03	3.61E-03	6.46E-03
Scenario 8+9d	Tier 1/no PPE	2.61E-03	1.07E-01	1.10E-01
	Tier 2a/gloves	2.61E-03	5.35E-03	7.97E-03

Scenario [11]: – Disposal of lime product after floor disinfection (Meta SPC 2 only)

Description of Scenario [11] : Post application - Disposal of lime product
According to the information reported in the provided field study, after the maturation task, the lime powder is swept off the treated floor and thrown into a suitable bag corresponding to the cleaning task. During this cleaning task, dermal and inhalation exposure of the professional can occur. For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 7a have been used. For inhalation exposure, measurements of professionals during the cleaning task have been provided by the field study. The results for inhalation exposures (95th percentile) from the study are as follow: - For full shift (normalised over 8 hours): 0.23 mg /m^3; - For task only: 2.79 mg/ m^3. For Tiers 3, a respiratory protection (APF 4) is taken into account.

Calculations for Scenario [11]

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Field study	Tier 3/no PPE	1.69E-02	9.35E+01	9.35E+01
	Tier 3a/ gloves	1.69E-02	4.67E+00	4.69E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Field study	Tier 3/no PPE	2.68E-04	1.48E+00	1.48E+00
	Tier 3a/ gloves	2.68E-04	7.40E-02	7.43E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	8.37E-01
	Tier 3b/ RPE (APF 4)	2.09E-01

Disinfection of floors of outdoor animal enclosures

As disclaimed in the SPC, the products could be used outdoor for the disinfection surfaces of animal enclosures (poultry).

Compared to the scenario [7], the variability of the model depends on only one parameter: the work area.
Indeed, in this context, both the source and the worker are located outdoors and not in a room with a specific size enclosed by walls on each side and a roof on top limiting the concentration of the product in the air.
As indoor scenarios have also been developed in the assessment and are worst case scenarios, it was considered more relevant to assess the outdoor exposure in very different conditions. Therefore, for outdoor scenarios, it was considered that the source of exposure was not located close to the building in order to simulate exposure during application in a wide open area.

Otherwise, the same parameters than those chosen and calculated for scenario [6] applied.

Calculations for Scenario [6]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6]	Tier 1/no PPE	1.47E-01	4.19E+00	4.34E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6]	Tier 1/no PPE	2.27E-03	6.45E-02	6.68E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m³)**
Scenario [6]	Tier 1/no PPE	3.30E+01
Scenario [6]	Tier 2b/ RPE (APF 40)	8.25E-01

Scenario [12]: Application– Manual spreading of dry product onto ground of animal enclosure (poultry) using a shovel – outdoor (Meta SPC 2 only)

The scenario [12] has been split into 2 sub-scenario taking into account minimum and maximum surfaces to be treated for poultry:

- Scenario [12a]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area (outdoor);**
- Scenario [12b]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area (outdoor).**

Description of Scenario [12a]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area (outdoor)**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during this task.
An application rate of 83.2 kg/min is calculated based on the intended dose of 4 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) is **542** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration on active substance in the meta-SPC 2 (30%) has been taken into account to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of bp/min is retained.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours), **1.8** mg bp/m^3
- For task only (19 min), **45** mg/ m^3.

For Tiers 2b, a respiratory mask APF 40 is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	19	see calculation above
	Dermal exposure – Hand only (mg/min)	542	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.8	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [12a]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [12a]	Tier 1/no PPE	1.33E-01	7.59E+01	7.60E+01
Scenario [12a]	Tier 2a/gloves	1.33E-01	3.79E+00	3.93E+00

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [12a]	Tier 1/no PPE	2.10E-03	1.20E+00	1.20E+00
Scenario [12a]	Tier 2a/gloves	2.10E-03	6.01E-02	6.22E-02

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [12a]	Tier 1/no PPE	1.35E+01
Scenario [12a]	Tier 2b/ RPE (APF 40)	3.38E-01

Description of Scenario [12b] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area (outdoor)**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during this task. An application rate of 83.2 kg/min is calculated based on the dose of 4 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above. A dermal exposure (75th percentile) is **542** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 10 – 100 kg of bp/min is retained as it corresponds to the dose range proposed by the model for a manual task.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):
- For full shift (normalised over 8 hours), **15** mg bp/m^3
- For task only (160 min), **45** mg/ m^3.

For Tiers 2, a respiratory protection APF 40 is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	160	see calculation above
	Dermal exposure – Hand only (mg/min)	542	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	15	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	BHEEM

Calculations for Scenario [12b]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**

Summary table: systemic exposure from professional uses				
Scenario [12b]	Tier 1/no PPE	1.11E+00	6.39E+02	6.40E+02
Scenario [12b]	Tier 2/gloves + RPE (APF 40)	2.76E-02	3.19E+01	3.20E+01

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [12b]	Tier 1/no PPE	1.75E-02	1.01E+01	1.01E+01
Scenario [12b]	Tier 2a/gloves	1.75E-02	5.06E-01	5.23E-01

Local exposure – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m³)**
Scenario [12b]	Tier 1/no PPE	1.35E+01
Scenario [12b]	Tier 2b/ RPE (APF 40)	3.38E-01

Measured inhalation exposure from field study- disinfection of outdoor floor surfaces

In the field study, no inhalation exposure measurements have been performed for outdoor application of lime products for surface disinfection. All the measurements have been performed for indoor activities (for more details please refer to the paragraph "*Monitoring data"* of the PAR).
It is assumed that inhalation exposure of professionals during outdoor manual application of powder product is of a low order compared to indoor application. Thus, it is considered that outdoor inhalation exposure is covered by the indoor exposure applying the same PPE. Please refer to scenario [7].

Scenario [13]: Loading – Semi automated loading into the tank of a tractor for disinfection of outdoor floors (Meta SPC 2 only)

Description of Scenario [13]

The product is available in big bags of 750 kg, which are mechanically raised and emptied into the tank of a tractor for application of the product onto floors of animal enclosures.

During this task, it's considered that the worker remains in the cabin of the tractor (partial enclosure) during the full discharge of the bag.

RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model). An application rate of 25 kg/min and a task duration of 10 min are taken into consideration by making the worst case hypothesis that worker holds the bag during the unloading.

The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2). For Tier 2, gloves are taken into account.

Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s and a transfer of 100 – 1000 kg of active substance/min. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.

The predicted 75th percentile obtained is equal to (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours), **0.18** mg bp/m^3
- For task only (10min), **8.8** mg/ m^3.

For Tier 2, a respiratory protection (mask with APF 40) is taken into account.

	Parameters	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.18	ART Model
	Inhalation exposure (mg/m^3)- task only	8.8	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	BHEEM

Calculations for Scenario [13]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13]	Tier 1/no PPE	1.33E-02	4.19E+00	4.20E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13]	Tier 1/no PPE	2.10E-04	6.64E-02	6.66E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [13]	Tier 1/no PPE	2.64E+00
Scenario [13]	Tier 2b/ RPE (APF 40)	6.60E-02

Scenario [14]: Application–Semi automated application of dry product onto ground of animal enclosure (poultry) – outdoor (Meta SPC 2 only)

As claimed in the SPC, the product could be used outdoor for the disinfection of the floor surfaces of poultry by semi-automated spreading.

In this context, both the source and the operator are located outdoor where the concentration of the product in the air is not retained by walls and roof top as in indoor conditions. This difference of exposure is taken into account in the modelling.

The scenario [14] has been split into 2 sub-scenario taking into account minimum and maximum surfaces to be treated for poultry:

- Scenario [14a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area (outdoor);**
- Scenario [14b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area (outdoor).**

Description of Scenario [14a] : Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area outdoor**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 333 kg/min is calculated based on the dose of 4 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
As the model does not allow entering a dose value up to **225** kg/min this dose has been selected.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of bp/min is retained as it corresponds to the dose range proposed by the model for an automatic process.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **0.12** mg bp/m^3
- For task only (5 min): **11** mg/ m^3.

For Tiers 2, a respiratory protection is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.12	ART Model

Description of Scenario [14a] : Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area outdoor**			
	Inhalation exposure (mg/m^3)- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 20	BHEEM

Calculations for Scenario [14a]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14a]	Tier 1/no PPE	8.84E-03	9.17E-01	9.26E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14a]	Tier 1/no PPE	1.40E-04	1.45E-02	1.47E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [14a]	Tier 1/no PPE	3.30E+00
	Tier 2b/ RPE (APF 20)	1.65E-01

Description of Scenario [14b] : Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area outdoor**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 333 kg/min is calculated based on the dose of 4 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m2/min calculated above.
As the model does not allow entering a dose value up to **225** kg/min this does has been selected.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. Then the concentration in active substance in the meta-SPC 2 (30%) is considered to estimate the inhalation exposure of the professional during the task.
A transfer of 100 – 1000 kg of bp/min is retained as it corresponds to the dose range proposed by the model for an automatic process.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours): **0.96** mg bp/m^3
- For task only (40 min): **11** mg/ m^3.

For Tiers 2, a respiratory protection (APF 20) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	$CaOH_2$ concentration	30%	Applicant's data
	Assumed calcium fraction	44.2%	Applicant's data
	Assumed magnesium fraction	0.7%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	24.9	RISKOFDERM Model
	Inhalation exposure (mg/m3)- full shift	0.96	ART Model
	Inhalation exposure (mg/m3)- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017

Description of Scenario [14b] : Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area outdoor**			
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 20	BHEEM

Calculations for Scenario [14b]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14b]	Tier 1/no PPE	1.14E-01	1.19E+01	1.20E+01
Scenario [14b]	Tier 2a/gloves	1.14E-01	5.93E-01	7.08E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14b]	Tier 1/no PPE	4.80E-03	4.98E-01	5.03E-01

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [14b]	Tier 1/no PPE	3.30E+00
	Tier 2b/ RPE (APF 20)	1.65E-01

Scenario [15]: Cleaning – Disposal of empty bags (Meta SPC 2 only)

Description of Scenario [15]
After loading the lime powder from the big bags into the tank of a tractor using a forklift or a tele handler (with a closed cabin), the bags are disposed of still using the same apparatus. For the disposal of small bags (25 kg), the potential exposure during this task is considered covered by the assessment performed for the manual application on the floor (using a shovel). Indeed, the potential exposure during this task is deemed to be of a lower extend compared to the application. The same parameters than those presented in scenario [10] have been used. Please for details refer to scenario [10]

Calculations for Scenario [15]

Systemic exposure – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [15]	Tier 1/no PPE	1.40E-03	-	1.40E-03

Systemic exposure – magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [15]	Tier 1/no PPE	2.22E-05	-	2.22E-05

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [15]	Tier 1/no PPE	2.73E-01

Combined exposure (M&L + application)

Regarding the very low systemic exposure during the disposal phase (please refer to the systemic calculations), the scenario [15] has not been taken into account in the combined exposure.

- ***Manual process (M&L and application)***

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 6+12a	Tier 1/no PPE	2.80E-01	8.01E+01	8.03E+01
	Tier 2a/gloves	2.80E-01	4.00E+00	4.28E+00
Scenario 6+12b	Tier 1/no PPE	1.25E+00	6.43E+02	6.44E+02
	Tier 2/gloves for loading and gloves + mask APF 40 for application	1.75E-01	3.22E+01	3.23E+01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 6+12a	Tier 1/no PPE	4.37E-03	1.27E+00	1.27E+00
	Tier 2a/gloves	4.37E-03	6.33E-02	6.77E-02
Scenario 6+12b	Tier 1/no PPE	1.98E-02	1.02E+01	1.02E+01
	Tier 2a/gloves	1.98E-02	5.09E-01	5.29E-01

- ***Semi-automated process (loading and application)***

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 13+14a	Tier 1/no PPE	2.21E-02	5.91E-02	8.12E-02
Scenario 13+14b	Tier 1/no PPE	1.28E-01	1.19E+01	1.20E+01
	Tier 2a/gloves	1.28E-01	8.03E-01	9.31E-01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 13+14a	Tier 1/no PPE	3.50E-04	8.09E-02	8.13E-02
Scenario 13+14b	Tier 1/no PPE	5.01E-03	5.64E-01	5.69E-01

Scenario [16]: – Disposal of lime product after application (Meta SPC 2)

Description of Scenario [16] – Post application – Disposal of lime product after application
According to the information reported in the provided field study, after the maturation step, the lime powder is swept off the treated floor and thrown into a suitable bag. During this cleaning task, dermal and inhalation exposure of the professional can occur. For inhalation exposure, the exposure measurements obtained for indoor activities described in the study have been used as a worst case approach. For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 7a has been used. The results for inhalation exposures (95th percentile) from the study are as follow: - For full shift (normalised over 8 hours): 0.23 mg /m^3; - For task only: 2.79 mg/ m^3. For Tiers 3, a respiratory protection (APF 4) is taken into account.

Calculations for Scenario [16]

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Field study	Tier 3/no PPE	1.69E-02	9.35E+01	9.35E+01
	Tier 3a/ gloves	1.69E-02	4.67E+00	4.69E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Field study	Tier 3/no PPE	2.68E-04	1.48E+00	1.48E+00
	Tier 3a/ gloves	2.68E-04	7.40E-02	7.43E-02

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	8.37E-01
	Tier 3b/ RPE (APF 4)	2.09E-01

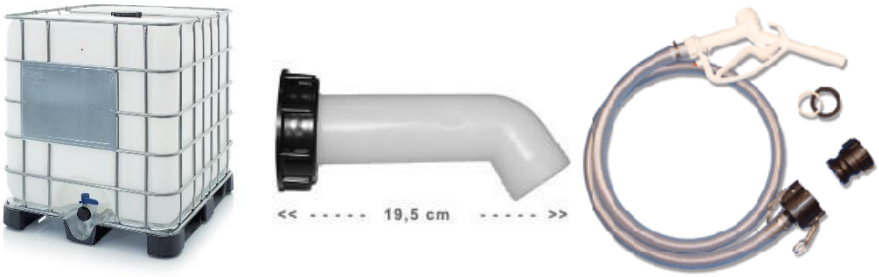
Disinfection of animal accommodations walls using a brush

Scenario [17] – Semi-automatic loading of the product from IBC/IDRA container to buckets for walls disinfection (Meta SPC 3 only)

Description of Scenario [17]

The products from META SPC 3 are available in IBC containing up to 1000 kg of product used for manual application of lime on walls using a brush.

The 1m³ IBCs are fitted with a drain valve, which can be fitted with a drain spout, or dispensing gun (see pictures below), and raised, which allows loading the product by gravity into buckets. Therefore, semi-automatic loading is expected.



Calcium hydroxide has a low vapour pressure (below 10^{-5} Pa), therefore no exposure by inhalation is expected during this task.

To determine dermal exposure during the semi-automatic loading, RISKOFDERM Toolkit for loading liquid, partly automated, has been used (HEEG Opinion 1).

Considering the application dose of 0.25 L/m^2 disclaimed in the SPC and the worst-case wall area for turkeys sheds of 1320 m^2 (ESD document for PT3), the worst-case volume of product to be painted on walls can be calculated as:

-330 L (0.25 L/m^2 × 1320 m^2 =330 L)

The applicant did not submit any information regarding time duration for the loading of 330 L of milk of lime before application on walls. Therefore, the exposure duration of the professional has been calculated based on several assumptions :
-Time spent for each loading in the bucket of 0.5 min;
-Volume of bucket = 20 L.

Considering these values and the worst-case volume of product calculated above, the duration of exposure has been calculated as :

- t= 8.25 min ((330 L/20 L) * 0.5 min = 8.25 min)

	Parameters	Value	References
Tier 1/no PPE	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2	Applicant's data

Description of Scenario [17]			
	Assumed magnesium fraction	1.1	Applicant's data
	Duration (min)	8.25	See calculation above
	Dermal exposure – Hands (mg b.p/min)	2.8	HEEG Opinion 1 (2008)
	Dermal exposure – Body (mg b.p/min)	8.7	HEEG Opinion 1 (2008)
	Dermal absorption	100%	Default value, CAR
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)

Calculations for Scenario [17]

Systemic effect - calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 17 – Semi-automatic loading to a bucket	Tier 1/ no PPE	-	4.30E-01	4.30E-01

Systemic effect - magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 17 – Semi-automatic loading to a bucket	Tier 1/ no PPE	-	1.74E-02	1.74E-02

Scenario [18] – Manual application on walls using a brush (Meta SPC 3 only)

Description of Scenario [18]
Exposure of the professional to the product may occur during painting on walls using a brush. Dermal exposure and inhalation exposure (splashes and aerosols) are expected during this task. According to the Ad Hoc Recommendation 10 (2016), dermal exposure is evaluated using Austrian/BfR study results and inhalation exposure using Consumer Product Painting Model 3. Considering the worst-case wall surface to be brushed (1320 m^2 for turkey sheds), an exposure duration of 6 hours has been considered according to expert judgment and duration of application by brush mentioned in the Excel spreadsheet for PT2-6-7-10-18 for brushing liquid in the *Biocides Human Health Exposure Methodology* (BHHEM, 2015). Considering the products of the META SPC 3 are water-based products and that hydrated lime is low-volatile, the indicative exposure value from the model are as follows: - Body: **1.7 µL/min**; - Hands: **4.07 µL/min;** - Inhalation: **1.63 mg/m³.**

	Parameters	Value	References
Tiers 1/no PPE	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2	Applicant's data
	Assumed magnesium fraction	1.1	Applicant's data
	Duration (min)	360	BHEEM, 2015 Expert judgment
	Density	1.394	Applicant's data
	Dermal exposure – Hand (mg b.p/min)	5.67	Ad Hoc Recommendation 10 (2016)
	Dermal exposure – Body (mg b.p/min)	2.37	Ad Hoc Recommendation 10 (2016)
	Inhalation (mg b.p/m^3)	1.63	Ad Hoc Recommendation 10 (2016)
	Inhalation absorption	100%	Default value, CAR
	Dermal absorption	100%	Default value, CAR
	Inhalation rate (m^3/h)	1.25	Ad Hoc Recommendation 14 (2017)
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
Tier 2a	Gloves	10% penetration	HEEG Opinion 9 (2010)
Tier 2b	Respiratory protection	RPE APF 4	BHEEM

Calculations for Scenario [18]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [18]	Tier 1/no PPE	5.54E-02	1.31E+01	1.32E+01
Scenario [18]	Tier 2a/gloves	5.54E-02	4.79E+00	4.85E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [18]	Tier 1/no PPE	2.30E-03	5.45E-01	5.48E-01
Scenario [18]	Tier 2a/gloves	2.30E-03	1.99E-01	2.01E-01

Local effect – calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m³)**
Scenario [18]	Tier 1/no PPE	8.15E-01
Scenario [18]	Tier 2b/ RPE (APF 4)	2.04E-01

Combined Exposure (scenario 17 + 18)

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 17+18	Tier 1/no PPE	5.54E-02	1.36E+01	1.36E+01
	Tier 2a/gloves	5.54E-02	5.13E+00	5.18E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 17+18	Tier 1/no PPE	2.30E-03	5.63E-01	5.65E-01
	Tier 2a/ gloves	2.30E-03	2.13E-01	2.15E-01

Scenario [19] – Cleaning of the brush equipment (Meta SPC 3 only)

According to the HEEG Opinion 11, it is expected that for water-based paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands. The products of the META SPC3 being a water-based products, no exposure during cleaning of the brush equipment is expected.

Scenario [20]: Secondary exposure – Contact with wet treated surfaces - Post application (Meta SPC 3 only)

Description of Scenario [20]			
Dermal exposure of the professional (adult) touching the wet wall with hands just after lime washing can occur. Considering that the milk of lime is a suspension strongly adhering to the wall to be efficiency, it can be compared to a paint. Therefore, the exposure assessment is performed according to the parameters of wet residues agreed in the Head Hoc Recommendation 5. The assumed calcium and magnesium fractions of the milk of lime has been considered in the calculation considering the dilution of the powder in the water (see above for more details). The dermal systemic dose, in mg a.s./kg b.w./d is calculated as follow: **Systemic dose** = (Amount of product in contact with skin* Skin contact factor*Transfer coefficient* Dermal abs)/Body weight			
	Parameters	**Value**	**References**
Tiers 1	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2	Applicant's data
	Assumed magnesium fraction	1.1	Applicant's data
	Product application rate	0.25 L/m^2	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
	Area of hands- palms only of both hands	410 cm^2	
	Proportion of palm hands in contact with wet product	100%	Recommendation 5
	Transfer coefficient from treated surfaces to hand	50%	

Calculations for Scenario [20]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [20]-wet surface	Tier 1/no PPE	-	2.91E+01	2.91E+01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [20]-wet surface	Tier 1/no PPE	-	1.18E+00	1.18E+00

Scenario [21]: Secondary exposure – Contact with dried surfaces -Post application (Meta SPC 3 only)

Description of Scenario [21]			
Dermal exposure of the professional (adult) touching the dried wall with hands well after the application can occur. Considering that the milk of lime is a suspension strongly adhering to the wall to be efficiency, it can be compared to a paint. Therefore, the exposure assessment is performed according to the parameters of dried residues agreed in the HEAd Hoc Recommendation 5. The assumed calcium and magnesium fractions of the milk of lime has been considered in the calculation considering the dilution of the powder in the water. The dermal systemic dose, in mg a.s./kg b.w./d is calculated as follow: **Systemic dose** = (Amount of product in contact with skin* Skin contact factor*Transfer coefficient* Dermal abs)/Body weight			
	Parameters	**Value**	**References**
Tiers 1	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2	See calculation above
	Assumed magnesium fraction	1.1	See calculation above
	Product application rate	0.25 L/m^2	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
	Area of hands-Palm only of both hands	410 cm^2	
	Proportion of palm hands in contact with dried product	40%	Ad Hoc Recommendation 5
	Transfer coefficient of paint from treated surface to hand	3%	

Systemic effect - calcium

Exposure scenario	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [21]	-	7.00E-01	7.00E-01

Systemic effect - magnesium

Exposure scenario	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [21]	-	2.83E-02	2.83E-02

Non-professional exposure

Products from the family are intended to be used by professionals only.

Exposure of the general public

Scenario [22] – Dermal and oral exposure to wet surfaces – Toddler (Meta SPC 3 only)

Description of Scenario [22]			
The secondary exposure of toddlers touching the wet treated walls with a hand to mouth transfer immediately after application is considered. Inhalation of volatilised residues after application (indoors) is considered to be negligible due to the low volatile properties of the active substance. Assessment is performed according the parameters agreed in Ad hoc Recommendation 5: "Non-professional use of antifouling paints: exposure assessment for a toddler".			
	Parameters	**Value**	**References**
Tiers 1	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2	Applicant's data
	Assumed magnesium fraction	1.1	Applicant's data
	Product application rate	225 mL/m^2	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Oral absorption	100%	Default value, CAR
	Toddler body weight (kg)	10	Ad Hoc Recommendation 14 (2017)
	Proportion of hands- palms only of both hands	115.2 cm^2	
	Proportion of palm hand in contact with wet product	100%	Ad Hoc Recommendation 5
	Transfer coefficient of wet product from treated surface to hand	50%	
	Transfer coefficient of wet product from treated surface to mouth	10%	

Systemic effect - calcium

Summary table: systemic exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [22]-wet surface	Tier 1/no PPE	-	4.91E+01	4.91E+00	5.41E+01

Systemic effect - magnesium

Summary table: systemic exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [22]-wet surface	Tier 1/no PPE	-	1.99E+00	1.99E-01	2.19E+00

Scenario [23] – Dermal and oral exposure to dried surfaces – Toddler (Meta SPC 3 only)

Description of Scenario [23]			
The secondary exposure of toddlers touching the dried treated walls with a hand to mouth transfer well after the application is considered. According to the Recommendation 5, it is possible to refine the Tier 1 assessment of dermal exposure and oral exposure through hand-to-mouth transfer of a toddler touching dried antifouling paint on a treated surface by using leaching data.			
	Parameters	**Value**	**References**
Tiers 1	$Ca(OH)_2$ concentration	50%	Applicant's data
	Assumed calcium fraction	27.2%	Applicant's data
	Assumed magnesium fraction	1.1%	Applicant's data
	Product application rate	225 mL/m^2	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Oral absorption	100%	Default value, CAR
	Toddler body weight (kg)	10	Ad Hoc Recommendation 14 (2017)
	Proportion of hands- palms only of both hands	115.2 cm^2	
	Proportion of palm hand in contact with dried product	40%	Recommendation 5
	Transfer coefficient of dried product from treated surface to hand	3%	
	Transfer coefficient of dried product from treated surface to mouth	50%	

Systemic effect - calcium

Summary table: systemic exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [23]	Tier 1/no PPE	-	2.95E+00	1.47E+00	4.42E+00

Systemic effect - magnesium

Summary table: systemic exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [23]	Tier 1/no PPE	-	1.19E-01	5.96E-02	1.79E-01

Monitoring data

Context of the study (LoA to the field study provided by EULA in the context of UA dossiers)

A measurement campaign of professional exposure was realized from February to March 2021 in a greenhouse of 37.8 m^2 without ventilation.

The inhalation exposure of professionals to lime dust has been measured during two tasks:

- the manual application of 25 kg of burnt lime powder onto floor surfaces of animal accommodations (concrete floor) using a shovel or a low impact spreader;
- the cleaning of the treated surfaces using a sweeper and a shovel to pick up the lime powder and throw it in a bag.

It should be noticed that the submitted exposure data are measured data performed in the frame of the OEL regulation. Indeed, this type of report data has to be submitted regularly to ensure that the use of the lime is in line with the OEL regulation.
Considering this the approach relating to the sampling strategy as well as the results calculations were carried out in accordance with the European Standard: EN 689 and NFX 43-289. Notably, reported inhalation exposure data from the study rely to the respirable fraction of lime powder (which is the reference particle fraction for lime OEL), which is not the reference fraction used for the setting of lime AEC value. However, considering the strong over estimation of inhalation exposure when using the exposure models and the absence of regular monitoring data on the inhalable fraction of lime particles, it has been considered that the monitoring study provided a more reliable idea of the inhalation exposure of the professionals than the models.

Worker selection

Before conducting air monitoring, exposed workers were divided into three Homogenous Exposure Groups (HEG). HEG is a group of professionals performing the same tasks and whose exposure profile is considered as similar. It is assumed that the exposure of the sample is representative of the professional user exposure.

Two HEGs have been determined based on the type of spreading: a shovel or a low impact spreader.
Another HEG was identified for the cleaning task. This post application task includes the collect of lime powder using a shovel and its emptying into a bag.

To be in accordance with the recommendations of the European Standard: NFX 43-258, nine measures were collected for each HEG in order to take into consideration the variability of the sources of exposure.

A summary of the three HEGs is presented in the table below.

Summary table : Construction of the Homogeneous Exposure Group

HEG N°	Performed task	Number of measurements	Treatment area	Substance of interest
1	Manual application with a shovel	9	Indoor (37.8m^2)	Calcium oxide
2	Semi-automated application with a low impact spreader	9	Indoor (37.8m^2)	Calcium oxide
3	Cleaning	9	Indoor (37.8m^2)	Calcium oxide

Sampling strategy

Exposure measurements have been repeated 9 times corresponding to 18 days of follow up:

- Day 1 : Manual application with a wheelbarrow and a shovel;
- Day 2 to Day 9 : Cleaning and manual application with a shovel;
- Day 10 to day 18: Cleaning and application with a low impact spreader.

It has been considered in the operating procedure that only one task would be performed per day. In the case where two tasks have to be performed on the same day, an ambient air sampling system is available to ensure that the calcium oxide concentration in air is back to zero before starting the new task.

Two types of sampling have been realized over the total duration of the work function (long term) and over the task duration (short term):

- An ambient air sampling using a sensor placed at 1.5 m from the ground. This type of measurement is not a good indicator of the professional exposure, as it does not take into account the behaviour nor the movement of the operator during the task. Based on it, the measured values obtained from this sampling are not retained for the exposure assessment;

- A personal sampling using a sensor fixed on the worker near his airways. This type of sampling is a good indicator of the professional exposure as it takes into account the behaviour of the worker during the task.

The sampling of the particles and their subsequent analysis have been performed in accordance with the NFX43-259 standard[8].

Ambient particles are sampled by aspiration into a cyclone device. After a selection based on their sizes, the ultrafine particles are aspirated and collected on a filter whereas the larger particles fall to the bottom of the receptacle. Then, the selected particles are treated to determine the concentration of particle per unit volume of air (gravimetric analysis).
The sampling support is composed of a Teflon filter with a porosity of 1 µm and a diameter of 37 mm.

Data processing

The exposure values were calculated from measured concentrations taking into account the duration of the measurement.

- Exposure values to be compared with the short-term reference value (STEL (15 min) = 4 mg/m^3)

Inhalation exposure has been calculated for each task.
As part of the biocidal assessment, the measured raw values are used. A summary of the results obtained is described in the table below.

Table 1: Measured exposure concentrations (mg/m3) on the task duration per HEG

	HEG N°1 (manual application with a shovel)	HEG N°2 (application with a spreader)	HEG N°3 (surface cleaning)
	10.5	1.93	0.453
	1.1	1.28	1.33
	1.02	3.01	1.13
	2.11	3.42	2.3
	8.20	1.55	2.54
	1.28	6.95	2.22
	3.96	2.8	2.95
	1.20	3.54	1.52
	3.30	2.29	1.42
Mean	**3.63**	**2.98**	**1.76**
95th percentile	**9.58**	**5.59**	**2.79**

- Exposure values to be compared with the long term reference value (8-hr TWA = 1 mg/m^3)

The exposure of professionals was calculated for each day of measurement.

Exposure was calculated by weighting the measured concentration to the reference time of a working day (8h). The obtained results were then extrapolated to a maximal surface of 100 m^2.

[8] *Air des lieux de travail. Prélèvement individuel ou à poste fixe de la fraction alvéolaire de la pollution particulaire Méthode de séparation par cyclone 10 mm.*

A summary of the results obtained is described in the table below.

Table 2: Measured Exposure concentrations (mg/m3) on the full shift per HEG

	HEG N°1 (manual application using a shovel)	HEG N°2 (application with a spreader)	HEG N°3 (surface cleaning)
	0.13	0.05	0.012
	0.017	0.029	0.044
	0.028	0.04	0.038
	0.036	0.06	0.073
	0.15	0.026	0.079
	0.033	0.11	0.06
	0.078	0.03	0.09
	0.034	0.05	0.04
	0057	0.03	0.04
Mean	**0.06**	**0.05**	**0.05**
95th percentile	**0.14**	**0.092**	**0.087**

Assessment of the field study values

In the frame of the biocidal assessment, the raw values of inhalation exposure obtained during the experiment have been retained, without weighting to 8hrs working day not extrapolation to 100 m². It has been assumed that the inhalation exposure of professionals during the application of lime product powder does not increase with the treated surface due to the good natural ventilation expected in animal accommodations, the moistening of the soil that is intended before treatment and considering the behaviour of the operator when applying the product (professional gesture and removal from the dust source).

The data from the field study allow to confirm that workers applying lime powder product with a shovel are more exposed than those applying the product with a spreader or performing the cleaning task.

With regard to the manual application of lime using a shovel, a large variability in the exposure levels is observed between professionals. Moreover, measured exposure data are not homogeneous over two different working days, for the same professional.
Taking into account the high variability observed in the data, the 95th percentile values have been retained for the exposure assessment.

Dietary exposure

Regarding intended uses on sewage sludge (TP2 use#1) and manure (TP3 use#2), no dietary exposure is expected.
Regarding intended uses on floors and walls surface indoor in livestock accommodations or transportations (TP3 use#3 and use#5) and uses on floors of outdoor animal enclosures (TP3 use#6), no dietary exposure is expected considering the risk mitigation measure (*"Animals should not be present during all the treatment duration"*).
Regarding intended uses on bedding materials (TP3 use#4), the animals may be in direct contact with the active substance. Therefore, an indirect exposure via food of animal origin might be expected for these uses. eCA has asked the applicant to compare the quantities of active substance as a biocides, to those of already authorized uses in the plant protection framework, including fertilisers. Hence, the applicant has proposed to estimate the animal exposure.
Nevertheless, in view of the toxicological properties of this active substance regarding oral exposure, but also the widely presence of calcium in food, eCA considers that those calculations are overestimated and not necessary to support this dossier.

Information of non-biocidal use of the active substance

Calcium hydroxide is listed as a basic substance (approval date 01/07/2015) in accordance with Regulation (EC) No. 1107/2009. (Implementing Regulation (EU) No 540/2011). It is included in Annex IV to (EC) No. 396/2005 and thus no MRL are required from PPP uses.
Calcium hydroxide islisted in table 1 of Regulation No. 37/2010 annex, as allowed pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.
Calcium hydroxide is also listed in annex II of regulation 1333/2008, as approved food additives at "quantum satis" and in annex II of regulation 1925/2006 as approved food supplements.

Residue definitions

When dissolved in water, calcium hydroxide dissociates into Ca^{2+} and OH-. Calcium is a natural constituent of the body and an essential element of the human diet.

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant Protection Products	Fungicide on various crops	No MRL required for calcium hydroxide. Default MRL of 0.01* mg/kg for calcium oxide
2.	Fertiliser	Application to agricultural soils	-
3.	Veterinary medicinal products	All food producing species	No MRL required
4.	Food additives	Added to some food categories	« Quantum satis »
5.	Food supplements	Mineral added to food	Calcium UL = 2500 mg/d for adults

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The active substance is composed of Ca^{2+}, which is an essential element of the body and an ubiquitous compound used in high amounts as fertilizer. Considering that potential exposure of livestock from the intended uses is expected to be regulated by the animal metabolism, human dietary exposure calculations via products of animal origin related to the intended uses is not considered to be relevant.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

No direct contamination of food is expected regarding to the intended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Only professional uses are intended in this dossier.

Exposure associated with production, formulation and disposal of the biocidal product

Not relevant for this dossier.

Aggregated exposure

Not relevant for this dossier.

Summary of exposure assessment

Systemic effect - calcium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures			
META SPC1			
Scenario [1]– manual loading	Professionals	Tier 1/no PPE	5.93E+00
		Tier 2a/gloves	5.41E-01
Scenario [2a] – semi-automated loading	Professionals	Tier 1/no PPE	6.09E+00
		Tier 2a/gloves	7.03E-01
Scenario [3a] – cleaning of the unit treatment	Professionals	Tier 1/no PPE	8.40E+00
		Tier 2a/gloves	3.57E+00
Scenario [4] – disposal of empty bags	Professionals	Tier 1/no PPE	1.20E-02
META SPC 3			
Scenario [2b]-Semi-automated loading	Professionals	Tier 1/no PPE	4.17E-02
Scenario [3b]-cleaning of the treatment unit	Professionals	Tier 1/no PPE	1.05E+01
		Tier 2a/gloves	4.40E+00
Disinfection of indoor floor of animal accommodations, transportation and bedding materials			
META SPC 2			
Scenario [6] – manual loading	Professionals	Tier 1/no PPE	4.34E+00
Scenario [7a] – manual application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	9.38E+01
		Tier 2a/gloves	4.99E+00
Scenario [7b] – manual application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	7.90E+02
		Tier 2/gloves + RPE (APF 40)	3.94E+01
Scenario [7c] – manual application – indoor – **Minimal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	3.95E+01
		Tier 2a/gloves	2.15E+00
Scenario [7d] – manual application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	2.76E+02
		Tier 2a/gloves	1.46E+01
Scenario [8] – semi-automated loading-indoor	Professionals	Tier 1/no PPE	4.26E+00

Scenario [9a] – semi-automated application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	9.98E-01
Scenario [9b] – semi-automated application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	7.62E+00
Scenario [9c] – semi-automated application – indoor – **Minimal** floor surfaces - C**attle**	Professionals	Tier 1/no PPE	4.77E-01
Scenario [9d] – semi-automated application – indoor – **Maximal** floor surfaces - C**attle**	Professionals	Tier 1/no PPE	2.66E+00
Scenario [10] – Disposal of empty bags	Professionals	Tier 1/no PPE	8.84E-03
Scenario [11] Disposal of lime product after application	Professionals	Tier 1/no PPE	9.35E+01
		Tier 2a/gloves	4.69E+00
Disinfection of floors of outdoor animal enclosures			
META SPC 2			
Scenario [12a] – manual application onto minimal floor surfaces- outdoor - Poultry	Professionals	Tier 1/no PPE	7.60E+01
		Tier 2a/gloves	3.93E+00
Scenario [12b] – manual application onto maximal floor surfaces- outdoor - Poultry	Professionals	Tier 1/no PPE	6.40E+02
		Tier 2/gloves + RPE (APF 40)	3.20E+01
Scenario [13] – Semi-automated loading-outdoor	Professionals	Tier 1/no PPE	4.20E+00
Scenario [14a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	9.26E-01
Scenario [14b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	1.20E+01
		Tier 2a/gloves	7.08E-01
Scenario [15]-Disposal of empty bags	Professionals	Tier 1/no PPE	1.40E-03
Scenario [16]-Disposal of lime product after application	Professionals	Tier 1/no PPE	9.35E+01
		Tier 2a/gloves	4.69E+00
Disinfection of animal accommodations walls using a brush			
META SPC 3			
Scenario [17]- Semi-automated transfer to a bucket	Professionals	Tier 1/no PPE	4.30E-01
Scenario [18]- Manual application on wall by brush	Professionals	Tier 1/no PPE	1.32E+01
Scenario [20]- Dermal contact with wet treated surfaces-	Professionals	Tier 1/no PPE	2.91E+01

Scenario [21]- Dermal contact with dried treated surfaces-	Professionals	Tier 1/no PPE	7.00E-01

Systemic effect - magnesium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures			
META SPC1			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	1.58E-01
Scenario [2a] – semi-automated loading	Professionals	Tier 1/no PPE	1.62E-01
Scenario [3a] – cleaning of the unit treatment	Professionals	Tier 1/no PPE	2.23E-01
Scenario [4] – disposal of empty bags	Professionals	Tier 1/no PPE	3.18E-04
META SPC 3			
Scenario [2b]-Semi-automated loading	Professionals	Tier 1/no PPE	1.73E-03
Scenario [3b]-cleaning of the treatment unit	Professionals	Tier 1/no PPE	4.37E-01
Disinfection of indoor floor of animal accommodations, transportation and bedding materials			
META SPC 2			
Scenario [6] – manual loading	Professionals	Tier 1/no PPE	6,68E-02
Scenario [7a] – manual application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	1.49E+00
		Tier 2a/gloves	7.91E-02
Scenario [7b] – manual application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	1.25E+01
		Tier 2a/gloves	6.61E-01
Scenario [7c] – manual application – indoor – **Minimal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	6.26E-01
		Tier 2a/gloves	3.40E-02
Scenario [7d] – manual application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	4.38E+00
		Tier 2a/gloves	2.31E-01
Scenario [8] – semi-automated loading-indoor	Professionals	Tier 1/no PPE	6.75E-02
Scenario [9a] – semi-automated application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	1.58E-02

Scenario [9b] – semi-automated application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	1.21E-01
Scenario [9c] – semi-automated application – indoor – **Minimal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	7.56E-03
Scenario [9d] – semi-automated application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	4.22E-02
Scenario [10] – Disposal of empty bags	Professionals	Tier 1/no PPE	1.40E-04
Scenario [11] – Disposal of lime product after application	Professionals	Tier 1/no PPE	1.48E+00
Disinfection of floors of outdoor animal enclosures			
META SPC 2			
Scenario [12a] – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	1.20E+00
		Tier 2a/gloves	6.22E-02
Scenario [12b] – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	1.01E+01
		Tier 2a/gloves	5.23E-01
Scenario [13] – Semi-automated loading-outdoor	Professionals	Tier 1/no PPE	6.66E-02
Scenario [14a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	1.47E-02
Scenario [14b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	5.03E-01
Scenario [15] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.22E-05
Scenario [16] – Disposal of lime product after application	Professionals	Tier 1/no PPE	1.48E+00
Disinfection of animal accommodations walls using a brush			
META SPC 3			
Scenario [17]- Semi-automated transfer to a	Professionals	Tier 1/no PPE	1.74E-02
Scenario [18]- Manual application on wall by brush	Professionals	Tier 1/no PPE	5.48E-01
Scenario [20]- Dermal contact with wet treated surfaces-	Professionals	Tier 1/no PPE	1.18E+00
Scenario [21]- Dermal contact with dried treated surfaces-	Professionals	Tier 1/no PPE	2.83E-02

Local effect – calcium hydroxide

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures			
META SPC1			
Scenario [1] – manual loading	Professionals	Tier 1/no RPE	1.62E+01
		Tier 2b/ RPE (APF 40)	4.06E-01
Scenario [2a] – semi-automated loading	Professionals	Tier 1/no RPE	1.19E+01
		Tier 2b/ RPE (APF 40)	2.98E-01
Scenario [3a] – cleaning of the unit treatment	Professionals	Tier 1/no RPE	1.62E+01
		Tier 2b/ RPE (APF 40)	4.06E-01
Scenario [4] – disposal of empty bags	Professionals	Tier 1/no RPE	3.99E+00
		Tier 2b/ RPE (APF 20)	2.00E-01
META SPC 3			
Scenario [3b]-cleaning of the treatment unit	Professionals	Tier 1/no RPE	1.16E+01
		Tier 2b/ RPE (APF 40)	2.90E-01
Disinfection of indoor floor of animal accommodations, transportation and bedding materials			
META SPC 2			
Scenario [6] – manual loading	Professionals	Tier 1/no RPE	2.91E+01
		Tier 2b/ RPE (APF 40)	7.28E-01
Scenario [7a] – manual application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no RPE	3.30E+01
		Tier 2b/ RPE (APF 40)	8.25E-01
Scenario [7b] – manual application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no RPE	2.91E+01
		Tier 2b/ RPE (APF 40)	7.28E-01
Scenario [7c] – manual application – indoor – **Minimal** floor surfaces - **Cattle**	Professionals	Tier 1/no RPE	4.20E+01
		Tier 2b/ RPE (APF 40)	1.05E+00
Scenario [7d] – manual application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no RPE	2.91E+01
		Tier 2b/ RPE (APF 40)	7.28E-01
Scenario [7] – manual loading + application onto floor surfaces- indoor – **Field study**	Professionals	Tier 1/no RPE	2.87E+00
		Tier 3b/ RPE (APF 10)	2.87E-01
Scenario [8] – semi-automated loading-indoor	Professionals	Tier 1/no RPE	1.35E+01
		Tier 2b/ RPE (APF 40)	3.38E-01
	Professionals	Tier 1/no RPE	3.30E+01

Scenario [9a] – semi-automated application – indoor – **Minimal** floor surfaces - **Poultry**		Tier 2b/ RPE (APF 40)	3.30E+01
Scenario [9b] – semi-automated application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no RPE	1.35E+01
		Tier 2b/ RPE (APF 40)	3.38E-01
Scenario [9c] – semi-automated application – indoor – **Minimal** floor surfaces - **Cattle**	Professionals	Tier 1/no RPE	1.08E+02
		Tier 2b/ RPE (APF 40)	2.70E+00
Scenario [9d] – semi-automated application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no RPE	1.35E+01
		Tier 2b/ RPE (APF 40)	3.38E-01
Scenario [9] – Semi automated loading + application onto floor surfaces- indoor – **Field study**	Professionals	Tier 1/no RPE	1.68E+00
		Tier 2b/ RPE (APF 10)	1.68E-01
Scenario [10] – Disposal of empty bags	Professionals	Tier 1/no RPE	1.71E+00
		Tier 2b/ RPE (APF 10)	1.71E-01
Scenario [11] – Disposal of lime product after application	Professionals	Tier 1/no RPE	8.37E-01
		Tier 3b/ RPE (APF 4)	2.09E-01
Disinfection of floors of outdoor animal enclosures			
META SPC 2			
Scenario [12a] – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no RPE	1.35E+01
		Tier 2b/ RPE (APF 40)	3.38E-01
Scenario [12b] – manual application onto **maximal** floor surfaces- outdoor - **Poultry** Scenario [12] – manual loading + application onto floor surfaces- outdoor – **Field study**	Professionals Professionals	Tier 1/no RPE	1.35E+01
		Tier 2b/ RPE (APF 40)	3.38E-01
		Tier 3/no RPE	2.87E+00
		Tier 3b/ RPE (APF 10)	2.87E-01
Scenario [13] – Semi-automated loading-outdoor	Professionals	Tier 1/no RPE	2.64E+00
		Tier 2b/ RPE (APF 40)	6.60E-02
Scenario [14a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no RPE	3.30E+00
		Tier 2b/ RPE (APF 40)	8.25E-02
Scenario [14b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no RPE	3.30E+00
		Tier 2b/ RPE (APF 40)	8.25E-02
	Professionals	Tier 3/no RPE	1.68E+00

Scenario [14] – Semi automated loading + application onto floor surfaces- outdoor– **Field study**		Tier 3b/ RPE (APF 10)	1.68E-01
Scenario [15] – Disposal of empty bags	Professionals	Tier 1/no RPE	2.73E-01
Scenario [15] – Disposal of lime product	Professionals	Tier 1/no RPE	8.37E-01
		Tier 3b/ RPE (APF 4)	2.09E-01
Disinfection of animal accommodations walls using a brush			
META SPC 3			
Scenario [18]- Manual application on wall by brush	Professionals	Tier 1/no PPE	8.15E-01
		Tier 2b/ RPE (APF 4)	2.04E-01

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference values to be used in Risk Characterisation – **calcium hydroxide ($Ca(OH)_2$)**

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEC short, medium & long-term	human volunteers (respiratory tract)	1 mg/m^3	3.2	-	0.3 mg/m^3

[1] default for dynamic intraspecies differences

Reference values to be used in Risk Characterisation – **calcium (Ca^{2+})**

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEL short, medium & long-term (UL calcium)*	-	-	-	-	42 mg/kg bw/day

Reference values to be used in Risk Characterisation – **magnesium (Mg^{2+})**

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEL short, medium & long-term (UL magnesium)*	-	-	-	-	4.2 mg/kg bw/day

* According to the CAR, exposure to calcium and magnesium **has to be less than 13%** of the **UL** to show an acceptable risk.

This arbitrary cut-off value of 13% of the ULs has been proposed as a threshold value for the contribution of calcium and magnesium from use of the lime products. This value was determined based on the results of the RA performed on the representative uses of the CAR, i.e. disinfection of sludge's and manures.
It is important to note that this cut-off value of 13% of UL is not designated as a toxicological reference value in the agreed document on active substances; i.e the list of endpoints (LoEP) and the BPC opinion. It is only presented in the introduction of the document I of the CAR.

The relevance of this value to conclude on the acceptability of the risk for the disinfection of floor surfaces may be questionable.
Indeed, as stated above, this value is directly related to the RA performed on the representative uses of the CAR that doesn't include disinfection of floor surfaces.
For the disinfection of sludge and manure (uses from the CAR), professional exposure is considered limited due to process automation, which is not the case during manual application of lime product on floor surfaces and bedding materials.
Consequently, an exceedance of 13% of the UL is expected for uses where more exposure to lime product occurs.

Furthermore, professional exposure during the disinfection of sludge and manure has been estimated using a field study available in the CAR.

In the PAR, a worst-case assessment has been performed by rMS to estimate systemic exposure during disinfection of floor and bedding materials. This assessment is based on many assumptions and the use of ART (Advanced Reach Tool) and Riskofderm Models leading to an overestimation of the systemic exposure.

Even when considering a recommended daily intake of 950 mg Ca^{2+}/d (corresponding to 15.8 mg/kg bw/d) from the diet[9], it can be demonstrated that the total calcium intake is still below the UL value for almost all scenarios excepted for the manual disinfection of a maximal surface value of 3330 m^2 (corresponding to poultry) (= scenario [7b] even with PPE.

The total calcium intake obtained for scenario [7b] can be calculated as follow:

TDI = 950 mg Ca^{2+}/d + 2364 mg Ca^{2+}/d = 3314 mg Ca^{2+}/d, which is above the UL value for calcium (2,500 mg Ca^{2+}/d)[10].

However, it is important to emphasize that, as described above, a worst-case assessment has been carried out for this scenario based on many assumptions (surfaces default value, walking speed value, task time duration, etc.) and the use of exposure models.
Thus, the indicative value obtained with RISKOFDERM can be considered as a worst-case value. Furthermore, the application rate of 5 kg pb/m^2 retained for this assessment is the application rate claimed by the applicant that is above the dose of 800 g/m^2 relevant for this use and corresponding to 4 kg/pb/m^2 (considering a product containing 20% a.s for Meta SPC 2) as claimed for the outdoor application (scenario [12]).
Considering this value, a calcium exposure value of 1920 mg/d (corresponding to 32 mg/kg bw/d) is estimated.
A TDI of 2870 mg Ca^{2+}/d (= 1920 + 950) is therefore calculated which is slightly above the UL value.
Considering all the uncertainties related to the exposure modelisation, the rMS is of the opinion that the risk is acceptable for the professionals during application of lime product.

Hence, the RA has been performed for systemic risk assessment using the UL values of 2,500 mg Ca^{2+}/d (= 42 mg/kg bw/d) and 250 mg/d (= 4.2 mg/kg bw/d) for Mg^{2+} as TRV.

This position has been discussed and agreed at the European level in the frame of the assessment of another lime based product dossier.

Maximum residue limits or equivalent
S**e**e Summary table of other (non-biocidal) uses.

Specific reference value for groundwater
No specific reference value for groundwater is required, due to the natural background levels of lime variants in soil and water.

Risk for industrial users

[9] Data from the French Agency for food, Environmental and Occupational Health and Safety (Anses,update January 2020), in line with values available in other European countries.
[10] Scientific opinion on the Tolerable Upper Intake Level of calcium, Efssa Journal 2012; 10(7): 2814

Not applicable.

Risk for professional users

Uses # 1.1 & 1.2 - Disinfection of sewage sludge and manures-indoor and outdoor

META SPC 1

Systemic effects (calcium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
META SPC 1					
Scenario [1] – manual loading	Tier 1/no PPE	42	5.93E+00	14.13%	YES
Scenario [2a] – semi-automated loading	Tier 1/no PPE	42	6.09E+00	14.51%	YES
Scenario [3a]-cleaning of the unit treatment	Tier 1/no PPE	42	8.40E+00	19.99%	YES
Scenario [4]-disposal of empty bags	Tier 1/no PPE	42	1,20E-02	0.03%	YES

Combined exposure – [Loading phase + cleaning phase]

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario 1-3a	Tier 1/no PPE	42	1.43E+01	34.12%	YES
	Tier 2a/ gloves		4.11E+00	9.78%	YES
Scenario 2a-3a	Tier 1/no PPE	42	1.45E+01	34.50%	YES
	Tier 2a/ gloves		4.27E+00	10.16%	YES

Systemic effects (magnesium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [1] – manual loading	Tier 1/no PPE	4.2	1.58E-01	3.75%	YES
Scenario [2a] – semi-automated loading	Tier 1/no PPE	4.2	1.62E-01	3.86%	YES
Scenario [3a]-cleaning	Tier 1/no PPE	4.2	2.23E-01	5.31%	YES
Scenario [4]-Disposal of empty bags	Tier 1/no PPE	4.2	3.18E-04	0.01%	YES

Combined exposure – [Loading phase + cleaning phase]

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario 1-3a	Tier 1/no PPE	42	3.81E-01	9.06%	YES
	Tier 2a/ gloves		1.09E-01	2.60%	YES
Scenario 2a-3a	Tier 1/no PPE	42	3.85E-01	9.17%	YES
	Tier 2a/ gloves		1.97E-01	4.68%	YES

- **(Semi)-quantitative local risk assessment (inhalation exposure)**

Task/ Scenario	Tier	AEC mg/m3	Estimated uptake mg/m3	Estimated uptake/ AEC (%)
Scenario [1] – manual loading	Tier 1/no RPE	0.3	1.62E+01	5413.3%
	Tier 2b/ RPE (APF40)	0.3	4.06E-01	135.3%
Scenario [2a] – semi-automated loading FORKLIFT - indoor	Tier 1/no RPE	0.3	1.19E+01	3966.7%
	Tier 2b/ RPE (APF40)	0.3	2.98E-01	99.2%
Scenario [3a] – cleaning of the unit treatment	Tier 1/no RPE	0.3	1.62E+01	5413.3%
	Tier 2b/ RPE (APF40)	0.3	4.06E-01	135.3%
Scenario [4] – Disposal of empty bags	Tier 1/no RPE	0.3	3.99E+00	1330.0%
	Tier 2b/ RPE (APF20)	0.3	2.00E-01	66.5%

META SPC 3

Systemic effects (calcium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable
Scenario [2b] – semi-automated loading	Tier 1/no PPE	42	4.17E-02	0.10%	YES
Scenario [3b]-cleaning	Tier 1/no PPE	42	1.05E+01	25.05%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable
Semi-automated loading – cleaning tasks	Tier 1/no PPE	42	1.06E+01	25.15%	YES
	Tier 2a/ gloves		4.44E+00	10.58%	YES

Systemic effects (magnesium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable
Scenario [2b] – semi-automated loading	Tier 1/no PPE	4.2	1.73E-03	0.04%	YES
Scenario [3b]-cleaning	Tier 1/no PPE	4.2	4.37E-01	10.41%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable
Semi-automated loading – cleaning tasks	Tier 1/no PPE	4.2	4.39E-01	10.45%	YES

- **(Semi)-quantitative local risk assessment (inhalation exposure)**

Task/ Scenario	Tier	AEC mg/m3	Estimated uptake mg/m³	Estimated uptake/ AEC (%)
Scenario [3b] – cleaning of the unit treatment	Tier 1/no RPE	0.3	1.16E+01	3867%
	Tier 2/ RPE (APF40)		2.90E-01	96.7%

- **<u>Qualitative local risk assessment</u>**

The products of the meta-SPC 1 & 3 are classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and are intended to be applied by professionals. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects for a product classified H315- H318 – H335 - - Disinfection of sewage sludge and manures

Hazard			Exposure				Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)	Risk	
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMM & PPE**	**Conclusion on risk**
High	Eye Dam.1, H318	-	2&3	Professionals	Opening and handling bags (only for Meta SPC 1) Loading Cleaning	Dermal Sources for contamination being from: - opening and handling bags (only for Meta SPC 1) - cleaning - hand to eye transfer	few minutes per day or less	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following PPE : Wear chemical goggles	Acceptable following the relevant RMM and PPE
Low	Skin Irrit.2, H315	-				Dermal Sources for contamination being from: - opening and handling bags(only for Meta SPC 1) - cleaning	More than few minutes but equal to or less than few hours per day	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following PPE: - Wear:	

Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags (only for Meta SPC 1) - cleaning	More than few minutes but equal to or less than few hours per day	- Substance/ task appropriate gloves - Protection coverall - Face shield - Substance/ task appropriate respirator	

Disinfection of sewage sludge's and manures (Uses #1.1 & 1.2) - Conclusion:

*__For Meta-SPC 1__

Acceptable risks are shown for human health **only by semi- automated process** (including loading and disposal of empty bags) considering the following PPE are worn:

- gloves;
- protective coverall;
- 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).

In addition to the above mentioned PPE, the following RMMs are required:

- 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).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.

*__For Meta-SPC 3__

Acceptable risks are shown for human health considering the following PPE are worn
During the loading into the unit treatment:

- gloves;
- protective coverall;
- face shield

During the cleaning of the unit treatment:

- gloves;
- protective coverall;
- chemical goggles
- 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)

Moreover, it is also likely that the addition of calcium hydroxide to sewage or manure leads to the production of ammonia gas, which may be of concern. During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is requiredin absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.

Additional RMM for both meta-SPC are required:

- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge and 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 EU OEL of 14 mg/m^3 for this gas.

Disinfection of indoor floor surfaces of animal accommodations, transportation and bedding materials

META SPC 2

Systemic effects (calcium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [6] – manual loading for floor application	Tier 1/no PPE	42	4.34E+00	10.33%	YES
Scenario [7a] – manual application onto **minimal floor surfaces- indoor - Poultry**	Tier 1/no PPE	42	9.38E+01	223.37%	NO
	Tier 2a/ gloves		4.99E+00	11.88%	YES
Scenario [7b] – manual application onto **maximal floor surfaces- indoor - Poultry**	Tier 1/no PPE	42	7.90E+02	1880.25%	NO
	Tier 2/ gloves + mask		3.94E+01	93.87%	YES
Scenario [7c] – manual application onto **minimal floor surfaces- in**door - Cattle	Tier 1/no PPE	42	3.95E+01	94.15%	NO
	Tier 2a/ gloves		2.15E+00	5.11%	YES
Scenario [7d] – manual application onto **maximal floor surfaces- indoor - Cattle**	Tier 1/no PPE	42	2.76E+02	658.05%	NO
	Tier 2a/ gloves		1.46E+01	34.74%	YES
Scenario [8] – semi-automated loading- indoor	Tier 1/no PPE	42	4.26E+00	10.14%	YES
Scenario [9a] – Semi-automated application onto **minimal floor surfaces- indoor - Poultry**	Tier 1/no PPE	42	9.98E-01	2.38%	YES
Scenario [9b] – Semi-automated application onto **maximal floor surfaces- indoor - Poultry**	Tier 1/no PPE	42	7.62E+00	18.14%	YES
Scenario [9c] – Semi-automated application onto **minimal floor surfaces- indoor - Cattle**	Tier 1/no PPE	42	4.77E-01	1.14%	YES
Scenario [9d] – Semi-automated application onto **maximal floor surfaces- indoor – Cattle**	Tier 1/no PPE	42	2.66E+00	6.34%	YES
Scenario [10] – Disposal of empty bags	Tier 1/no PPE	42	8.84E-03	0.02%	YES
	Tier 1/no PPE	42	9,35E+01	222.65%	NO

Scenario [11] – Disposal of lime product after application	Tier 2a/ gloves		4,69E+00	11.17%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	9.82E+01	233.70%	**NO**
	Tier 2a/gloves		5.35E+00	12.73%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	7.94E+02	1890.59%	**NO**
	Tier 2/gloves + mask		3.98E+01	94.72%	**YES**
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	4.39E+01	104.49%	**NO**
	Tier 2a/gloves		2.50E+00	5.96%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	2.81E+02	668.39%	**NO**
	Tier 2a/gloves		1.49E+01	35.59%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	5.26E+00	12.52%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	1.18E+01	28.17%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	4.74E+00	11.28%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	6.88E+00	16.38%	YES

Systemic effects (magnesium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [6] – manual loading for floor application	Tier 1/no PPE	4.2	6.68E-02	1.59%	YES
Scenario [7a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.49E+00	35.38%	YES
	Tier 2a/ gloves		7.91E-02	1.88%	YES
Scenario [7b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.25E+01	297.78%	**NO**
	Tier 2a/ gloves		6.61E-01	15.73%	YES
Scenario [7c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	6.26E-01	14.91%	YES
	Tier 2a/ gloves		3.40E-02	0.81%	YES
Scenario [7d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	4.38E+00	104.22%	**NO**
	Tier 2a/ gloves		2.31E-01	5.5%	YES
Scenario [8] – semi-automated loading- indoor	Tier 1/no PPE	4.2	6.75E-02	1.61%	YES
Scenario [9a] – Semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.58E-02	0.38%	YES
Scenario [9b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.21E-01	2.87%	YES
Scenario [9c] – Semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	7.56E-03	0.18%	YES
Scenario [9d] – Semi-automated application onto maximal floor surfaces- indoor – Cattle	Tier 1/no PPE	4.2	4.22E-02	1.00%	YES
Scenario [10] – Disposal of empty bags	Tier 1/no PPE	4.2	1,40E-04	0%	YES
Scenario [11] – Disposal of product	Tier 1/no PPE	4.2	1.48E+00	35.26%	YES

Combined effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.55E+00	36.96%	YES
	Tier 2a/gloves		8.45E-02	2.01%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.26E+01	299.37%	**NO**
	Tier 2a/gloves		1.30E+00	30.86%	YES
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	6.93E-01	16.50%	YES
	Tier 2a/gloves		3.95E-02	0.94%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	4.44E+00	105.81%	**NO**
	Tier 2a/gloves		2.37E-01	5.63%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	8.33E-02	1.98%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.87E-01	4.46%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	7.43E-02	1.77%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	1.09E-01	2.59%	YES

- **Semi-quantitative local risk assessment**

Task/ Scenario	Tier	AEC mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEC (%)
Scenario [6] – manual loading for floor application	Tier 1/no PPE	0.3	3.30E+01	11000.0%
	Tier 2b/ RPE (APF40)		8.25E-01	275.0%
Scenario [7a] – manual application onto **minimal floor surfaces- indoor - Poultry**	Tier 1/no PPE	0.3	3.30E+01	11000.0%
	Tier 2b/ RPE (APF 40)		8.25E-01	275.0%
Scenario [7b] – manual application onto **maximal floor surfaces- indoor - Poultry**	Tier 1/no PPE	0.3	2.91E+01	9700.0%
	Tier 2b/ RPE (APF 40)		7.28E-01	242.5%
Scenario [7c] – manual application onto **minimal floor surfaces- indoor - Cattle**	Tier 1/no PPE	0.3	4.20E+01	14000.0%
	Tier 2b/ RPE (APF 40)		1.05E+00	350.0%
Scenario [7d] – manual application onto **maximal floor surfaces- indoor - Cattle**	Tier 1/no PPE	0.3	2.91E+01	9700.0%
	Tier 2b/ (APF 40)		7.28E-01	242.5%
Scenario [7] – manual application onto floor surfaces - indoor – Field study	Tier 1/no PPE	0.3	2.87E+00	958.0%
	Tier 3b/ RPE (APF 10)		2.87E-01	95.8%
Scenario [8] – semi-automated loading- indoor	Tier 1/no PPE	0.3	1.35E+01	4500.0%
	Tier 2b/ RPE (APF 40)		3.38E-01	112.5%
Scenario [9a] – Semi-automated application onto **minimal floor surfaces- indoor - Poultry**	Tier 1/no PPE	0.3	3.30E+01	11000.0%
	Tier 2b/ RPE (APF 40)		8.25E-01	916.7%
Scenario [9b] – Semi-automated application onto **maximal floor surfaces- indoor - Poultry**	Tier 1/no PPE	0.3	1.35E+01	4500.0%
	Tier 2b/ RPE (APF 40)		3.38E-01	112.5%
Scenario [9c] – Semi-automated application onto **minimal floor surfaces- indoor - Cattle**	Tier 1/no PPE	0.3	1.08E+02	36000.0%
	Tier 2b/ RPE (APF 40)		2.70E+00	900.0%
Scenario [9d] – Semi-automated application onto **maximal floor surfaces- indoor - Cattle**	Tier 1/no PPE	0.3	1.35E+01	4500.0%
	Tier 2b/ RPE (APF 40)		3.38E-01	112.5%
Scenario [9] – Semi-automated application onto floor surfaces of - indoor – Field study	Tier 1/no PPE	0.3	1.68E+00	559.0%
	Tier 2b/ RPE (APF 10)		1.68E-01	55.9%
	Tier 1/no PPE	0.3	1.71E+00	570.0%

Scenario [10] – Disposal of empty bags	Tier 2b/ RPE (APF 10)		1.71E-01	57.0%
Scenario [11] – Disposal of product after application- Field study	Tier 1/no PPE	0.3	8.37E-01	279.0%
	Tier 3b/RPE (APF 4)		2.09E-01	69.750%

- **Qualitative local risk assessment**

The products of the meta-SPC 2 are classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and are intended to be applied by professional. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects – Qualitative assessment for disinfection of indoor floor surfaces of animal accommodation and animal transportation

Hazard			Exposure				Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)	Risk	
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMM & PPE**	**Conclusion on risk**
Very High	Eye Dam.1, H318	-	3	Professionals	-Loading from the bags to the wheelbarrow/tractor -Application on the floor surfaces -Disposal of the lime product after application	Dermal Sources for contamination being from: - opening and handling bags - cleaning - hand to eye transfer	few minutes per day or less	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM: - Wear: - Substance/ task appropriate gloves - Protective coverall - Face shield - Substance/	Acceptable following the relevant RMM and PPE
Low	Skin Irrit.2, H315	-				Dermal Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day	task appropriate respirator	

Disinfection of indoor floor surfaces of animal accommodation and animal transportation (Meta SPC 2 only) - Conclusion

Using ART model for floor surfaces disinfection leads to an overestimation of the inhalation exposure and then to unacceptable risks for professionals.
In this context, a field study has been provided by EuLA in order to obtain specific exposure data for this use (see "Monitoring data").
The provided monitoring data have been deemed reliable by the rMS.
However, it has to be noted that the inhalation exposure measurements from the study refers to the **respirable** fraction (particles with a diameter ≤ 1µm) whereas the AEC value set for CaO refers to the **inhalable** fraction. A direct comparison of the exposure values from the study with the AEC is therefore considered not reliable to conclude on the acceptability of the risk.

In this context and without any additional data, FR rMS proposed a weight of evidence approach to conclude on the acceptability of the risk for professionals using lime product during disinfection of floor surfaces of animal accommodations and transportation.
The WoE approach is divided into two points:

- The local risk assessment;
- The setting of AEC.

The products of meta-SPC 2 are formulated with maximum 30% active substance.
Based on the toxicological properties of the a.s, the following classification has been proposed for these products:

- STOT SE 3 (H335, May cause respiratory irritation);
- Eye Dam 1 (H318, Causes serious eye damage);
- Skin irrit 2 (H315, causes skin irritation).

According to the "Guidance on the BPR, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017", a classification STOT SE 3 – H335 triggers a qualitative risk assessment based on the irritant properties of the respiratory tract. Considering this, an appropriate respiratory protection is required and recommended during the activities of work, to counteract the local irritant effects of lime.

In order to select the most appropriate RPE based on the irritant properties of lime, different factors have to be taken into account including the type of chemical contaminants and the filtering efficiency.
Considering the type of chemical contaminant (particles suspended in the air), a filtering facial piece using P filters is considered the most appropriate equipment for exposure of professionals to dust exposure.
According to the European standard *NF EN 149*[11] *and NF EN 143*[12], there are three classes of particle filters based on their filtering efficiency; P1, P2 and P3 in ascending order to filtering efficiency.
In order to ensure the highest protection to the workers against the irritant properties of the product, a **P3 filter** (corresponding to an assigned protection factor (APF) of 40) is proposed by the eCA.
Considering the type of mask to be used, lime products being classified for eye and skin irritant properties, a **full-face respiratory protective equipment** (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149) is required.

[11] NF EN 159: Respiratory protective devices – Recommendations for selection, use, care and maintenance – Guidance document.
[12] NF EN 143: Respiratory protective devices – Particles filters – Requirements, testing, marking.

Moreover as stated in the NF EN 149, it is recommended to apply other means to decrease professional exposure before using RPE.
In the context of lime products, the following RMMs are proposed:

- Use only in a well-ventilated area;
- Moisten the soil before application (in order to prevent the aerosols generation).

Finally, it is assumed that during the application of the product, the professional won't stay in the generated "cloud of aerosols" (this information is available in the field study where the behaviour of the applicator has been observed) which will tend to reduce inhalation exposure.

Regarding the toxicological reference value set in the CAR on the active substance, it has to be noted that the AEC value of 0.3 mg/m^3 (short, medium and long-term) is based on an epidemiological study in humans (*Cain et al., 2004* [13]).
In this study, 12 volunteers were exposed during 20 min to 0, 1, 2 and 5 mg/m^3 CaO dust. The parameters studied included nasal resistance, nasal secretion, mucociliary transport time and chemestetic magnitude (irritation, pungency, piquancy, cooling and burning).
According to the authors, there were no significant effects in quantified parameters (nasal secretion, etc…) at any tested doses; however chemestetic effects (pungency) have been reported at all concentrations (in the nose, eyes and throat). As stated in the CAR (Doc IIA), a NOAEC value of 1 mg/m^3 CaO for 20-min exposure has been identified for this study based on subjective descriptions of sensory irritation of the nose and throat at the next higher concentrations of 2 and 5 mg/m^3.
This means that the NOAEC has been based on the psychophysical judgments of few volunteers. Using this NOAEC value and a factor of 3.2 (default for dynamic intra-species differences) leads to a very low AEC value of 0.3 mg/m^3.
This value is deemed **very conservative** by the rMS since it only takes into account the beginnings of a feeling of irritation as a relevant effect to set a TRV. This effect is considered very subjective and therefore very dependent on the number of volunteers in the study (only 12). In this context, using this TRV in a risk assessment is very conservative since it is designed to protect against a feeling of irritation and not effects that can be quantified with parameters such as nasal secretion, nasal resistance and so on.
Finally, it is important to note that the proposal for classification STOT SE 3 – H335 is based on the effects observed in the study using to derive the AEC value (*Cain et al., 2004*).

Based on the elements presented above, FR MS considered that the recommended respiratory protective equipment (**a full-face mask with P3 filters (APF 40)**), combined with relevant RMMs are sufficient to prevent inhalation exposure and protect the professionals against the irritation properties of the lime on the respiratory tract.

This point has been extensively discussed at the European level in the frame of the assessment of another lime based product dossier; the majority of the Member states agreed with this approach.

Regarding the exposure of the person sweeping the soil before the re-entry of the animals, it is assumed that exposure is equal or lower than the exposure of the professional applying the product. Therefore, the same RPE and PPEs as those required for the professional user has to be used during the sweeping of the floors.

[13] Cain *et al*., 2004 : Sensory and associated reactions to mineral dusts : sodium borate, calcium oxide and calcium sulphate. Journal of Occupational and Environmental Hygiene, 1 : 222-236 (2004).

Disinfection of floors of outdoor animal enclosures (Meta SPC 2 only)

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [12a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	7.60E+01	180.94%	**NO**
	Tier 2a/gloves		3.93E+00	9.35%	YES
Scenario [12b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	6.40E+02	1523.67%	**NO**
	Tier 2/gloves + RPE (APF 40)		3.20E+01	76.12%	YES
Scenario [13] – semi-automated loading- outdoor- **Poultry**	Tier 1/no PPE	42	4.20E+00	10.01%	YES
Scenario [14a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	42	9.26E-01	2.20%	YES
Scenario [14b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	42	1.20E+01	28.53%	YES
Scenario [15] – Disposal of empty bags	Tier 1/no PPE	42	8.84E-03	0.021%	YES
Scenario [16] – Disposal of lime products after application	Tier 1/no PPE	42	9.35E+01	222.65%	**NO**
	Tier 2a/gloves		4.69E+00	11.17%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Manual loading – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Tiers 1/no PPE	42	8.03E+01	191.27%	**NO**
	Tier 2a/gloves		4.28E+00	10.20%	YES
Manual loading – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Tier 1/no PPE	42	6.44E+02	1534.01%	**NO**
	Tier 2/gloves + mask		3.23E+01	76.97%	**NO**
Semi-automated loading-semi-automated application onto **minimal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	42	8.12E-02	0.19%	YES
Semi-automated loading-semi-automated application onto **maximal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	42	1.20E+01	28.60%	YES
	Tier 2a/gloves		9.31E-01	2.22%	YES

Systemic effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [12a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.20E+00	28.66%	YES
Scenario [12b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.01E+01	241.31%	**NO**
	Tier 2a/gloves		5.23E-01	12.46%	YES
Scenario [13] – semi-automated loading- outdoor- **Poultry**	Tier 1/no PPE	4.2	6.66E-02	1.59%	YES
Scenario [14a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE		1.47E-02	0.35%	YES
Scenario [14b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	4.2	5.03E-01	11.97%	YES
Scenario [15] – Disposal of empty bags	Tier 1/no PPE	4.2	2.22E-05	0%	YES
Scenario [16] – Disposal of lime product after application	Tier 1/no PPE	4.2	1.48E+00	35.26%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Manual loading – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Tiers 1/no PPE	4.2	1.27E+00	30.25%	YES
	Tier 2a/gloves		6.77E-02	1.61%	YES
Manual loading – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Tier 1/no PPE	4.2	1.02E+01	242.89%	**NO**
	Tier 2a/gloves		5.29E-01	12.59%	YES
Semi-automated loading-semi-automated application onto **minimal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	4.2	8.13E-02	1.93%	YES
Semi-automated loading-semi-automated application onto **maximal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	4.2	5.69E-01	13%	YES

- **Semi-quantitative local risk assessment**

Task/ Scenario	Tier	AEC (mg/m^3)	Estimated concentration (mg/m^3)	Estimated concentration / AEC (%)
Scenario [12a] - manual application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.35E+01	4500.0%
	Tier 2b/ RPE (APF40)		3.38E-01	112.5%
Scenario [12b] – manual application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.35E+01	4500.0%
	Tier 2b/ RPE (APF40)		3.38E-01	112.5%
Scenario [12] - Manual application onto floor surfaces– **Field study**	Tier 1/no RPE	0.3	2.87E+00	958.0%
	Tier 3b/ RPE (APF 10)		2.87E-01	95.8%
Scenario [13] - semi-automated loading- outdoor- poultry	Tier 1/no RPE	0.3	2.64E+00	880.0%
	Tier 2b/ RPE (APF40)		6.60E-02	22.0%
Scenario [14a] - semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	3.30E+00	1100.0%
	Tier 2b/ RPE (APF40)		8.25E-02	27.5%
Scenario [14b] - semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	3.30E+00	1100.0%
	Tier 2b/ RPE (APF40)		8.25E-02	27.5%
Scenario [14] - Semi-automated application onto floor surfaces of **Field study**	Tier 1/no RPE	0.3	1.68E+00	559.0%
	Tier 3b/ RPE (APF 10)		1.68E-01	55.9%
Scenario [15] – Disposal of empty bags	Tier 1/no PPE	0.3	2.73E-01	91.0%
Scenario [16] - Disposal of lime- outdoor – **Field study**	Tier 1/no RPE	0.3	8.37E-01	279.0%
	Tier 3b/ RPE (APF 4)		2.09E-01	69.75%

- **Qualitative local risk assessment**

The products of the meta-SPC 2 are classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and is intended to be applied by professional. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects – Qualitative assessment for disinfection on floors of outdoor animal enclosures

Hazard			Exposure				Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)	Risk	
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
Very High	Eye Dam.1, H318	-	3	Professionals	-Loading from the bags to the wheelbarrow/tractor -Application on the floor surfaces-outdoor -Disposal of the lime product after application	Dermal Sources for contamination being from: - opening and handling bags - cleaning - hand to eye transfer	few minutes per day or less	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM: - Wear: - Substance/ task appropriate gloves - Protective coverall - Face shield - Substance/ task appropriate respirator	Acceptable following the relevant RMM and PPE
Low	Skin Irrit.2, H315	-				Dermal Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		
Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Disinfection of floor of outdoor animal enclosures - Conclusion:

Using ART model for outdoor floor surfaces disinfection and considering that the source is located or not to buildings lead to an overestimation of the real inhalation exposure.

It is assumed that inhalation of the professional applying lime product outdoor is of a low order compared to the disinfection of indoor animal accommodations.
In this context and based on the weight of evidence approach presented for Use #2.3 above, the rMS considered that the recommended respiratory protective equipment (**a full-face mask with P3 filters (APF 40)**), combined with relevant RMMs are sufficient to prevent inhalation exposure and protect the professionals against the irritation properties of the lime on the respiratory tract for outdoor application.

This point has been extensively discussed during the WG I 2022 for another authorisation (UA) of lime based product; the majority of the Member states agreed with this approach.

Regarding the exposure of the person sweeping the soil before the re-entry of the animals, it is assumed that exposure is equal or lower than the exposure of the professional applying the product. Therefore, the same RPE and PPEs as those required for the professional user has to be used during the sweeping of floors.

Disinfection of animal accommodations walls using a brush (Use #3.5) (Meta SPC 3 only)

META SPC 3

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (YES/NO)
Scenario [17]- Semi-automated transfer from IBC to a bucket	Tier 1/no PPE	42	4.30E-01	1.02%	YES
Scenario [18]- application on walls by brush	Tier 1/no PPE	42	1.32E+01	31.39%	YES
Scenario [20] – dermal contact with **wet** treated surfaces - adults	Tier 1/no PPE	42	2.91E+01	69.4%	**NO**
Scenario [21] – dermal contact with **dried** treated surfaces - adults	Tier 1/no PPE	42	7.00E-01	1.70%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (YES/NO)
Semi-automated transfer -application	Tiers 1/no PPE	42	1.36E+01	32.41%	YES

Systemic effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (YES/NO)
Scenario [17]- Semi-automated transfer to a bucket	Tier 1/no PPE	4.2	1.74E-02	0.41%	YES
Scenario [18]- application on walls by brush	Tier 1/no PPE	4.2	5.48E-01	13.04%	YES
Scenario [20] – dermal contact with **wet** treated surfaces - adults	Tier 1/no PPE	4.2	1.18E+00	28.10%	NO
Scenario [21] – dermal contact with **dried** treated surfaces - adults	Tier 1/no PPE	4.2	2.83E-02	0.70%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (YES/NO)
Semi-automated transfer -application	Tiers 1/no PPE	4.2	5.65E-01	13.45%	YES

- **Semi-quantitative local risk assessment**

Task/ Scenario	Tier	AEC (mg/m^3)	Estimated concentration (mg/m^3)	Estimated concentration / AEC (%)
Scenario [18]- application on walls by brush	Tier 1/no PPE	0.3	8.15E-01	271.67%
	Tier 2b/ RPE (APF4)		2.04E-01	67.92%

- **Qualitative local risk assessment**

The products of meta-SPC 3 are classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and are intended to be applied by professional. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects – Qualitative assessment for disinfection of animal accommodations walls with a brush

Hazard			**Exposure**				**Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)**	**Risk**	
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	*Frequency and duration of potential exposure*	**Relevant RMM & PPE**	**Conclusion on risk**
LOW	STOT RE 3, H335	-	3	Professional	-Loading from the containers to the bucket - Application on walls with milk of lime	Inhalation	More than few minutes but equal to or less than few hours per day	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following PPE: - Wear: - Substance/ task appropriate gloves - Protective coverall - Face shield - Substance/ task appropriate respirator RMM: -Minimization of splash and spills	Acceptable following the relevant RMM and PPE
HIGH	Skin Irrit.2, H315	-				Dermal	More than few minutes but equal to or less than few hours per day		
HIGH	Eye Dam.1, H318	-				Ocular	Few minutes per day or less		

Conclusion for Use #3.5 : Disinfection of animal accommodations; lime washing of walls- PT 3

Taking into consideration the results on quantitative and qualitative risk assessments, the risk for human health is considered acceptable for the loading from containers to a bucket considering the following PPE:

- ✓ gloves
- ✓ protective coverall;
- ✓ face shield

During the application of water suspended lime on the walls, the risk is considered acceptable taking into account the following PPE:

- ✓ gloves;
- ✓ protective coverall,
- ✓ 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)

Moreover, the following RMM are needed:

- ✓ Minimisation of splash and spills during application of water suspended lime;
- ✓ Do not touch the treated surfaces until complete drying.
- ✓ Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration

Risk for non-professional users

No foreseen relevant.

Risk for the general public

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	**Acceptable (yes/no)**
Scenario [22] – dermal and oral contact with wet treated surfaces - toddler	Tier 1/no PPE	42	5.41E+01	127.8%	**NO**
Scenario [23] – dermal and oral contact with dried treated surfaces - toddler	Tier 1/no PPE	42	4.42E+00	10.50%	YES

Systemic effects (magnesium)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	**Acceptable (yes/no)**
Scenario [22] – dermal and oral contact with wet treated surfaces - toddler	Tier 1/no PPE	4.2	2.19E+00	52.0%	YES
Scenario [23] – dermal and oral contact with dried treated surfaces - toddler	Tier 1/no PPE	4.2	1.79E-01	4.30%	YES

Local effects

Not relevant.

Overall conclusion for human health

Disinfection of sewage sludge's and manures (Uses #1.1 & 1.2) – Meta SPC 1 & 3

*__For Meta-SPC 1__

Acceptable risks are shown for human health **only by semi- automated process** (including loading and disposal of empty bags) considering the following PPE are worn:

- gloves;
- protective coverall;
- 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).

In addition to the above mentioned PPE, the following RMMs are required:

- 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).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.

*__For Meta-SPC 3__

Acceptable risks are shown for human health considering the following PPE are worn.
During the loading into the unit treatment:

- gloves;
- protective coverall;
- face shield

During the cleaning of the unit treatment:

- gloves;
- protective coverall;
- 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).

Moreover, it is also likely that the addition of calcium hydroxide to sewage or manure leads to the production of ammonia gas, which may be of concern. 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/m^3 for this gas.

Additional RMM for both meta-SPC are required:

- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge and manures, the wear of air fed or canister RPE specific for ammonia gas, is requiredin absence of collective management measures to estimate and prevent an exposure greater than the EU OEL of 14 mg/m^3 for this gas.

Disinfection of indoor floor surfaces of animal accommodations and transportation, bedding materials and outdoor floor surfaces (Uses 2.3-2.4-2.6) – Meta SPC 2 only

***META SPC 2**

The risk for human health is considered acceptable for the loading, the application and the disposal of empty bags considering the following PPE:

- gloves;
- protective coverall;
- 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).

In addition to above-mentioned PPE, the following RMM are needed:

- 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).
- 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.
- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimize the remaining powder;
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- 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 tele handler (including a closed cabin).
- Use in a well ventilated area.

Disinfection of animal accommodation walls by brush – Meta SPC 3 only

***META SPC 3**

The risk for human health is considered acceptable for the loading and the disposal of empty bags considering the following PPE:

-
- gloves;
- protective coverall;
- face shield

During the application of water suspended lime on the walls, the risk is considered acceptable taking into account the following PPE:

- gloves;
- protective coverall;
- 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).

Moreover, the following RMM are needed:

- Minimization of splash and spills during application of water suspended lime.
- Do not touch the treated surfaces until complete drying.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration

Risk for consumers via residues in food

Considering that the active substance is composed from Ca^{2+}, which is an essential element of the body expected to be regulated by the animal metabolism, the general public dietary exposure related to the intended uses is not considered to be relevant.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

2.2.7 Risk assessment for animal health

See Annex 1 (section 3.7 Other)

2.2.8 Risk assessment for the environment

CALCIUM DIHYDROXIDE BLENDS is a PT2 and PT3 product containing calcium dihydroxide, Hydrated lime (CAS 1305-62-0) that is applied for:

- disinfection of sewage sludge (PT02),
- disinfection of manure (PT03),
- disinfection of indoor floor of animal accommodations (PT03),
- disinfection of animal bedding materials (PT03),
- disinfection of indoor walls of animal accommodations (PT03),
- disinfection of indoor floor of animal transportation (PT03),
- disinfection of floors of outdoor animal enclosures (PT03).

The products of the family are blends of the active substance (at concentrations from 30 to 70%) and the inert filler calcium carbonate. Calcium carbonate is the starting material used to manufacture the active substance. They both are naturally occurring inorganic salts.
No environmental SoCs were identified for the CALCIUM DIHYDROXIDE BLENDS and no metabolites are formed that would need to be addressed in a risk evaluation for the environment. The following risk assessment is therefore based on the data obtained from the active substance only (CAR, Calcium dihydroxide, Hydrated lime CAS 1305-62-0, Product Type 2: Disinfectants and algaecides not intended for direct application to humans or animals and 3: Veterinary hygiene, RMS UK, May 2016).

Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime (Ca(OH)2).

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Ecotoxicological data about the biocidal product CALCIUM DIHYDROXIDE BLENDS are not available. Therefore, all data pertaining to the active substance are derived from the Calcium dihydroxide, Hydrated lime CAR (2016).

Further Ecotoxicological studies

No data required.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data available.

Supervised trials to assess risks to non-target organisms under field conditions

No data available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Further information on the secondary ecological effect is not required.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Indirect routes: to soil and groundwater from uses in manure, indoor floor of animal accommodations, animal bedding materials, indoor walls of animal accommodations, and sewage sludge.

Direct routes:

- ✓ to soil and groundwater from use in animal outdoor enclosures,
- ✓ to STP from use in animal transportation.

Further studies on fate and behaviour in the environment (ADS)

No data available.

Leaching behaviour (ADS)

No data available.

Testing for distribution and dissipation in soil (ADS)

Standard aerobic degradation studies in soil are not considered necessary for hydrated lime. This is because upon addition to soil hydrated lime would simply dissociate to its respective

ion constituents where they would form part of existing chemical cycles in the natural environment (Doc IIA of calcium dihydroxide, Hydrated lime UK, 2016).

Testing for distribution and dissipation in water and sediment (ADS)

Distribution

Hydrated lime would simply dissociate to its respective ion constituents (Ca^{2+} and OH^-) where they would form part of existing chemical cycles in the natural environment. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+} and OH^- ions in nature.

Dissipation

Hydrated lime would simply dissociate to its respective ion constituents (Ca^{2+} and OH^-) where they would form part of existing chemical cycles in the natural environment. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+} and OH^- ions in nature.

Testing for distribution and dissipation in air (ADS)

Since hydrated lime is expected to have a vapour pressure well below 10^{-5} Pa, exposure via air is not expected.

Summary table of half-lives identified relevant metabolites and transformation products in air

No data available.

Dissipation

No data available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant for the use of CALCIUM DIHYDROXIDE BLENDS.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant for the use of CALCIUM DIHYDROXIDE BLENDS.

PNECs

The following table contains a summary of PNECs of the active substance Calcium dihydroxide for the respective compartments (Calcium dihydroxide CAR, Hydrated lime

2016). Since hydrated lime was the only form tested in the fate and effects studies, toxicity has been expressed in the form of the hydrated lime equivalents.

Summary of PNECs of the active substance Calcium dihydroxide				
Compartment	**Species**	**Endpoint**	**Safety factor**	**PNEC (Hydrated lime equivalents)**
Surface water	*Daphnia magna*	48h EC_{50} = 49.1	100	0.491 mg/L
Sediment	-	-	-	Not relevant
Microorganisms (STP)	*Activated sludge*	3h EC_{50} = 300.4 mg/L	100	3.004 mg/L
Soil	*Spinacia oleracea*	21d $NOEC_{plant}$ = 1080 $mg.kg^{-1}$ dw*	10	108 $mg.kg^{-1}$ dw*
Bird	-	-	-	Not relevant
Mammal	-	-	-	Not relevant

*For the effects assessment of the soil compartment, endpoints are presented in terms of mg a.s/kg dry weight (dw) of soil. This is consistent with the application rates for the PT2 uses all being expressed as rates per dry solid weight of sludge. For consistency, dry weight has been used for the PT3 use patterns.

According to the CAR, various MS recommended a risk assessment based on a qualitative approach, particularly since the dissociation products of the lime variants (Ca^{2+}, Mg^{2+} and OH^-) form parts of existing chemical cycles in the natural environment. In addition, for the terrestrial compartment, the contribution to the total environmental loading of lime from the biocidal use may be much less significant than from the routine agricultural use of lime used to amend soil pH and maintain soil fertility (a use of the active substance that is outside the scope of the BPR).

Thus, the PNEC values will not be always used in the risk assessment (especially for the terrestrial compartment). As proposed during the assessment of the active substance at the European level, a qualitative assessment will be conducted. For the terrestrial compartment, it involves the calculation of lime emissions on arable land due to the biocidal claimed uses and the comparison with routine agricultural use of lime to control soil pH. According to EU wide good agricultural practices, the guideline recommends application rates to neutralise agricultural soil up to 16 tons/ha per year (as CaO) in lime deficient soils.

2.2.8.2 Exposure assessment

CALCIUM DIHYDROXIDE BLENDS is a PT2 and PT3 family product containing calcium dihydroxide, Hydrated lime (CAS 1305-62-0) that is applied for:

	Uses	**META-SPC 1 (60-70% a.s) Dustable powder**	**META-SPC 2 (20-30% a.s) Dustable powder**	**META-SPC 3 (20-50% a.s) Suspension**

PT02	disinfection of sewage sludge	**Yes** 2kg a.s/kg dry sludge = At 60%: 3.4kg product At 70%: 2.8kg product	-	**Yes** 2kg a.s/kg dry sludge = At 20%: 10kg product (i.e 9.4L, d=1.06) At 50%: 4kg product (i.e 2.89 L, d=1.38)
PT03	disinfection of manure	**Yes** 100kg a.s/m^3 of manure = At 60%: 170kg product At 70%: 142.8 kg product	-	**Yes** 100kg a.s/m^3 of manure = At 20%: 500kg product (i.e 471.7L, d=1.06) At 50%: 200kg product (i.e 144.9L, d=1.38)
	disinfection of indoor floor of animal accommodations	-	**Yes** 1kg a.s/m²** = At 20%: 5kg product At 30%: 3.3kg product	-
	disinfection of animal bedding materials	-	**Yes** <u>For cattle</u> (veal calves): 1.5kg a.s/animal <u>For poultry</u> (turkey): 0.2kg a.s/m² = At 20%: <u>For cattle</u> (veal calves): 7.5kg product/animal <u>For poultry</u> (turkey): 1kg product/m² At 30%: <u>For cattle</u> (veal calves): 5kg product/animal <u>For poultry</u> (turkey): 0.67kg product/m²	-
	disinfection of indoor walls of animal accommodations	-	-	**Yes** 0.8 kg a.s/m²
	disinfection of indoor floor of animal transportation	-	**Yes** 1kg a.s/m²** = 20%: 5kg product 30%: 3.3kg product	-
	disinfection of floors of outdoor animal enclosures	-	**Yes** 0.8 kg a.s/m² = 20%: 4kg product/m² 30%: 2.67kg product/m²	-

*****Worst-case product identified for meta-SPC 3, taking into account concentration of the product and its application rate.

** The validated doses in the efficacy section (0.8 kg/m²) were modified late in the process of the evaluation. Therefore, the calculations were not changed in the Environment section, but the assessment of the dose of 1 kg/m² covers the dose of 0.8 kg/m²

For the use "disinfection of indoor walls of animal accommodations", the final application rate of active substance is different between the products of the Meta-SPC 3. Therefore, only the worst-case product (at 50% of active substance) is assessed for this use.
For all other uses, final application rate of active substance is the same between all claimed products. Therefore, for clarity and better understanding, the risk assessment is presented in active substance dose.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Application to sewage sludge
ESD(s) used	Not applicable.
Approach	Qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Distribution in the environment	Vol IV Part B+C (2017)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes Service life: No
Remarks	

Assessed PT	PT 3
Assessed scenarios	Scenario 2.1: Application to manure, Scenario 2.2: Application on animal bedding materials, Scenario 2.3: Application on indoor walls of animal accommodations, Scenario 2.4: Application on indoor floor of animal accommodations, Scenario 3: Application on indoor floor of animal transportation, Scenario 4: Application on floors of outdoor animal enclosures (poultry).
ESD(s) used	Scenario 2.1: ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 ✓ ESDTP18, Emission scenario document for Insecticides for stables and manure storage systems, 2006 Scenario 2.2, 2.3, 2.4 and 3: ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 Scenario 4: Not applicable

Approach	Semi-qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Distribution in the environment	
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenario 2, 3, 4: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

Scenario 1 (PT2): disinfection of sewage sludge in an open mixer

For this use a qualitative assessment and a comparison with the CAR assessment is proposed.

The product is mixed with sewage sludge in an open mixer by professionals. After the disinfection process, the treated sludge is spread on agricultural fields. Therefore, an indirect exposure to soil is considered

This use has been assessed in the CAR of the active substance Hydrated Lime PT2, with the following application rate in comparison with the product CALCIUM DIHYDROXIDE BLENDS:

Application rate of active substance in sewage sludge		
	Representative product of the CAR Hydrated Lime, 2016	**CALCIUM DIHYDROXIDE BLENDS product**
Application rate of the a.s (in % of dry solid weight of sludge)	50	200 (i.e. 2 kg a.s/kg dry solid weight of sludge)

It has been demonstrated that the use of the representative product of the CAR generates applications of lime in agricultural soil lower than 16t/ha/year. The same reasoning can be used for the product CALCIUM DIHYDROXIDE BLENDS (see table below).

Application rate of active substance in agricultural fields		
	Representative product of the CAR Hydrated lime, 2016	**CALCIUM DIHYDROXIDE BLENDS product**
Input		
Application rate of the a.s for the use described in the CAR	50% of dry solid weight of sludge	200% of dry solid weight of sludge
Maximum application rate of sludge in agricultural land per year	5000 kg dry solid sludge/ha/year	
Output		
Amount of lime added to the sludge during the treatment	2500 kg	10000 kg
Total dry weight of treated sludge after the treatment	7500 kg	15000 kg

Application of a.s per ha per year due to the final 5000 kg of actual sludge landed in agricultural field	5000/7500 * 2500 = 1.7 t/ha/year	5000/15000*10000 = 3.3 t/ha/year

As the use of CALCIUM DIHYDROXIDE BLENDS will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 2 (PT3): disinfection of animal accommodation

For the four following uses:

- 2.1: disinfection of manure,
- 2.2: disinfection of animal bedding materials,
- 2.3: disinfection of walls of indoor animal accommodations and
- 2.4: disinfection of indoor floor of animal accommodations,

the product is mixed to manure for its disinfection or released into manure after application on surfaces. The mix hydrated lime/manure is removed when accommodations are cleaned and sent to manure storage for use in fields. The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Indeed, the lime/manure mix represents large quantities of solid material that cannot be discharged to the STP, as would liquid poultry slurry. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:
"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".

The manure could be spread on fields, therefore the soil compartment is directly exposed to the active substance.

All parameters (area of accommodations, number of animals…) considered are from ESDTP3, 2011 and ESDTP18 for stables and manure storage systems, 2006. For an easier reading of the PAR, only worst-case situations are presented:

- ✓ For cattle: veal calves emissions,
- ✓ For poultry: turkeys emissions.

Scenario 2.1: disinfection of manure

The product is mixed with a manure, litter or manure/litter mixture, outdoor in a manure storage silo/pit (for any type of animal accommodations) or is gathered in a specific area inside the animal house and treated inside (for poultry only).

It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

In order to estimate this, the following parameters are calculated:

1) **The concentration of a.s in manure** after the application of the product.

Then,

2) **The maximum application rate of manure in grassland and arable land**, based on the nitrogen immission standard. The concentration of nitrogen in manure are calculated according to ESDTP3 and ESDTP18 for stables adapted parameters.

Finally,

3) **The maximum application rate of substance in agricultural soil**, considering the concentration of a.s in manure after the application, and the maximum application rate of manure.

The concentration rate of active substance in manure is calculated as follow:

1) Concentration of a.s in manure after the application of product			
	Symbol	**Value**	**Unit**
		CALCIUM DIHYDROXIDE BLENDS product Scenario 2.1	
Concentration of a.s in manure after the last application of product	**-**	**100**	[kg/m^3 of manure]

As no scenario exists for this use, some parameters from ESDTP3, (2011) and ESDTP18 for stables (2006) were adapted to calculate the maximal application rate of manure in agricultural soil.

1) Application rate of manure in arable and grassland					
Parameters	**Symbol from ESDTP3/18**	**Value**		**Unit**	**Remarks**
Input					
		Scenario 2.1 - Manure			
		Veal calves	**Turkey**		
Amount of nitrogen produced per animal per day	$Qnitrog_{i1}$	0.02382	0.00482	[kg/day /animal]	ESDTP3, 2011
Amount of manure produced per animal per day	-	0.007	0.00036	[m^3/animal/d]	ESDTP18, 2006 Table in Appendix 5 with conversion of L to m^3
Maximum emission standard for nitrogen on grassland	Qn, grassland	170		[kg/ha/ year]	ESDTP3, 2011
Maximum emission standard for nitrogen on arable land	Qn, arable land	170		[kg/ha/ year]	ESDTP3, 2011

Intermediate Calculations					
Concentration of nitrogen in the manure	-	3.40	13.39	[kg/m^3]	Concentration of nitrogen in the manure = Amount of nitrogen produced per animal per day / Amount of manure produced per animal per day
Output					
Maximum application rate of manure on grassland	-	**49.96**	**12.69**	[m^3/year/ha soil]	Maximum application rate of manure on grassland or arable land = Maximum emission standard for nitrogen on grassland or arable land / Concentration of nitrogen in the manure
Maximum application rate of manure on arable land	-	**49.96**	**12.69**	[m^3/year/ha soil]	

Therefore, the application rate of s.a on agricultural field is calculated as follow:

1) Application rate of active substance in arable land and grassland			
Input			
Parameters	**Value**		**Unit**
	Scenario 2.1 - Manure		
	Veal calves	**Turkey**	
Concentration of a.s in manure	100	100	[kg/m^3 of wet manure]
Maximum application rate of manure on grassland and arable land	49.96	12.69	[m^3/year/ha soil]
Output			
3) Maximum application rate of active substance on grassland or arable land per year per hectare	**5.00**	**1.27**	[T/year/ha]

As the use of CALCIUM DIHYDROXIDE BLENDS will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 2.2: disinfection of animal bedding materials

The dry product is applied on animal bedding material (straw, sawdust, woodchip) once (for cattle) or twice a week (for poultry) and will be mixed in manure after application.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) claimed by the applicant are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:
"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". Therefore, for poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

In the ESDTP3, no individual value for the bedding material surface is available. It is therefore calculated by adding the "floor surface" value to "other areas inside" value, Therefore, for treatment in:

- Veal caves accommodations, the surface of bedding material is 160+20 = 180 m².
- Turkeys accommodations, the surface of wall is 3330+60 = 3390 m².

Concerning the application rate:

- For veal calves, 1.5kg of a.s/animal are considered. Therefore, 80 x 1.5 = 120 kg of active substance are needed to treat the bedding material of 80 animals distributed over 180m².
- For turkeys, the value given by the applicant is 0.2kg a.s/m² at a maximum.

Calculations are done according to scenario "Disinfection of animal housing" from ESDTP3 (2011). It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Input					
Type of House	cat-subcat (i1)	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype (i2)	Disinfectant	Disinfectant	[-]	D
Emission to STP	$Elocal_{wastewater}$	Not relevant	Not relevant	[-]	O

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Amount of a.s prescribed to be used per m²	Qprod m²	Not relevant	0.2	[kg/m²]	S
Amount of a.s prescribed to be used per animal	Qprod ani	1.5	Not relevant	[kg/animal]	S
Area of the housing for application (bedding material surfaces only)	$AREA_{i1}$	not relevant	3390	[m^2]	D
Amount of active ingredient to be used for one application	Qai-prescri1,i2,i3	120	678	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	52*	104*	[-]	D
Biocide application interval	Tbioc-int	7*	3*	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	$Nanimal_{i1}$	80	10000	[-]	D
Amount of nitrogen per animal	$Qnitrog_{i1}$	0.02382	0.00482	[kg/d]	D
IF NITROGEN IMMISSION STANDARDS ARE APPLIED					
Nitrogen immission standard for one year - grassland	$Q_{N,grassland}$	170	170	[$kg.ha^{-1}$]	D
Nitrogen immission standard for one year - arable land	$Q_{N,arable\_land}$	170	170	[$kg.ha^{-1}$]	D
Intermediate Calculations					
Fraction of a.s released to slurry/manure	Fslurry/manure	0.5	0.2+0.3=0.5	[-]	
Number of biocide applications – grassland / arable land	Napp-manure grassland and arable land	1*	1*	[-]	O
Amount of active ingredient in manure - grassland / arable land	$Qai\text{-}grass/arab_{i1,i2,i3,i4}$	60	339	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	101	2555	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	404	10218	[kg]	O

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Outputs					
Soil exposure via manure spreading					
Annual application rate per hectare (arable land)	-	25.2	5.64	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	101**	22.6**	[kg/yr/ha]	O

*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manure$_{gr}$ and Napp-manure$_{ar}$ = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) claimed by the applicant are presented for information only and not taken into account in the calculations of the emission.
** Worst-case used in the risk assessment.

As the use of CALCIUM DIHYDROXIDE BLENDS will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 2.3: disinfection of indoor walls of animal accommodations

The product is mixed with water and applied on walls of indoor animal accommodations, annually or before a production cycle, at a frequency that depends on sanitary breaks of animal cycles.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:
"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". Therefore, for poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

In the ESDTP3, no individual value for the walls surface is available. It is therefore calculated from the "Wall+roof" value, considering that the individual roof value could be equal to the "Floor" value.
Therefore, for treatment in:

- Veal caves accommodations, the surface of walls is 330-160 = 170 m².

- Turkeys accommodations, the surface of walls is 4650-3330 = 1320 m².

Calculations are done according to scenario "Disinfection of animal housing" from ESDTP3 (2011). It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Input					
Type of House	cat-subcat $_{(i1)}$	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype $_{(i2)}$	Disinfectant	Disinfectant	[-]	D
Emission to STP	$Elocal_{wastewater}$	Not relevant	Not relevant	[-]	O
Amount of active substance prescribed to be used per m²	Qa.s	0.8	0.8	[kg/m²]	S
Area of the housing for application (walls only)	$AREA_{i1}$	170	1320	[m²]	D
Amount of active ingredient to be used for one application	Qai-prescri1,i2,i3	136	1060	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	1*	1*	[-]	D
Biocide application interval	Tbioc-int	365*	365*	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	Nanimal $_{i1}$	80	10000	[-]	D
Amount of nitrogen per animal	Qnitrog $_{i1}$	0.02382	0.00482	[kg/d]	D
IF NITROGEN IMMISSION STANDARDS ARE APPLIED					
Nitrogen immission standard for one year - grassland	$Q_{N,grassland}$	170	170	[kg.ha^{-1}]	D
Nitrogen immission standard for one year - arable land	$Q_{N,arable\_land}$	170	170	[kg.ha^{-1}]	D
Intermediate Calculations					
Fraction of a.s released to slurry/manure	Fslurry/manure	0.5	0.2+0.3=0.5	[-]	
Number of biocide applications – grassland / arable land	Napp-manure grassland and arable land	1*	1*	[-]	O
Amount of active ingredient in manure - grassland / arable land	Qai-grass/arab$_{i1,i2,i3,i4}$	68	528	[kg]	O

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	101	2555	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	404	10218	[kg]	O
Outputs					
Soil exposure via manure spreading					
Annual application rate per hectare (arable land)	-	28.6	8.78	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	114**	35.1**	[kg/yr/ha]	O

*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations ($Napp\text{-}manure_{gr}$ and $Napp\text{-}manure_{ar}$ = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) claimed by the applicant are presented for information only and not taken into account in the calculations of the emission.
** Worst-case used in the risk assessment.

As the use of CALCIUM DIHYDROXIDE BLENDS will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path

Scenario 2.4: disinfection of indoor floor of animal accommodations

The dry product is applied on concrete or mud floor before a production cycle, at a frequency that depends on sanitary breaks of animal cycles.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:

"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". Therefore, for poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

Calculations are done according to scenario "Disinfection of animal housing" from ESDTP3 (2011). It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Input					
Type of House	cat-subcat (i1)	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype (i2)	Disinfectant	Disinfectant	[-]	D
Emission to STP	$Elocal_{wastewater}$	Not relevant	Not relevant	[-]	O
Amount of active substance prescribed to be used per m²	Qa.s	1	1	[kg/m²]	S
Area of the housing for application (floor only)	$AREA_{i1}$	160	3330	[m²]	D
Amount of active ingredient to be used for one application–	Qai-prescri1,i2,i3	160	3330	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	4*	2*	[-]	D
Biocide application interval	Tbioc-int	91*	182*	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	$Nanimal_{i1}$	80	10000	[-]	D
Amount of nitrogen per animal	$Qnitrog_{i1}$	0.02382	0.00482	[kg/d]	D
IF NITROGEN IMMISSION STANDARDS ARE APPLIED					
Nitrogen immission standard for one year - grassland	$Q_{N,grassland}$	170	170	[kg.ha^{-1}]	D
Nitrogen immission standard for one year - arable land	$Q_{N,arable\_land}$	170	170	[kg.ha^{-1}]	D
Intermediate Calculations					
Fraction of a.s released to slurry/manure	Fslurry/manure	0.5	0.2+0.3=0.5	[-]	

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Number of biocide applications – grassland / arable land	Napp-manure grassland and arable land	1*	1*	[-]	O
Amount of active ingredient in manure - grassland / arable land	Qai-grass/arab$_{i1,i2,i3,i4}$	80	1670	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	Qnitrog-grass$_{i1,i4}$	101	2555	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	Qnitrog-arab$_{i1,i4}$	404	10218	[kg]	O
Outputs					
Soil exposure via manure spreading					
Annual application rate per hectare (arable land)	-	33.7	27.7	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	135**	111**	[kg/yr/ha]	O

*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manure$_{gr}$ and Napp-manure$_{ar}$ = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) claimed by the applicant are presented for information only and not taken into account in the calculations of the emission.
** Worst-case used in the risk assessment.

As the use of CALCIUM DIHYDROXIDE BLENDS will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 3: disinfection of indoor floor of animal transportation

The dry product is applied on floor inside of vehicle every day after every transport. In ESDTP3 of 2011, the main emission pathway is emission to the wastewater, but also emission to air may take place. Based on a low vapour pressure (<<1.0E-05 Pa), negligible exposure via air is expected and therefore not further assessed.

To calculate the emissions to the STP of active substances such as lime is difficult because of the nature of the substance and the lack of data about their behavior in the STP, as this pathway was not assessed at the approval stage.

The doc IIA of the CAR (2016) specifies that adding lime up to 1000 mg/L in activated sludge test media causes high rises in pH (>12) which reduces to pH 10.6 after 3h. Other studies in different water media conducted with the same dose conclude that the reduction of the

pH to background values can last up to 7 days. Such pH changes in the STP over such times (3h as much as 7 days) would result in the elimination of microorganisms and disruption of its functioning.

Although a complete quantitative risk assessment is not possible due to a lack of data, the $Elocal_{wastewater}$ is calculated to estimate a PEC_{STP} and compare it with doses used in the activated sludge test of the CAR.

The calculation of the $Elocal_{wastewater}$ is done according to the ESDTP3, 2011, and presented in the table below:

Input	**Symbol**	**Value**	**Unit**	**Remarks**
Area of trucks (mammal transports)	AREAmam	4546	[m²]	ESDTP03, 2011
Area of trucks (poultry transports)	AREApoul	1120	[m²]	ESDTP03, 2011
Area of containers (poultry transports)	AREAcont	3355	[m²]	ESDTP03, 2011
Amount of active substance prescribed to be used per m²	Qa.si2,i3	1000	[g/m²]	S
Dilution factor (for preparation of the working solution from the formulation	Fdil	1	[-]	ESDTP03, 2011
Fraction released to waste water	Fstpi2i3i4	0.9	[-]	ESDTP03, 2011
Number of disinfectant applications in one year	Napp-bioc	365	[-]	ESDTP03, 2011
Output				
Emission from one application to a standard STP or an on-site waste water treatment plant (mammal)	**Elocal wastewateri2i3i4 mammal**	**4091**	[kg/d]	
Emission from one application to a standard STP or an on-site waste water treatment plant (poultry)	**Elocal wastewateri2i3i4 poultry**	**4028**	[kg/d]	
PEC_{STP} calculation				
Input				
Fraction of release to water from the STP	Fwater	1*	[-]	
Effluent discharge rate of STP	EFFLUENTstp	2000000	[L/d]	Vol IV Part B+C; 2017
Output				

PEC_{STP} resulting of one application to a standard STP or an on-site waste water treatment plant (mammal)	**$PEC_{STP\ mammal}$**	**2.05**	[g/L]	
PEC_{STP} resulting of one application to a standard STP or an on-site waste water treatment plant (poultry)	**$PEC_{STP\ poultry}$**	**2.01**	[g/L]	

*As the Koc is set to 0 kg/L and no information is available about biodegradation in STP, a fraction of release to water from the STP (Fwater) of 100% is considered.

As both PEC_{STP} are higher than the doses assessed in the CAR (and more than 500 times higher than the $PNEC_{STP}$ of 3.004 mg/L), high rises of the pH in the STP are expected. Therefore a release to the STP of the product after its use for animal transport disinfection leads to non-acceptable risks.

According to the applicant, a common practice to remove the lime consists in brushing the resulting dry waste before starting new transport to recycle them as agricultural liming material.

To prevent any releases to the STP from the disinfection of animal transport, the following two RMM are applied:
"Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant or other aquatic environment".

Scenario 4: disinfection of floor of outdoor animal enclosures

According to the applicant, the dry product is applied on the ground of poultry enclosures before each production cycle, every two weeks.

However, it has to be considering that as for manure and sludge spreading, 16 tons/ha /year of a.s is the maximum amount of lime that can be spread on soil. An application rate of 0.8 kg a.s/m² of soil corresponds to an application rate of 8 tons of a.s/ha. Therefore, only 2 applications per year at a maximum should be authorised. Higher application frequencies would lead to non-acceptable risks.

Moreover, in accordance with a French opinion[14], the disinfection of the rangeland using such biocidal active substances is only carried out when the farms have been detected infected. Expert considers that an at least 6 weeks of fallowing is mandatory after the treatment.
In routine, zootechnical measures are recommended.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
Use		Scenario	Fresh-water	Freshwater sediment	STP	Air	Soil	Groundwater
TP2	Disinfection of sewage sludge	Scenario 1	No	No	No	No	Yes	Yes
TP3	Disinfection of manure	Scenario 2.1	No	No	No	No	Yes	Yes

[14] AVIS du 14/10/16 révisé le 08/03/17* de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) relatif aux « procédés efficaces de désinfection des parcours en exploitations de volailles »

	Disinfection of bedding material	Scenario 2.2	No	No	No	No	Yes	Yes
	disinfection of walls of indoor animal accommodations	Scenario 2.3	No	No	No	No	Yes	Yes
	Disinfection of indoor floor surfaces of animal accommodations	Scenario 2.4	No	No	No	No	Yes	Yes
	Disinfection of animal transportation area	Scenario 3	Yes	Yes	Yes	No	Yes	Yes
	Disinfection of floors of outdoor animal enclosures	Scenario 4	No	No	No	No	Yes	Yes

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	74.09	g/mol	(IIB, 2016)
Vapour pressure	<1.0E-05	Pa	Not conducted as melting point above 300°C. It can be assumed the vapour pressure is $<10^{-5}$ Pa. (CAR 2016)
Water solubility (at 0°C)	1.85	g/l	(CAR, 2016)
Log Octanol/water partition coefficient	<<3	Log 10	(CAR, 2016)
Organic carbon/water partition coefficient (Koc)	0	l/kg	Worst-case specified in the CAR of 2016
Henry's Law Constant	-	$Pa/m^3/mol$	Not applicable (CAR, 2016)
Biodegradability	-		Not applicable 6(CAR, 2016)
DT_{50} for biodegradation in surface water	-	d or hr (at 12ºC)	When dissolved in water, Hydrated lime dissociates into Ca^{2+} and OH^-, which are chemically and biologically not further degradable (CAR, 2016)
DT_{50} for hydrolysis in surface water	-	d or hr (at 12ºC /pH)	When dissolved in water, Hydrated lime dissociates into Ca^{2+} and OH^-, which are chemically and

			biologically not further degradable (CAR, 2016)
DT_{50} for photolysis in surface water	-	d or hr	Not applicable, see Hydrolysis (CAR, 2016)
DT_{50} for degradation in soil (T0 to T=6h after application of lime in soil)	0.742h	hr	(CAR, 2016)
DT_{50} for degradation in soil (T=6h to T=+∞ after application of lime in soil)	372	hr	(CAR, 2016)

Calculated PEC values

For uses assessed in scenarios:
- ✓ 1 (treatment of sewage sludge),
- ✓ 2.1 (treatment of manure),
- ✓ 2.2 treatment of bedding material),
- ✓ 2.3 (treatment of indoor walls of animal accommodations),
- ✓ 2.4 (treatment of indoor floor animal accommodations),
- ✓ 4 (treatment of outdoor floor enclosures):

As all the uses generate lower emissions than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of CALCIUM DIHYDROXIDE BLENDS on soil. A qualitative assessment is deemed sufficient as proposed during the assessment of the active substance at the European level.

For use assessed in scenario 3 (treatment of vehicle for animal transport), only PEC_{STP} is calculated (see Emission estimation section):
- ✓ For mammals: PEC_{STP} = 2.05 g/L
- ✓ For poultry: PEC_{STP} = 2.01 g/L

Primary and secondary poisoning

Primary poisoning

It is not believed that powders are in a form that could be sufficiently appetent to bird or mammal so they would be at risk.
Moreover, for scenarios 1 and 2, as the product is mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca^{2+}, Mg^{2+}, and OH^-) in the environment.

2.2.8.3 Risk characterisation

Atmosphere

For hydrated lime, exposure via air (and subsequent phototransformation in air) would be negligible based on its structure and its expected low vapour pressure (<<1.0E-05 Pa).

Due to the negligible exposure, no formal risk assessment of air compartment is considered necessary.

Aquatic compartment (surface water, sediment and sewage treatment plant)

For uses assessed in scenarios:
- ✓ 1 (treatment of sewage sludge),
- ✓ 2.1 (treatment of manure),
- ✓ 2.2 treatment of bedding material),
- ✓ 2.3 (treatment of walls of indoor animal accommodations),
- ✓ 2.4 (treatment of animal indoor floor accommodations),
- ✓ 4 (treatment of animal outdoor enclosures):

According to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path. Moreover, the following RMM will be included to prevent any releases to the STP: "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".

For use assessed in scenario 3 (treatment of indoor floor of animal transportation), a risk assessment for the STP compartment is conducted for mammal and poultry:

Uses	PEC_{STP} (mg/L)	$PNEC_{STP}$ (mg/L)	PEC/PNEC
Scenario 3 – indoor floor of animal transportation - Mammals	2050	3.004	**681**
Scenario 3 – indoor floor of animal transportation - Poultry	2010	3.004	**670**

Thus, unacceptable risks are foreseen for the STP compartment for this use.
The following RMM will be included to prevent any releases to the STP:
"Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant or other aquatic environment".

Terrestrial compartment

All the uses of CALCIUM DIHYDROXIDE BLENDS that lead to emissions to soil will generate application rate of lime on agricultural soil lower than the routine agricultural use of lime spread to correct soil pH and maintain soil fertility (16T/ha/year, see table below).

Uses	Emissions to soil (agricultural land, in T/ha/year)

PT2		
1 – Disinfection of sewage sludge	3.3	
PT3	Veal calves	Turkeys
2.1 – Disinfection of manure	5.00	1.27
2.2 - Disinfection of bedding material	0.10	0.02
2.3 - Disinfection of indoor walls of animal accommodations	0.11	0.04
2.4 - Disinfection of indoor floor surfaces of animal accommodations	0.20	0.17
3 - Disinfection of animal transportation area	n.r.	n.r.
4 - Disinfection of floor of outdoor animal enclosures	n.r.	16

Therefore, the use of CALCIUM DIHYDROXIDE BLENDS leads to acceptable risk to the terrestrial compartment.

Groundwater

Hydrated lime dissociates into Ca^{2+} and OH^- when in contact with water.

The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, Ca^{2+} ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwater.

Primary and secondary poisoning

Primary poisoning

It is not believed that powders are in a form that could be sufficiently appetent to birds or mammals so they would be at risk.
In the case of the application of a suspension (scenario 1 and 2 only), as the product is mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not

significantly influence the distribution of the constituents (Ca^{2+}, Mg^{2+}, and OH^-) in the environment.

Aggregated exposure (combined for relevant emissions sources)

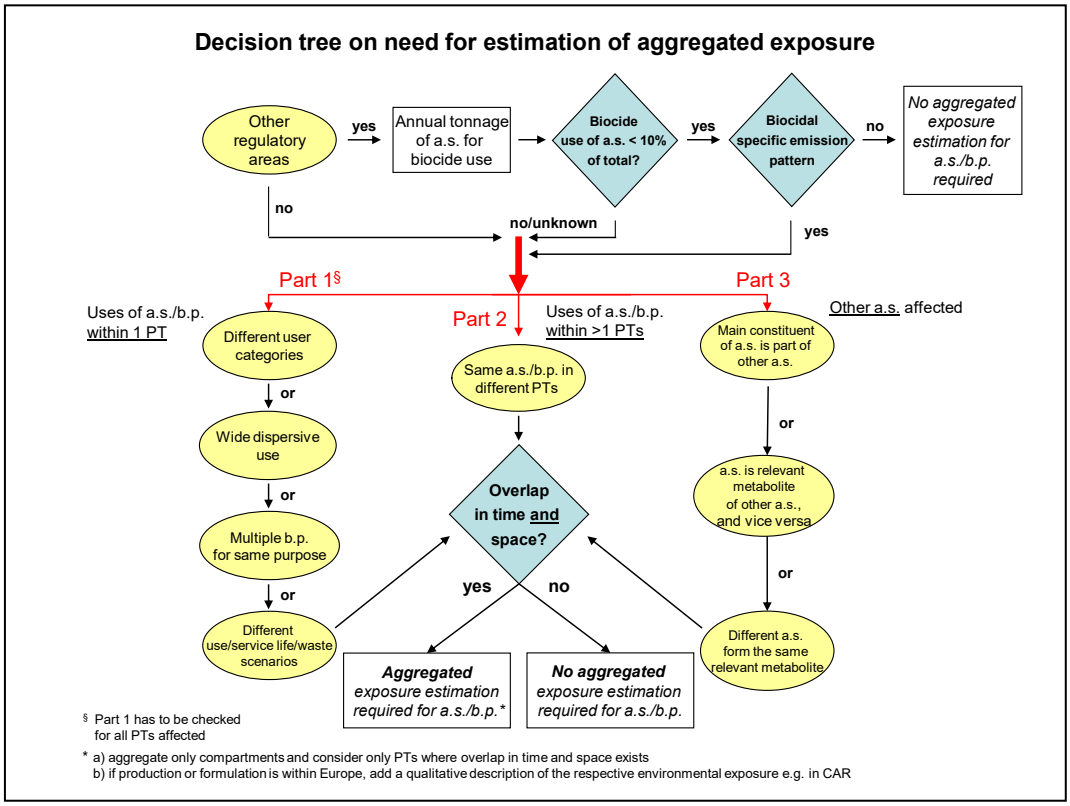


Figure 1: Decision tree on the need for estimation of aggregated exposure

No aggregated exposure is relevant for this dossier. However, an aggregated risk assessment leads to acceptable risks when all the uses are considered.
In the CAR of the active substance, it is recommended to verify the pH of the soil to be amended or the pH of the spread sludge/manure in order not to have a pH disruption.

It is considered that this verification is part of good spreading/amendments practices. For example, in France several norms and regulation ensure the correct spreading of lime treated materials on agricultural fields, including soil pH monitorings. Hence eCA considers that such RMM is not necessary nor relevant in the SPC of the biocidal product.

Nevertheless, it is recommended to verify the pH of the soil to be amended or of the spread sludge/manure in order not to have a pH disruption.

Overall conclusion on the risk assessment for the environment of the product
Acceptable risks for the environment are foreseen for the uses: **META-SPC1 (dustable powder):** <u>In PT2:</u> ✓ disinfection of sewage sludge,

In PT3: and considering the following RMM: "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".

- ✓ disinfection of manure,

META-SPC2 (dustable powder):

In PT3, considering the following RMM "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.":

- ✓ disinfection of animal bedding material,
- ✓ disinfection of indoor floor of animal accommodations and transportation,

In PT3, and considering the following RMM "Do not exceed two applications per year."

- ✓ disinfection of floors of outdoor animal enclosures.

META-SPC3 (suspension):

In PT2:

- ✓ disinfection of sewage sludge,

In PT3: and considering the following RMM "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".

- ✓ disinfection of manure,
- ✓ disinfection of indoor walls of animal accommodations,

2.2.9 Measures to protect man, animals and the environment

[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

3 ANNEXES[15]

3.1 List of studies for the biocidal product (family)

Author(s)	Year and Report date	Annex II/III requirements and IUCLID section	IUCLID document name	Title and Report number	Type of publication	Source (where different from company) and Study sponsor	GLP	Data Protection Claimed (Yes/No)
Author: Anon	Year: 2019	**Annex II/III requirement:** Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	IUCLID Document name: Appearance (at 20°C and 101.3 kPa)_meta-SPC 1_Biocalco SL70	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	IUCLID Document name: Appearance (at 20°C and 101.3 kPa)_meta-SPC 2_Optilit 20	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	IUCLID Document name: Appearance (at 20°C and 101.3 kPa)_meta-SPC 3_Biocalco M20	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	IUCLID Document name: Appearance (at 20°C and 101.3 kPa)_meta-SPC 3_Biocalco M50	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity	IUCLID Document name: pH_meta-SPC 3_meta-SPC	Title: Report of Carmeuse biocide lime products analysis	Type of publication: study report		yes	Yes

15 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

		IUCLID Section No. 3.2	1_Biocalco SL70 - Eurofins 2019	No report number provided				
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco SL70 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco SL70 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Physico-chemical Properties of Optilit 20 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:**	IUCLID Document	Title: Report of Carmeuse biocide	Type of publication:		yes	Yes

		Acidity, alkalinity **IUCLID Section No.** 3.2	name: Acidity, alkalinity_meta-SPC 2_Optilit 20 - Eurofins 2019	lime products analysis No report number provided	study report			
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Physico-chemical Properties of Optilit 20 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco M20 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco M20 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes

[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: pH_meta-SPC 3_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco M50 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco M50 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
[redacted]	Year: 2018	**Annex II/III requirement:** Relative density (liquids) and bulk, tap density (solids) **IUCLID Section No.** 3.3	IUCLID Document name: Relative density (liquids) -meta-SPC 3_waiver	Title: Milk of lime stability study report No report number provided	Type of publication: other company data		not specified	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Relative density (liquids) and bulk, tap density (solids) **IUCLID Section No.** 3.3	IUCLID Document name: bulk, tap density (solids) -meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Dry Sieve Analysis of Biocalco SL70 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Relative density (liquids) and bulk, tap density (solids) **IUCLID Section No.** 3.3	IUCLID Document name: bulk, tap density (solids) -meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Dry Sieve Analysis of Optilit 20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve	yes	Yes

						Belgium		
Author: Anon	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco SL70 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 2_Optilit 20-Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 2_Optilit 20-Eurofins 2019	Title: Physico-chemical Properties of Optilit 20 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Storage stability tests	IUCLID Document name: Storage stability test_Accelerate	Title: Physico-chemical Properties of Biocalco M20 before and after	Type of publication: study report	Company Owner: Carmeuse Europe Boulevar	yes	Yes

		IUCLID Section No. 3.4.1	d_meta-SPC 3_Biocalco M20 - Eurofins 2019	Accelerated Storage for 2 weeks at 54 °C No report number provided		d de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium		
Author: Anon	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Physico-chemical Properties of Biocalco M50 before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dry sieve test_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dry sieve test_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Dry Sieve Analysis of Biocalco SL70 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product	IUCLID Document name: Dustibility_meta-SPC 1_Biocalco SL70 - Eurofins	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes

		IUCLID Section No. 3.5	2019					
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dustibility_meta-SPC 1_Biocalco SL70 - Eurofins 2019	Title: Determination of the Dustiness of Biocalco SL70 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dry sieve test_meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dry sieve test_meta-SPC 2_Optilit 20 - Eurofins 2019	Title: Dry Sieve Analysis of Optilit 20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dustibility_meta-SPC 2_Optilit 20- Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dustibility_meta-SPC 2_Optilit 20- Eurofins 2019	Title: Determination of the Dustiness of Optilit 20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348	yes	Yes

						Louvain-la-Neuve Belgium		
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: PSD_meta-SPC 3_Biocalco M20	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: PSD_meta-SPC 3_Biocalco M50	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Wet sieve_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Wet sieve_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Wet Sieving of Biocalco M20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Wet sieve_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics	IUCLID Document name: Wet sieve_meta-	Title: Wet Sieving of Biocalco M50 No report number	Type of publication: study report	Company Owner: Eurofins Agroscie	yes	Yes

		of the biocidal product **IUCLID Section No.** 3.5	SPC 3_Biocalco M50 - Eurofins 2019	provided		nce Services EcoChem GmbH Eutinger Straße 24 D – 75223 Niefern-Öschelbronn Germany Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium		
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Suspensibility_ meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Suspensibility_ meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Suspensibility of Biocalco M20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Suspensibility_ meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical	IUCLID Document name:	Title: Suspensibility of Biocalco M50	Type of publication: study report	Company Owner: Carmeus	yes	Yes

[redacted]		characteristics of the biocidal product **IUCLID Section No.** 3.5	Suspensibility_ meta-SPC 3_Biocalco M50 - Eurofins 2019	No report number provided		e Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium		
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Pourability_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Pourability_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Pourability of Biocalco M20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Pourability_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Pourability_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Pourability of Biocalco M50 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author:	Year:	**Annex II/III**	IUCLID	Title: Report of	Type of		yes	Yes

Anon	2019	**requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	Document name: Persistent foam_meta-SPC 3_Biocalco M20 - Eurofins 2019	Carmeuse biocide lime products analysis No report number provided	publication: study report			
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Persistent foam_meta-SPC 3_Biocalco M20 - Eurofins 2019	Title: Persistent Foam of Biocalco M20 No report number provided	Type of publication: study report	Company Owner: Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium	yes	Yes
Author: Anon	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Persistent foam_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report			Yes
[redacted]	Year: 2019	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Persistent foam_meta-SPC 3_Biocalco M50 - Eurofins 2019	Title: Persistent Foam of Biocalco M50 No report number provided	Type of publication: study report	Company Owner: Eurofins Agroscience Services EcoChem GmbH Eutinger Straße 24 D – 75223 Niefern-Öschelbronn Germany Carmeuse Europe. Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve		Yes

						Belgium		
[redacted]	Year: 2018	**Annex II/III requirement:** Viscosity **IUCLID Section No.** 3.9	IUCLID Document name: Viscosity - Milk of Lime	Title: Milk of lime stability study report No report number provided	Type of publication: other company data		not specified	Yes
[redacted]	Year: 2012	**Annex II/III requirement:** Corrosive to metals **IUCLID Section No.** 4.16	IUCLID Document name: Corrosive to metals_ CTL 2012	Title: Corrosion Testing per OSHA Regulations CFR 1910.1200 Appendix B No report number provided	Type of publication: study report	Company Owner: Corrosion Probe, Inc. 12 Industrial Park Rd. P.O. BOX 178 Centerbrook, CT 06409-0178		Yes
[redacted]	Year: 2013	**Annex II/III requirement:** METHODS OF DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	IUCLID Document name: Analytical methods for determination in air	Title: ISO 17091:2013 Workplace air — Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide — Method by measurement of corresponding cations by suppressed ion chromatography Report no. ISBN 978 0 580 77732 5	Type of publication: publication			Yes
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	IUCLID Document name: 6.7-01 Meta SPC 2 Optillit C+, 3000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Optilit C 3000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse Europe, Boulevard de Lazelle, 65, B-1348, Louvain la Neuve, Belgium	not specified	Yes

		IUCLID Section No. 6.7						
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-02 Meta SPC 2 Optillit C+ , 4000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Optilit C 4000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse euope, Bvd de Lauzelle, Louvain-la-Neuve, Belgium	not specified	Yes
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-03 Meta SPC 2 Optillit C+ , 5000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Optilit C 5000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse Europe , Louvain la Neuve, Belgium	not specified	Yes
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance	IUCLID Document name: 6.7-05 Meta SPC 3 Biocalco M, 3000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Biocalco M 3000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse Europe, Louvain-la-Neuve, Belgium	not specified	Yes

		standards where appropriate and relevant **IUCLID Section No.** 6.7						
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-06 Meta SPC 3 Biocalco M , 4000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), BIOCALCO M 4000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse Europe, Louvain-la-Neuve, Belgium	not specified	Yes
[redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-07 Meta SPC 3 Biocalco M , 5000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), BIOCALCO M 5000g/m2 Report no. 201800315	Type of publication: study report	Source: NA Company Owner: Carmeuse Europe, Louvain-la-Neuve, Belgium	not specified	Yes
[redacted]	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols,	IUCLID Document name: 6.7- 08 Meta 3 Biocalco M20, Simulated Use , Placeholder	Title: Biocalco M20: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281 Report no. N°RE-	Type of publication: study report	Company Owner: CARMEUSE EUROPE SA Rue du château 13A		Yes

		laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7		1101/0220		5300 SEILLES BELGIQUE		
[redacted]	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7- 09 Meta 1 Biocalco SL60, Simulated Use , Placeholder	Title: BIOCALCO SL 60: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281 Report no. N°RE-1104/0220	Type of publication: study report	Company Owner: CARMEUSE EUROPE SA Rue du château 13A 5300 SEILLES BELGIQUE		Yes
[redacted]	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7- 09 Meta 1 Biocalco SL60, Simulated Use , Placeholder	Title: BIOCALCO SL 60: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281 (March 2020) Report no. RE-141/1119	Type of publication: study report	Company Owner: CARMEUSE EUROPE SA Rue du château 13A 5300 SEILLES BELGIQUE		Yes
[redacted]	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims,	IUCLID Document name: 6.7-10, Meta SPC 2, OPTILIT 20,	Title: OPTILIT 20: Determination of microbicide activity of lime according a methodology	Type of publication: study report	Company Owner: CARMEUSE EUROP		Yes

		including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Simulated Use, Placeholder	modelled on NF T 72-281 Report no. N°RE-1108/0220		E SA Rue du château 13A 5300 SEILLES BELGIQUE		
[redacted]	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-10, Meta SPC 2, OPTILIT 20, Simulated Use, Placeholder	Title: OPTILIT 20: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281 (April 2020) Report no. RE-1439/1119/A	Type of publication: study report	Company Owner: CARMEUSE EUROPE SA Rue du château 13A 5300 SEILLES BELGIQUE		Yes
[redacted]	Year: 2003	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-11 from AS A5.10.01 Schirm et al. Hygienisation of biowaste. 2003	Title: Development of a safe method to hygienise bio-waste with lime Report no. 336-0201	Type of publication: publication	Source: Forschungsgemainschaft Kalk, 1/03/ C 023 Jan 2003 Company Owner: NA	not specified	No
[redacted]	Year:	**Annex II/III**	IUCLID	Title: Liming as an	Type of	Source:	not	No

[redacted]	2004	**requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Document name: 6.7-12 from AS A5 10.02 Capizzi-Banas et al Liming as an advanced treatment for sludge sanitisation. 2004	advanced treatment for sludge sanitisation: helminth eggs elimination - Ascaris as a model Report no. NA	publication: publication	Water Research 38: 3251-3258: Doc. No. 392-024 Company Owner: NA	specified	
[redacted]	Year: 1984	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-13 From AS A5 10.03 Pfuderer G Hygenic aspects related to the treatment and use of sewage sludge. 1985	Title: Hygenic aspects related to treatment and use of sewage sludge Report no. NA	Type of publication: publication	Source: Ed P. L'Hermite, Elsevier, pp 85-97; Doc No 392-035 Company Owner: NA	not specified	No
[redacted]	Year: 2008	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	IUCLID Document name: 6.7-14 - Evaluation of Liming in liquid and solid manure, Daugshies, 2008	Title: Evaluation of limingin liquid and solid manure Report no. not assigned	Type of publication: study report	Source: NA Company Owner: EuLA	not specified	Yes

		IUCLID Section No. 6.7						
[redacted]	Year: 2008	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-15 - Evaluation of Liming in liquid manure - 90 day, Daugshies, May 2008	Title: Evaluation of the effect of liming in liquid pig and cattle manure on Ascaris suum eggs Report no. NA	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	Yes

3.2 Output tables from exposure assessment tools

Exposure calculations.zip

ART modelisation.zip

Riskofderm modelisation.zip

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[16]

3.6 Confidential annex

3.7 Other

Annex 1 – Risk assessment for animal health

Disinfection of indoor floor surfaces, animal transportation, bedding materials and outdoor floor surfaces

16 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

According to the information provided by the applicant, the biocidal product is always removed after the treatment of the floor surfaces of animal accommodations, transportation, bedding materials and outdoor enclosures. Animals are not present during the treatment (which includes the application, the contact time of 48h and the removal of the product by sweeping).

Animals are not expected to be directly in contact with residues as the floor has to be covered with fresh straw before the re-entry. Moreover, after a contact time of 48h, no lime residues is expected on floor surfaces but only reaction products (with no irritant properties expected) that are swept at the end of the treatment. Considering that, no local RA is performed.

Regarding systemic RA, it is not considered relevant taking into account that animal exposure via feed is excluded by the addition of a specific RMM to remove feed during the treatment. Furthermore, the Ca^{2+} and Mg^{2+} intake from the product is considered negligible compared to those from the normal feeding of livestock.

The following RMM will be added:

- 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;
- 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.

Disinfection of animal accommodation walls by brush

Animals are not present during the treatment of walls that includes the application, the contact time and the drying period.
In order to avoid exposure to the wet treated surfaces, a RMM is proposed to not let animals re-enter the accommodations before complete drying of surfaces.
Regarding the exposure to dried surfaces, no local risk assessment has been performed based on the fact that the irritant properties of the water suspended lime applied on the walls are no longer expected after drying. Indeed, after application of the water suspended lime, water evaporates and hydrated lime reacts with CO_2 from the air to form $CaCO_3$ that does not present any irritant properties.
Considering a systemic risk assessment due to exposure to Ca^{2+} and Mg^{2+}, it is not considered relevant taking into account that intake from the product from a licking behaviour is considered negligible compared to those from the normal feeding of livestock.

The following RMMs are proposed:
- Animals should not be present during all the treatment duration;
- Do not let animal re-enter the accommodations before complete drying of surfaces.