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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

BIOCALCO QL

Product type(s) 2, 3

Calcium Oxide

Case Number in R4BP: BC-FW038812-16

Evaluating Competent Authority: FR

Date: [December 2023]

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1. CONCLUSION

The biocidal product BIOCALCO QL is a calcium oxide based PT2 and 3 product intended to be used as a disinfectant for the treatment of sewage sludge and manure, for professional users only.

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

The product is a blend of the active substance and an inert filler. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts.
The product is a white dusty solid of naturally occurring origin. The solid is alkaline with a 1% diluted pH of 12.4 at 22°C and an alkalinity of 69% w/w as NaOH.
The product has been shown to be stable after 2weeks 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 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 (see EULA OXILIME products for more details). Long-term storage stability is on-going and will be required in post-authorization, including specifications of active substance. Based on the accelerated storage, a 2 years shelf life could be set.

Implication for labelling: Protect from humidity
Store away from acids

Calcium oxide will react exothermically upon contact with water to form calcium dihydroxide.
Mitigation measure needed: **EUH014 - reacts violently with water**.
The product is not classified for other physical hazard properties.

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

<u>Conclusion on efficacy</u>

The product BIOCALCO QL has 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 and temperature > 50°C during the exposure time.
The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature and should be calculated by the user based on 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. This target organism is therefore not proposed for authorisation for this use.

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

The effective final use concentration and contact time are variable. pH should be > 12 and temperature > 60°C during the exposure time.
The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature and should be calculated by the user based on the dry weight of the substrate.

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

Conclusion on risk for Human Health

For local effects (due to the calcium oxide), the risk is considered acceptable for the scenarios of loading (manual, semi-automated and automated), cleaning and disposal of empty bags (semi-automated) taking into account appropriate RPE.

Regarding the results of the RA for manual disposal of empty bags indoor and outdoor, the %AEC is above 100% even considering a RPE (APF 40).

Based on these results, the risk is deemed not acceptable for the professional during handling of small bags of 25kg of lime powder product.

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

For semi-automated loading and cleaning of the unit treatment:
- gloves;
- protective coverall;
- goggles;
- Respiratory protective equipment at least APF 40.

For fully automated loading and disposal of big bags:
- gloves;
- protective coverall;
- goggles;
- Respiratory protective equipment at least APF 10.

In addition to the above mentioned PPE, the following RMMs are required:
- The loading of burnt lime powder into the treatment unit and the application must be done semi or fully 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).
- Wear protective gloves and protective coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge/manures, wearing RPE specific for air fed ammonia gas or for canisters, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.
- 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 and the disposal of empty bags).

- Use in a well ventilated area.

Conclusion on risk for Animal Health

No exposure of animals with lime based product occurs during disinfection of sludge and manures as the application is done in a closed system (unit treatment). Consequently, no unacceptable risk for animal health is expected.

Conclusion on risk for consumers via residues in food

Considering that the intended uses on sludge (TP2) and manure (TP3), no dietary exposure is expected.

Conclusion on Risk for environment

Acceptable risks are foreseen for the following uses:

In PT2:

- disinfection of sewage sludge,

In PT3:

- disinfection of manure, with 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."

2. ASSESSMENT REPORT

2.1. Summary of the product assessment

2.1.1. Administrative information

2.1.1.1. Identifier of the product

Identifier	Country (if relevant)
BIOCALCO QL	France, Romania

2.1.1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	Carmeuse Europe S.A.
	Address	Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve, Belgium
Authorisation number	**FR-2023-0080**	
Date of the authorisation	**09/01/2024**	
Expiry date of the authorisation	**08/01/2034**	

2.1.1.3. Manufacturer(s) of the products

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 Garii 2, 135100 Fieni, Romania. Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Privat, 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 SA
Address of manufacturer	Rue du Château 13a, 5300 Seilles, Belgium

Location of manufacturing sites	Rue de Boudjesse 1, 5070 Aisemont, Belgium. 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 Košice, Vstupný areál U.S. Steel, 044 54 Košice, Slovakia. závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia.

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

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

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2.1.2. Product composition and formulation

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1. Identity of the active substance

Main constituent(s)	
ISO name	Calcium oxide
IUPAC or EC name	Calcium oxide
EC number	215-138-9
CAS number	1305-78-8
Index number in Annex VI of CLP	N/A
Minimum purity / content	800 g/kg (the value provides the content of Ca expressed as CaO)
Structural formula	**Ca – O**

2.1.2.2. Candidate(s) for substitution

The active substance 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 product1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Burnt lime	Calcium oxide	Active substance	1305-78-8	215-138-9	50
See confidential annex for details					

2.1.2.4. Information on technical equivalence

Not applicable.

2.1.2.5. Information on the substance(s) of concern

No substance fulfil the criteria to be defined as a substance of concern.

1 Please delete as appropriate.

2.1.2.6. Assessment of endocrine disruption (ED) properties of the biocidal product

According to the ED conclusions in the BPC opinions (ref. BPC OPI PT2, BPC OPI PT3, 2016) from the active substance approval, burnt lime is not considered to have endocrine disrupting properties.

There is no indication of concern regarding ED properties of any of the co-formulants contained in the product BIOCALCO QL. Please refer to Confidential Annex.

Hence, the biocidal product does not have ED properties.

2.1.2.7. Type of formulation

DP – Dustable Powder

2.1.3. Hazard and precautionary statements[2]

Classification and labelling of the products according to the Regulation (EC) 1272/2008

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

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
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 soap and 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	EUH014 - reacts violently with water

2.1.4. Authorised use(s)

2.1.4.1. Use description

Table 1. Use # 1 – Disinfection of sewage sludge

Product Type	PT 02
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 high enough to achieve a pH of > 12 and a temperature >50°C during the contact time. Contact time: 24h
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks : 750 kg

2.1.4.2. Use-specific instructions for use

- The dose must be high enough to achieve a pH of > 12 and a temperature >50°C during 24 hours.
- Application rate: 0.4 – 4.0 kg product (0.2 – 2 kg a.s) / 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.

2.1.4.3. Use-specific risk mitigation measures

-The loading of burnt lime powder into the treatment unit must be done semi or fully 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 semi-automated loading and the cleaning of the unit treatment, wear :

- a respiratory protective equipment at least APF 40;
- 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).;
- chemical goggles.

During the fully automated loading of the product and the disposal of big empty bags, wear:

- a respiratory protective equipment at least APF 10;
- 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);
- chemical goggles.

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

-Wear protective gloves and protective coverall during the manual handling of treated sewage sludge.

2.1.4.4. 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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2.1.4.5. Where specific to the use, the instructions for safe disposal of the product and its packaging

See 2.1.5.4

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

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2.1.4.7. Use description

Table 2. Use # 2 – Disinfection of manure

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Virus, 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 of product The product is mixed with the manure. The product should be loaded by fully automated processes. The application rate must be sufficient to maintain a pH of > 12 and a temperature > 60°C during the contact time. Contact time: 24 hours
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750 kg

2.1.4.8. Use-specific instructions for use

- The application rate must be sufficient to maintain a pH of > 12 and a temperature > 60°C during the contact time.
- Remove the manure from the animal house.

<u>Application rate:</u>

- 1. Do not apply more than 200 kg product (100 kg a.s) /m^3 of manure.
- 2. The mixture should be moistened and any self-ignition that might occur should be extinguished with water.
- 3. After the necessary contact time, dispose of the lime treated manure according to local legislation.

2.1.4.9. Use-specific risk mitigation measures

-The loading of burnt lime powder into the treatment unit must be done semi or fully 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 semi-automated loading and the cleaning of the unit treatment , wear :

- a respiratory protective equipment at least APF 40;
- 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).;
- chemical goggles.

During the fully automated loading of the product and the disposal of empty bags, wear :

- a respiratory protective equipment at least APF 10;
- 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).;
- chemical goggles.

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

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

- 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.

2.1.4.10. 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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2.1.4.11. Where specific to the use, the instructions for safe disposal of the product and its packaging

See 2.1.5.4

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

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2.1.5. General directions for use

2.1.5.1. Instructions for use

- Comply with the instructions for use.
- Respect the indicated contact time and pH for the required antimicrobial activity.
- For outdoor uses, do not apply in case of rain of wind.

2.1.5.2. Risk mitigation measures

- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application of the product, the disposal of empty bags and the acting time).
- Use only in a well ventilated area.

2.1.5.3. 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.

2.1.5.4. 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.

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

- Protect from humidity.
- Shelf-life: 2 years.

- Store away from acids.

2.1.6. 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.

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 (Yes/No)**
Big bag/sack	750 kg	Paper	plastic foil	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 has been supplied.

2.2. Assessment of the biocidal product

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

Table 1. Intended 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. 0.4 - 4.0 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 sacks: 25 kg

Table 2. Intended 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, nematode eggs
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	Application to manure/litter outside animal houses Remove the manure or litter from the animal house. 1. For prevention: Add approximately 0.2 kg product/m3 of litter or manure. 2. For treatment: Add approx. 20 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 treated manure.

	5. After at least 24h, dispose of the treated manure according to local legislation. Application of product to litter or manure inside animal houses 1. For Prevention: Spread approx. 20 kg/m3 (4 kg of product /m2 for 20 cm litter) on the litter or manure inside the poultry house 2. For treatment: Spread approx. 200 kg/m3 (40 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 product/manure or product/litter mixture from the animal house 5. Homogenise the product/manure or litter mixture 6. Stockpile the treated manure 7. After at least 24 h, dispose the treated manure according to the local legislation
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk Big bags or sacks: 750kg Paper sacks: 25 kg

2.2.2. Physical, chemical and technical properties

The product is a dustable powder (DP) ready to use.
There is no hydrocarbons or H304 co-formulants in the product.
Packaging: big bag (paper/PP).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical state at 20 °C and 101.3 kPa	OPPTS 830 6301, 6303 and 6304	BIOCALCO QL: 50% calcium oxide	Solid (homogeneous powder)	Carmeuse 2019	Acceptable
Colour at 20 °C and 101.3 kPa			White		
Odour at 20 °C and 101.3 kPa			Not specified		
Acidity / alkalinity pH	CIPAC MT 191 CIPAC MT 75.3	BIOCALCO QL: 50% calcium oxide	69.04 % w/w as NaOH pH (1%): 12.42 (22.2°C)	Carmeuse 2019	Acceptable
		BIOCALCO QL: 50% calcium oxide	pH: 12.73 (21.4°C) Alkalinity: 74.89% w/w NaOH	Eurofins 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
		BIOCALCO QL: 50% calcium oxide	Tap density : 1.12 g/mL	Eurofins 2019	Acceptable
Storage stability test – **accelerated storage**	CIPAC MT 46.3	BIOCALCO QL: 50% calcium oxide	<table><tr><td></td><td>Initial</td><td>After 2w at 54°C in paper bag</td></tr><tr><td>pH (20°C)</td><td>12.73</td><td>12.68</td></tr></table>	Eurofins 2019	Acceptable No significant changes of the determined

<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>Alkalinity (% w/w NaOH)</td><td>74.89</td><td>71.46</td></tr></table></td><td></td><td>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 (see EULA OXILIME products for more details).</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td></td><td>Batch n° : 20190306_O20 Opilit 20</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">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>69.04 % w/w as NaOH

pH (1%): 12.42 (22.2°C)</td><td>67.94 % w/w as NaOH

pH (1%): 12.38 (22.2°C)</td></tr></table></td><td>Study report Carmeuse</td><td>Product is stable after 1 month at 20°C.
Based on accelerated storage, the shelf-life can be extrapolated to 24months.

No data about specification of active substance during storage is</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>Dry sieve</td><td>% residue at:
- 45 µm = 18.20 %
- 63 µm = 7.44 %
- 90 µm = 2.60 %
- 125 µm = 0.68 %
- 1 mm = 0 %</td><td>% residue at:
- 45 µm = 21.44 %
- 63 µm = 10.4 %
- 90 µm = 3.68 %
- 125 µm = 1.08 %
- 1 mm = 0 %</td></tr>
<tr><td>Particle size</td><td>D(0.1) = 1.29 µm
D(0.5) = 11.63 µm
D(0.9) = 59.70 µm</td><td>D(0.1) = 1.45 µm
D(0.5) = 14.23 µm
D(0.9) = 68.92 µm</td></tr>
</table>
</td><td></td><td>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
Determination of active part of the lime mixture can be assessed using alkalinity before and after storage.

Final results of long term storage is required in post-authorization (including specification of active substance).</td></tr>
<tr><td></td><td>Norm EN 459-2

CIPAC MT31</td><td>Oxilime 90, DP</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 15months in big-bags</td></tr>
<tr><td>Content (%w/w)</td><td></td><td></td></tr>
<tr><td>CaO</td><td>78.5</td><td>80.7</td></tr>
<tr><td>CO2</td><td>10.2</td><td>8.4</td></tr>
<tr><td>SO3</td><td>1.15</td><td>1.2</td></tr>
<tr><td>MgO</td><td>5.6</td><td>4.7</td></tr>
<tr><td>SiO2</td><td>2.1</td><td>2.1</td></tr>
<tr><td>Fe2O3</td><td>0.5</td><td>0.5</td></tr>
</table>
</td><td>  </td><td>Results of long term storage of OXILIME product (100% active substance) is added here for information. A LoA to EULA products is provided by the applicant.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			Al2O3 0.4 0.4 K2O 0.13 0.14 Na2O 0.05 0.02 MnO2 0.06 0.06 pH 12.5 12.5 Alkalinity 0.27% NaOH 0.29% NaOH Particle size D10: 1.4µm D50: 23µm D90: 118µm D100: 350µm D10: 1.5µm D50: 27µm D90: 162µm D100: 350µm		The specifications of active substance are considered stable after 15months in big bag.
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		Active substance is water reactive, therefore, a note should be added on the label.		A note should be added from label: **Protect from humidity** Mention EUH014: "reacts violently with water" is also added.
Effects on content of the active substance and technical characteristics of the biocidal	CIPAC MT 46.3	BIOCALCO QL: 50% calcium oxide	There was no significant change in the product or the packaging after 4 weeks at 50° C	Carmeuse 2019	CIPAC MT 46.3

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
product - **reactivity towards container material**					
Wettability	Waiver		Not relevant for a DP formulation		
Suspensibility, spontaneity and dispersion stability	Waiver		Not relevant for a DP formulation		
Wet and dry sieve	CIPAC MT 59.1	BIOCALCO QL: 50% calcium oxide	Dry sieve Percentage residue at: - 45 µm = 18.20 % - 63 µm = 7.44 % - 90 µm = 2.60 % - 125 µm = 0.68 % - 1 mm = 0 % - 1.4 mm = 0 % D(0.1) = 1.29 µm D(0.5) = 11.63 µm D(0.9) = 59.70 µm	Carmeuse 2019	Acceptable
	CIPAC MT 186	BIOCALCO QL: 50% calcium oxide	The product is defined as very dusty with all particles in the range 5-125 µm	Eurofins 2019	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		Not relevant for a DP formulation		
Disintegration time			Not relevant for a DP formulation		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	BIOCALCO QL: 50% calcium oxide	D(0.1) = 1.29 µm D(0.5) = 11.63 µm D(0.9) = 59.70 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 QL: 50% calcium oxide	Not performed – the product is a dusty solid as indicated by the dry sieve and PSD test,	Carmeuse 2019	Acceptable
	CIPAC MT 171.1		The dustiness of the test item is categorized as essentially non dusty	Eurofins 2019	
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 long-time experience, quicklime (CaO) products (and consequently the hydrated lime ($Ca(OH)_2$) products) can be stored without		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			any 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. Incompatibility with stainless steel packaging was not demonstrated too.		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			Not applicable to solids		
Viscosity			Not applicable to solids		

Conclusion on the physical, chemical and technical properties of the product
The product is a blend of the active substance and an inert filler. The substances are naturally occurring inorganic salts. The product is a white dusty solid of naturally occurring origin. The solid is alkaline with a 1% diluted pH of 12.4 at 22°C and an alkalinity of 69% w/w as NaOH. 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 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). Base on the accelerated storage, a 2 years shelf life could be set. **Implication for labelling:** Protect from humidityEUH014 : reacts violently with water.

2.2.3. Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Explosives	Waiver		Not explosive According to the CLP regulation, "*A substance or mixture is not classified as explosive when there are no chemical groups associated with explosive properties present in the molecule*". As Ca-O does not contain chemical group having explosive properties, the product is not considered classified.	AS dossier IIIA 3.15	Acceptable as active substance and co-formulants are not classified Not explosive product.
			Not explosive There are no chemical groups within the structure that would imply explosive properties according to the manual of recommendation on the Transport of dangerous goods.	[redacted]	
Flammable solids	Waiver		According to CLP regulation, "*For inorganic material, testing may be waived in cases where the substance is commonly known to be not flammable (i.e. stable salts or metal oxides) or where a flammability hazard can be excluded by any other scientific reasoning."* In CaO, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded. As Ca-O is a metal oxide, the product is not considered having flammable properties.	AS dossier IIIA 3.11	Acceptable Not flammable
	EEC A10 (Test N.1)	CaO Batch BE1110.144.1	The substance does not ignite within the 2min screening test.	[redacted]	The test was performed on CaO.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
				Project number 2937/0004	Nevertheless, viewing the composition, it is not expected that the product has flammable properties.
Self-reactive substances and mixtures	Waiver		The melting point of active substance is > 2500 °C. Therefore it can be excluded that CaO is instable at high temperatures. CaO is produced from limestone ($CaCO_3$) at 900 – 1300 °C. It can be concluded that CaO 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.	AS dossier	Not self-reactive according to CLP regulation
Pyrophoric liquids	Waiver		Not relevant		
Pyrophoric solids	Waiver		In CaO, Calcium and Oxygen are in their respective preferred oxidation state. Moreover, the substance is not known having pyrophoric properties as CaO is produced from limestone ($CaCO_3$) at 900 – 1300 °C. It can be concluded that CaO is stable at least at this temperature range.	AS dossier	The product is not pyrophoric solid
Self-heating substances and mixtures	Waiver		The CaO is produced from limestone ($CaCO_3$) at 900-1300°C. Therefore we can considered that the product does not react with air at temperature up to 400°C and is not classified self-heating.	AS dossier	Not self-heating according to CLP regulation
	UN Test N.4	Calcium oxide Oxi Lime 23 Batch number BE1121.5.6	After 24h in an "Fan Assisted" oven at an isothermical temperature of 140°C, the sample does not self-heat more than 140°C.	[redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			Basket Size (mm cube): 100; Test Temperature (°C): 140; Test System: 9; Test Item Weight (g): 1154.1; Ignition Yes / No: No	Report N° S3016011300R1/2022	
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. However, according to CLP regulation, "*EUH014 – 'Reacts violently with water' For substances and mixtures which react violently with water, such as acetyl chloride, alkali metals, titanium tetrachloride. There are no criteria or test methods provided for these EUH statements.*"	AS dossier	Acceptable As the active substance is water reactive, a mention on the label should be added: EUH014 - reacts violently with water.
Oxidising solids	Waiver		Not oxidising Base on chemical structure, the calcium oxide does not contain a surplus of oxygen or any structural groups known to correlated with tendency to react exothermally with combustible material. The calcium and oxygen are in their preferred oxidation state. The substance is inorganic and does not contain halogens.	AS dossier IIIA 3.16	Acceptable as active substance and filler are not classified
	Waiver based on composition	CaO Batch BE1110.144.1	The substance is inorganic and does not contain halogens or oxygen bond directly to another oxygen.	[redacted] Project number 2937/0004	
Organic peroxides	Waiver		Not applicable		
Corrosive to metals	waiver		Not required for solid		The test is not required for solid product. Not corrosive to metal

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Auto-ignition temperatures of products (liquids and gases)	Waiver		Not relevant		
Relative self-ignition temperature for solids	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that CaO is instable at high temperatures. Therefore, the substance is not considered having self-ignition properties. Moreover, the substance/product is not flammable.	AS dossier	Acceptable
	EEC A16	CaO Batch BE1110.144.1	No self-ignition point below 400°C	[redacted] Project number 2937/0004	
Dust explosion hazard	Waiver		Calcium oxide will react with water to generate the hydroxide form in a highly exothermic reaction. A stream explosion rather than a dust explosion may potentially occur.	AS dossier	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
Calcium oxide will react exothermically upon contact with water to form calcium dihydroxide. Mitigation measure needed : EUH014 - reacts violently with water. The product is not classified for other physical hazard properties.

2.2.4. Methods for detection and identification

The product is a blend of the active substance and an inert filler. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended 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) *Impurities* *(SiO_2, combined oxides, Iron, moisture, CO_2, S, P, Mn, free Si, C and $CaCO_3$)*	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, Al, Si, P, S, Cl, K, Ca, Ti, Mn, Fe, Sr, Ba and Pb,)	X-ray spectrometric analysis	5							ASTM C1271-99 (1999)
	Ca as % CaO				53,347		0,28 %		
					53,683		0,30 %		
					54,304		0,23 %		
					55,599		0,20 %		
					55,837		0,26 %		
	Mg as % MgO				0,176		8,52 %		
					0,216		2,78 %		
					0,637		1,10 %		
					0,919		1,09 %		
					1,406		3,49 %		
	Si as % SiO_2				0,054		22,22 %		
					0,156		5,77 %		
					0,627		1,75 %		
					0,875		2,97 %		
					1,866		3,32 %		
	Fe as % Fe_2O_3				0,0244		5,33 %		
					0,0359		5,01 %		
					0,1357		1,69 %		
					0,1917		1,10 %		
					0,8792		1,56 %		
	Al as % Al_2O_3				0,0463		3,24 %		
					0,0736		5,43 %		
					0,1142		2,63 %		
					0,1159		3,11 %		
					0,4404		3,70 %		
					0,0024		12,50 %		
					0,0035		8,57 %		
					0,017		21,18 %		

	Mn as % Mn				0,0248 *0,09*		1,21 % 0,44 %		
Active substance *(calcium, magnesium, oxide and hydroxide.* *Impurities minerals of silicon (silicates), aluminium, iron (pyrite), manganese, carbon (carbonates), sulphur (sulphates, pyrite) and water.)*	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

ASTM C25 – 99:

TABLE 3 Precision Summary of Classical Test Methods

Section	Test Method	Average,[A] % Found	Range,[A] % Found	Repeatability (R_1, E 173)	Reproducibility (R_2, E 173)
8	Insol + SiO_2 (Standard)	. . .	. . .	. . .	. . .
9	Insol + SiO_2 (Optional)	1.405	0.09–6.40	0.184	0.351
10	SiO_2	1.177	0.03–5.36	0.128	0.146
11	Insoluble Matter	0.242	0.02–0.93	0.169	0.204
12	Combined Oxides	0.459	0.22–1.21	0.181	0.282
13	Fe_2O_3	0.180	0.05–0.36	0.064	0.183
15	Al_2O_3	0.268	0.10–0.88	0.165	0.223
16	CaO (Gravimetric)	54.46	53.4–55.1	0.558	1.020
17	CaO (Volumetric)	30.57	30.4–30.7	0.371	1.132
17	CaO (Volumetric)	53.82	49.6–55.3	0.187	0.298
18	MgO (Gravimetric)	0.817	0.19–2.28	0.158	0.210
18	MgO (Gravimetric)	21.34	21.1–21.5	0.652	1.716
19	Loss on Ignition	43.73	43.6–43.9	0.158	0.463

[A] Average and range of the limestones tested.

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 quicklime (CaO) 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 quicklime (CaO) 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 tissues
The determination of analytical methods for human body fluids and tissues is not justified as quicklime (CaO) 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 product. 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 product BIOCALCO QL is a dustable powder, intended for use in the disinfection of liquid and dry sludge prior to spreading on the land or prior incineration (PT2) and manures (PT3).

It is not intended to be used for direct contact with food or feeding stuffs.
For 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

The product BIOCALCO QL is intended to control bacteria, yeast, fungi, viruses and endoparasites: helminth eggs in sewage sludge and manures.

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 endoparasites: helminth eggs under defined conditions.

2.2.5.4. Mode of action, including time delay

Several effects of Burnt lime 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.

3) Increased temperature - Burnt lime (CaO) react with water to form Calcium hydroxide in an exothermic reaction. A typical initial temperature following addition of Burnt lime to wet sewage sludge would be in the range of 45-75 °C. Pathogens are inactivated during exposure to heat, which must be above their optimum growth

temperature in order to be effective. The exposure time required depends both on the temperature and on the species. In a study contracted for the European Commission Directorate-General Environment (Carrington, 2001), the following graph is included, in which results from numerous studies have been collated to indicate a "safety zone". When the operating parameters in this zone are above the minimum requirements, the heat-treated sewage sludge is virtually pathogen-free. The increase in temperature has a synergistic effect on the denaturation of protein structures in the alkaline environment.

4) Decreased water availability and increased osmotic pressure - When Burnt lime is added to wet organic matter, some water is utilised in the reaction to form Hydrated lime and more water evaporates due to the increase in temperature. The dry matter content (solid components) of sewage sludge increases by 30-40 % due to the Burnt lime treatment. The result is a loss in water availability for microbial populations present. While absolute desiccation does not occur, the drying effect does result in increased osmotic pressure of the microbes' environment with resultant water egress, and cell lysis.

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 hydroxide 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 hydroxide in contact with water.

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

- **<u>Use # 1 - Disinfection of sewage sludge (PT2)</u>**

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 6.7-01).
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) 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.
It has to be noted that no negative control has been performed in the test.

In a second study (6.7.02), 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.
It has to be noted that in the conditions tested, efficacy is related to the effects of pH and heat.

In the third study (6.7.03), 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 oxide is demonstrated for the disinfection of sewage sludge, against bacteria and endoparasites: helminth eggs. Effective treatment is due to raised pH (>12) and temperature greater than 50°C, that should be maintained during the contact time needed (from 24 hours until several weeks). No data has been provided for yeast and fungi.

Conclusion: Efficacy of calcium oxide is demonstrated 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. Therefore FR CA concluded that the efficacy against virus is not validated.

- **Use #2 - Disinfection of manure (PT3)**

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 (6.7-06) 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 hydroxide (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 oxide, in solid pig and poultry manure:
- For bacteria, more than 7 log reduction are observed for a contact time of 30 minutes at the temperature of 70 °C and for a contact time of 60 minutes at the temperature of 60 °C;
- For virus, more than 5 log reduction are observed for a contact time of 30 minutes at the temperature of 70 °C and for a contact time of 60 minutes at the temperature of 60 °C;
- For *Ascaris suum* eggs, 100 % inhibition of development are obtained for a contact time of 30 minutes at the temperature of 70 °C and for a contact time of 60 minutes at the temperature of 60 °C.

Based on this study, it can be concluded that calcium oxide at a pH> 12 and at a temperature greater than 60 °C is efficient against bacteria, virus and endoparasites: helminth eggs in solid pig and poultry manures.
Since liquid manure differs only from solid manure with the content of water, similar efficacy of calcium oxide is expected in liquid manure.

From the efficacy study, the quantity of lime to be applied should be enough to reach a pH>12 and a temperature > 60°C in all the cases. Contact time should be at least 24H. Two recommendations are presented by the applicant, one for routine application (20 kg lime/m3 of manure) and one in case of outbreak (200 kg lime/m3 of manure). Since application rate should be adapted to the type of manure in order to achieve a pH>12 and a temperature >60 °C, the SPC should only specify that 200 kg lime/m3 of manure should not be exceeded whatever the circumstances of manure treatment.

<table>
<tr><th colspan="7">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Disinfectant for sewage sludge</td><td>PT2 – Use 1</td><td>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.</td><td><u>Bacteria</u> (2,3.10^3 – 23.10^6 CFU/g)

Salmonella senftenberg (H_2S positive DSM 10062 SIT 100, H2S negative DSM 10062 SIT 112), Streptococci, Clostridium perfringens DSM 765, E.coli DSM 498

<u>Virus</u> (2,3.10^5-6,16.10^6 TID50 / ml)
Bovine parvovirus, ECBO

<u>Nematodes</u>
Ascaris suum eggs

Culture collection, except Ascaris eggs source unknown</td><td>Simulated study

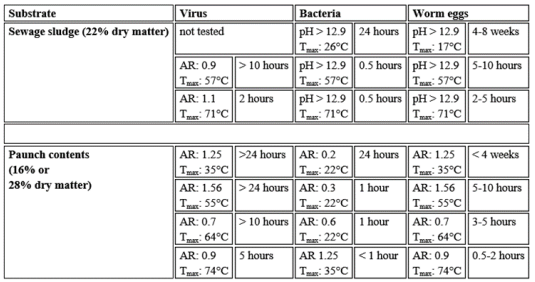
Direct mixing of sewage sludge with the biocidal product
The test was applied on two different scales: one to simulate small scale use (mixers of 130 L and 145 L) and the second to simulate industrial scale treatment (cavity mixer-unknown volume).
For the small scale tests, burnt lime was homogeneously 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</td><td>0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solids

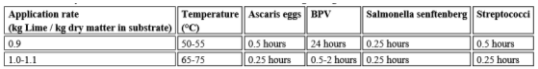
Contact time: 1-24 hours, until 8 weeks for Ascaris suum

temperatures and pH values were recorded over the time</td><td>0.9 – 1.1 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</td><td>6.7-01

R.I=2 supporting data in the absence of negative control</td></tr>
</table>

				the numbers of viable bacteria, viruses or Ascaris eggs.			
Disinfectant for sewage sludge	PT2 – Use 1	Milk of lime ($Ca(OH)_2$) suspension in water Dry hydrated lime ($Ca(OH)_2$) Burnt lime (CaO)	<u>Nematodes</u> *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 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.	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 min at 60°C will lead to a negligible level of viable Ascaris eggs	6.7-02 RI=2

				When the stockpile target temperature was reached, bags containing Ascaris eggs were inserted in it.			
Disinfectant for sewage sludge	PT2 – use 1	Calcium hydroxide (10% Ca(OH)2 in water: milk of lime)	<u>Bacteria</u> *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	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.	6.7-03 RI=2

					11.6), Digester 2 is also treated with Lime.		
Disinfectant for manure and litter	PT3 – Use 2	Calcium hydroxide (liquid manure) Calcium oxide (solid manure) (EuLA specifications)	<u>Bacteria</u> (lab collection) *Salmonella senftenberg 775W (H2S negative)* *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)	Simulated test Direct mixing of manure with the biocidal product 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	Liquid manure: Bacteria and viruses: 72H and 96 hours contact 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	Liquid pig and cattle manure (Ca(OH)2) at 72H and 96H contact time: 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	6.7-06 RI=2

Conclusion on the efficacy of the product
The product BIOCALCO QL has shown a sufficient efficacy, for the following uses claimed: - 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 and temperature > 50°C during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature. It should be calculated by the user 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 in the first study. Therefore FR CA concluded that the efficacy against virus is not validated - For the disinfection of manure (PT3), against bacteria, virus and endoparasites (helminth eggs). The effective final use concentration and contact time are variable. pH should be > 12 and temperature > 60°C during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature. It should be calculated by the user with regard to the dry weight of the substrate. No data has been provided for yeast and fungi for the disinfection of manure.

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 are no known limitations 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)

Not applicable

2.2.6. Risk assessment for human health

The classification of the product is determined following the information available in the CAR on the active substance and by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017).

2.2.6.1. Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritation to the skin
Justification for the value/conclusion	No new data on skin corrosion and irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product, a classification Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is needed.
Classification of the product according to CLP	Classification Skin irritation, category 2 - H315: Causes skin irritation is required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to the eye
Justification for the value/conclusion	No new data on eye irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product, a classification Eye Dam.1 H318 (in accordance with Regulation EC/1272/2008) is needed
Classification of the product according to CLP	Classification Serious eye damage cat. 1, H318: Causes serious eye damage is required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No new data on irritation in the respiratory tract was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product, a classification STOT SE 3 H335 is needed.
Classification of the product according to CLP	Classification STOT SE 3 H335: May cause respiratory irritation is required.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin
Justification for the value/conclusion	No new data on skin sensitisation was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance and co-formulant that are not classified for skin sensitization, no classification is required for the product.
Classification of the product according to CLP	No classification for skin sensitisation is required.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	No new data on respiratory sensitisation was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance and co-formulant that are not classified for respiratory sensitization, no classification is required for the product.
Classification of the product according to CLP	No classification for respiratory sensitisation is required.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route
Justification for the selected value	No new data on acute oral toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance and co-formulant in the product that are not classified for acute oral toxicity, no classification is required for the product.
Classification of the product according to CLP	No classification for acute oral toxicity is required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via inhalation.
Justification for the selected value	No new data on acute inhalation toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance and co-formulant in the product that are not classified for acute inhalation toxicity, no classification is required for the product
Classification of the product according to CLP	No classification for acute inhalation toxicity is required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	No new data on acute dermal toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance and co-formulant in the product that are not classified for acute dermal toxicity, no classification is required for the product
Classification of the product according to CLP	No classification for acute dermal toxicity is required.

Information on dermal absorption

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

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, no co-formulant has been identified as SoC.

2.2.6.2. Exposure assessment

BIOCALCO QL is used for disinfection of sewage sludge (PT2) and for disinfection of manures (PT3) by professionals.

Burnt lime powder is packed in small sacks of 25 kg, or in big bags of 750 kg.
For the disinfection of sewage sludge and manure, the lime powder is poured into the hopper of the dosing equipment for the disinfection treatment. After that, it is mixed with the dewatered sludge/sewage or the manure with a blender in a fully automated process corresponding to the application task.

Considering the different mode of application and the available packaging sizes, exposure is expected to occur during the following tasks:
- the loading phase (manual, semi-automated or automated);
- the cleaning task (including the disposal of empty bags).

Inhalation and dermal exposure are considered for these different operations.

Adverse effects

The mode of action of lime leads to an increase of the alkalinity of the treated substrates (sewage sludge, manures).
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, an assessment of **calcium and magnesium** is proposed.
In the product BIOCALCO QL, the following contents are considered for exposure assessment:

Calcium and magnesium contents in BIOCALCO QL	
CaO (nominal)	50%
MgO	≤ 2.5%
Ca (equivalent) (max.)*	**55.7%**
Mg (equivalent) (max.)	**≤ 1.5%**

*Content in Ca considering CaO and co-formulant

In the following, exposure to several compounds are estimated:
- For systemic risk assessment, dermal and inhalation exposures to total Ca (equivalent) and Mg (equivalent);
- For local risk assessment, inhalation exposure to CaO.

Identification of main paths of human exposure towards active substance 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 (Uses # 1 & 2)			
1.	Loading (manual)	**Primary exposure** –Manual loading of the product to sewage sludge and manures. This scenario takes into account also the opening of the bags.	Professionals
2.	Loading (semi-automated)	**Primary exposure** – Semi-automated loading of the product to sewage sludge and manures	Professionals
3.	Loading (automated)	**Primary exposure** – Automated loading to sewage sludge and manures	Professionals
4.	Cleaning	**Primary exposure**- Cleaning of the treatment unit	Professionals
5.	Disposal	**Primary exposure** - Manual disposal of empty bags	Professionals
6.	Disposal	**Primary exposure** - Semi-automated disposal of empty bags	Professionals
7.	Disposal	**Primary exposure**- Disposal of treated waste	Professionals

Industrial exposure

No industrial use for this product.

Professional exposure

Scenario [1]: Mixing and loading – Manual loading to sewage sludge and manures

Description of Scenario [1]

BIOCALCO QL is available in small bags of 25 kg for manual loading to sewage sludge and manures. The bags are manually opened and emptied in the storage container (hopper) of the unit of treatment. Workers are not enclosed in any cab. The lime is then transferred to the sludge mixer through a screw conveyor (closed system). The actual mixing can occur before or after dewatering. The same assumption is made for manures, by opening and emptying manually a 25 kg sack 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 by EULA in the CAR on the active substance[3].
The objective of the study was to measure inhalation exposure of two operators opening and emptying lime sacks 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 to inhalable dust was 0.27 to 2.58 mg of bp/m^3, with an average of 1.07 mg/m^3. The value retained from the study for the assessment is therefore equal to **2.58** mg pb/m^3.
For Tier 2, a respiratory mask (APF 40) is taken into account.

	Parameters	Value	References
Tier 1	CaO concentration	50%	Applicant's data
	Assumed calcium fraction	55.7%	Applicant's data
	Assumed magnesium fraction	1.5%	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/m^3) – full shift	2.58	Field study from the CAR PT 2
	Inhalation exposure (mg/m^3) – task only	23.2	Field study from the CAR PT 2
	Dermal absorption	100%	Active substance data (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	Recommendation no. 14[4], 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95% (solid)	HEEG Opinion 9[5], 2010
Tier 2b	Respiratory Protection	PF = 40	HEEG Opinion 9[6], 2010

Calculations for Scenario [1]

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 [1]	Tier 1/no PPE	2.40E-01	5.28	5.52
Scenario [1]	Tier 2a/gloves	2.40E-01	2.64E-01	5.04E-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 [1]	Tier 1/no PPE	6.45E-03	1.42E-01	1.49E-01
Scenario [1]	Tier 2a/gloves	6.45E-03	7.11E-03	1.36E-02

Local exposure – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [1]	Tier 1/no PPE	11.6
Scenario [1]	Tier 2b/ respiratory mask (RPE APF 40)	2.90E-01

Scenario [2]: Mixing and loading – Semi-automated application to sewage sludge and manures

Description of Scenario [2]
BIOCALCO QL is available in big bag of 750 kg for semi-automated loading to sewage sludge and manures.

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

[4] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products, May 2017.

[5] HEEG opinion Default protection factors for protective clothing and gloves (agreed in TM I 2010), 2010

[6] HEEG opinion Default protection factors for protective clothing and gloves (agreed in TM I 2010), 2010

The big-bag is lifted onto the hopper/discharger using a **tele handler (closed cabin) or a forklift (no cabin)** where it is automatically cut at the bottom to discharge the product.
The worker can stay in the vehicle 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 treatment of manures.
Exposure is 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 pure material (100%) and a transfer of 100 to 1000 kg of active substance/min. Then, the concentration in active substance in the product (=50% 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/m³ and 1.8 mg/m³ for telehandler** for outdoor and indoor activities, respectively.
- **0.62 mg/m³ and 4.3 mg/m³ for forklift** for outdoor and indoor activities, respectively.

For task only:

- **1.1 mg/m³ and 7.3 mg/m³ for telehandler** for outdoor and indoor activities, respectively.
- **2.5 mg/m³ and 17 mg/m³ for forklift** for outdoor and indoor activities, respectively

The values estimated indoor using a forklift are chosen for inhalation exposure as a worst-case.

	Parameters	Value	References
	CaO concentration	50%	Applicant's data
	Assumed calcium fraction	55.7%	Applicant's data
	Assumed magnesium fraction	1.5%	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 (solid)	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [2]

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 [2]	Tier 1/no PPE	3.90E-01	5.28	5.68
Scenario [2]	Tier 2a/gloves	3.90E-01	2.64E-01	6.63E-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 [2]	Tier 1/no PPE	1.08E-02	1.42E-01	1.53E-01
Scenario [2]	Tier 2a/gloves	1.08E-02	7.11E-03	1.79E-02

Local exposure – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [2] FORKLIFT	Tier 1/no PPE	8.50
Scenario [2] FORKLIFT	Tier 2b/ respiratory mask (RPE APF 40)	2.13E-01

Scenario [3]: Mixing and loading – Automated application to sewage sludge and manures

Description of Scenario [3]

BIOCALCO QL is available in powder tanker for automated loading to sewage sludge and manures.

Lime is unloaded automatically thanks to a pipe connected from the tanker to a silo that is a closed system (containing a pressure vacuum valve) having on the top a filter to prevent dust emission during the pneumatic loading. This system is described in the CAR on a.s for sludge's.
The same assumption is made for the treatment of manures.

Potential exposure is limited to the exposure of the truck driver during the valve opening. Indeed, this task corresponds to an automated process which requires no actual handling of the material.

The RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure by taking into account an application rate of 225 kg/min and a task duration of 10 min. The resulting dermal exposure (75^{th} percentile) is **7.97 mg/min**.
For Tier 2, gloves are taken into account.

Potential inhalation exposure of the product is estimated using ART (Advanced Reach Tool) taking into account pure material (100%) and a transfer of 100 to 1000 kg of active substance/min. Then, the concentration in active substance in the product (=50% a.s) is considered to estimate the inhalation exposure of the professional during the task.

The predicted 75^{th} percentile is equal to (see Annex 3.2 for reports):
For full shift:
- **0.97** mg/m^3

For task only:
- **3.9** mg/m^3

	Parameters	Value	References
	CaO concentration	50%	Applicant's data
	Assumed calcium fraction	55.7%	Applicant's data
	Assumed magnesium fraction	1.5%	Applicant's data
	Dermal exposure – Hand only (mg/min)	7.97	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.97	ART model
	Inhalation exposure (mg/m^3)- task only	3.9	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 = 10	HEEG Opinion 9, 2010

Calculations for Scenario [3]

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 [3]	Tier 1/no PPE	9.00E-02	7.40E-01	8.30E-01
Scenario [3]	Tier 2a/gloves	9.00E-02	3.70E-02	1.27E-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 [3]	Tier 1/no PPE	2.43E-03	1.99E-02	2.24E-02
Scenario [3]	Tier 2a/gloves	2.43E-03	9.96E-04	3.42E-03

Local exposure – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [3]	Tier 1/no PPE	1.95
Scenario [3]	Tier 2b/ respiratory mask (RPE APF 10)	1.95E-01

Scenario [4]: Cleaning of the treatment unit

Description of Scenario [4]

According to the information presented in the CAR (PT2) on calcium oxide, 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 such as keeping surfaces clean in order and protected against corrosion (by lubricating components and equipment) 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 (with paper, rag or brush) 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.

	Parameters	Value	References
Tier 1	CaO concentration	50%	Applicant's data
	Assumed calcium fraction	55.7%	Applicant's data
	Assumed magnesium fraction	1.5%	Applicant's data
	Duration (min)	30	Default value for this task
	Product density (tap density)	1.12 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	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2	Gloves	PF = 90%	HEEG Opinion 9, 2010
	Coated coverall	PF = 90%	HEEG Opinion 9, 2010
	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

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	1.35E-01	1.54E+01	1.55E+01
Scenario [4]	Tier 2a/gloves	1.35E-01	6.37E+00	6.50E+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 [4]	Tier 1/no PPE	3.63E-03	4.14E-01	4.17E-01
Scenario [4]	Tier 2a/gloves	3.63E-03	1.72E-01	1.75E-01

Local exposure – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [4]	Tier 1/no PPE	1.16E+01
Scenario [4]	Tier 2/ (RPE APF 40)	2.90E-01

Scenario [5]: Cleaning – Manual disposal of empty bags

Description of Scenario [5]
After loading the lime powder product from the small bags of 25kg into the treatment unit, the empty bags are disposed of by professional users. Assuming that the bags are thoroughly emptied during the loading and that the remaining residues of lime product are inside and not outside the bags, dermal exposure is deemed negligible. Potential inhalation exposure is estimated using ART taking into account pure material (100%) and a task duration of 10 min. Then, the concentration in active substance in the product (=50% a.s) is considered 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: - **1.2** mg/m^3 (outdoor); - **0.8** mg/m^3 (indoor). For task only: - **57** mg/m^3 (outdoor); - **38** mg/m^3 (indoor).

	Parameters	**Value**	**References**
	CaO concentration	50%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	1.2 (out) 0.8 (in)	ART model
	Inhalation exposure (mg/m^3)- task only	0.39 (out) 2.5 (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 2	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [5]

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 [5]	Tier 1/no PPE	1.11E-01	-	1.11E-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 [5]	Tier 1/no PPE	3.00E-03	-	3.00E-03

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [5]-**indoor**	Tier 1/no PPE	1.90E+01
	Tier 2/ RPE (APF 40)	4.75E-01

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [5]-**outdoor**	Tier 1/no PPE	2.85E+01
	Tier 2/ RPE (APF 40)	7.13E-01

Scenario [6]: Cleaning – Semi-automated disposal of empty bags

Description of Scenario [6]
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 concentration in active substance in the product (=50% a.s) is considered 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: - 0.0055 mg/m^3 (outdoor); - 0.083 mg/m^3 (indoor). For task only: - 0.27 mg/m^3 (outdoor); - 4 mg/m^3 (indoor). As a worst-case approach, only indoor values using a forklift is retained for the risk assessment.

	Parameters	**Value**	**References**
	CaO concentration	50%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	0.083	ART model
	Inhalation exposure (mg/m^3)- task only	4	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 2	Respiratory protection	APF = 10	HEEG Opinion 9, 2010

Calculations for Scenario [6]

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 [6]	Tier 1/no PPE	7.43E-03	-	7.43E-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 [6]	Tier 1/no PPE	2.00E-04	-	2.00E-04

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [6]	Tier 1/no PPE	2.00E+00
Scenario [6]	Tier 2/ RPE (APF 10)	2.00E-01

Combined effect (scenario 1-2 + 4)

It's considered that on a work day, the professional performs different tasks (loading, cleaning), that's why a combined risk assessment is done.

As described in the scenario 3, the automatically unloading of the burnt lime powder in the treatment unit is usually performed by the truck driver and not the professional that's why no combined exposure has been performed with this scenario.
Regarding the very low systemic exposure during the disposal phase (please refer to the systemic calculations), the scenarios 5 & 6 have not been taken into account in the combined risk assessment.

Systemic exposure – 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+4	Tier 1/no PPE	3.74E-01	2.06E+01	2.10E+01
	Tier 2/gloves	3.74E-01	6.63E+00	7.01E+00
Scenario 2+4	Tier 1/no PPE	5.34E-01	2.06E+01	2.12E+01
	Tier 2/gloves	5.34E-01	6.63E+00	7.17E+00

Systemic exposure – 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+4	Tier 1/no PPE	1.01E-02	5.56E-01	5.66E-01
Scenario 2+4	Tier 1/no PPE	1.44E-02	5.56E-01	5.70E-01

Scenario [7]: Disposal of treated sludge and manures

Description of Scenario [7]
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.

Non-professional exposure
Product is intended to be used by professionals only.

Exposure of the general public
Exposure to the general public is not foreseen.

Monitoring data
Not submitted

Dietary exposure

Considering that the intended uses on sludge (TP2) and manure (TP3), no dietary exposure is expected.

Information of non-biocidal use of the active substance

Calcium oxide is not approved under Reg. (EC) No 1107/2009 and thus default MRL of 0.01* mg/kg apply according to Art 18(1)(b) Reg 396 / 2005.
Calcium oxide is listed in table 1 of Regulation No. 37/2010 annex, as allowed pharmacologically active substances for which a MRL in foodstuffs of animal origins is not required.
Calcium oxide are 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 oxide is converted through an exothermic reaction to calcium hydroxide which 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

Considering the intended uses on sludge (TP2) and manure (TP3) , no livestock exposure is expected.

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

Considering the intended uses on sludge (TP2) and manure (TP3), no food exposure is expected.

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 applicable

Aggregated exposure

Not applicable

Summary of exposure assessment

Systemic exposure – calcium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	5.52E+00
		Tier 2a/gloves	5.04E-01
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	5.68E+00
		Tier 2a/gloves	6.63E-01
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	8.30E-01
		Tier 2a/gloves	1.27E-01
Scenario [4] – cleaning equipment	Professionals	Tier 1/no PPE	1.55E+01
		Tier 2a/gloves	6.50E+00
Scenario [5] – Manual disposal of empty bags	Professionals	Tier 1/no PPE	1.11E-01
Scenario [6] – Semi automated disposal of empty bags	Professionals	Tier 1/no PPE	7.43E-03

Systemic exposure – magnesium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	1.49E-01
		Tier 2a/gloves	1.36E-02
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	1.53E-01
		Tier 2a/gloves	1.79E-02
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	2.24E-02
		Tier 2a/gloves	3.42E-03
Scenario [4] – cleaning equipment	Professionals	Tier 1/no PPE	4.17E-01
		Tier 2a/gloves	1.75E-01
Scenario [5] – Manual disposal of empty bags	Professionals	Tier 1/no PPE	3.00E-03
Scenario [6] – Semi automated disposal of empty bags	Professionals	Tier 1/no PPE	2.00E-04

Local exposure – Oxide calcium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/m3)**
Scenario [1] – manual loading	Professionals	Tier 1/no RPE	1.16E+01
		Tier 2/ RPE APF 40	2.90E-01
Scenario [2] – semi automatic loading FORKLIFT indoor	Professionals	Tier 1/no RPE	8.50E+00
		Tier 2/ RPE APF 40	2.13E-01
Scenario [3] – automated loading	Professionals	Tier 1/no RPE	1.95E+00
		Tier 2/ RPE APF 10	1.95E-01
Scenario [4] – cleaning equipment	Professionals	Tier 1/no RPE	1.16E+01
		Tier 2/ RPE APF 40	2.90E-01
Scenario [5] – Manual disposal of bags-outdoor	Professionals	Tier 1/no RPE	2.85E+01
		Tier 2/ RPE APF 40	7.13E-01
Scenario [6] – Semi auto disposal of bags	Professionals	Tier 1/no RPE	2.00E+00
		Tier 2/ RPE APF 10	2.00E-01

2.2.6.3. Risk characterisation for human health

Reference values to be used in Risk Characterisation – **calcium oxide (CaO)**

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
ARfD	Not applicable				
ADI	Not applicable				

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 UL has been proposed as a threshold value for the contribution of calcium and magnesium from use of the lime based products.

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. During the approval of the active substances, the UL for calcium value (2 500 mg/d/person corresponding to 42 mg/kg/day for an adult of 60 kg) has been identified as the reference value to be used in risk characterization.

To ensure acceptable systemic risk of the professionals exposed to product, calcium content arising from exposure to lime should contribute minimally to the overall calcium UL (according to the CAR).

Even considering a recommended daily intake of 950 mg Ca^{2+}/d (corresponding to 15.8 mg/kg bw/d) from the diet, it can be demonstrated that the total calcium intake is still below the UL value for all the envisaged scenarios (please refer to the supporting document in Annex 3.3).

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
Not applicable.

Risk for professional users

Systemic effects **(calcium)**

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	42	5.52E+00	13.2%	YES
	Tier 2a/gloves	42	5.04E-01	1.2%	YES
Scenario [2] – semi-automated loading	Tier 1/no PPE	42	5.68E+00	13.5%	YES
	Tier 2a/gloves	42	6.63E-01	1.6%	YES
Scenario [3] – automated loading	Tier 1/no PPE	42	8.30E-01	2.0%	YES
	Tier 2a/gloves	42	1.27E-01	0.3%	YES
Scenario [4] – cleaning equipment	Tier 1/no PPE	42	15.5	36.9%	YES
	Tier 2a/gloves	42	6.5	15.5%	YES
Scenario [5]– Manual disposal of empty bags	Tier 1/no PPE	42	1.11E-01	0.27%	YES
Scenario [6] – Semi automated disposal of empty bags	Tier 1/no PPE	42	7.43E-03	0.02%	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 1-4	Tier 1/no PPE	42	2.10E+01	50.04%	YES
	Tier 2/ gloves		7.01E+00	16.68%	YES
Scenario 2-4	Tier 1/no PPE	42	2.12E+01	50.42%	YES
	Tier 2/ gloves		7.17E+00	17.06%	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	1.49E-01	3.5%	Yes
	Tier 2a/gloves	4.2	1.36E-02	0.3%	Yes
Scenario [2] – semi-automated loading	Tier 1/no PPE	4.2	1.53E-01	3.6%	Yes
	Tier 2a/gloves	4.2	1.79E-02	0.4%	Yes
Scenario [3] – automated loading	Tier 1/no PPE	4.2	2.24E-02	0.5%	Yes
	Tier 2a/gloves	4.2	3.42E-03	<0.1%	Yes
Scenario [4] – cleaning equipment	Tier 1/no PPE	4.2	4.17E-01	9.9%	Yes
	Tier 2a/gloves	4.2	1.75E-01	4.2%	Yes
Scenario [5]– Manual disposal of empty bags	Tier 1/no PPE	4.2	3.00E-03	0.07%	Yes
Scenario [6] – Semi automated disposal of empty bags	Tier 1/no PPE	4.2	2.00E-04	0%	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 1-4	Tier 1/no PPE	4.2	5.66E-01	13.48%	YES
	Tier 2/ gloves		1.89E-01	4.49%	YES
Scenario 2-4	Tier 1/no PPE	4.2	5.70E-01	13.58%	YES
	Tier 2/ gloves		1.93E-01	4.60%	YES

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

Task/ Scenario	Tier	AEC mg/m3	Estimated concentration (mg/m³)	Estimated concentration / AEC (%)
Scenario [1] – manual loading	Tier 1/no RPE	0.3	11.6	3867%
	Tier 2/ RPE (APF40)		2.90E-01	96.7%
Scenario [2] – semi-automated loading FORKLIFT - indoor	Tier 1/no RPE	0.3	8.50	2833%
	Tier 2/ RPE (APF40)		2.13E-01	70.8%
Scenario [3] – automated loading	Tier 1/no RPE	0.3	1.95	650%
	Tier 2/ RPE (APF10)		1.95E-01	65.0%
Scenario [4] – cleaning of the unit treatment	Tier 1/no RPE	0.3	11.6	3867%
	Tier 1/no RPE Tier 2/ RPE (APF40)		2.90E-01	96.7%
Scenario [5] – Manual disposal of empty bags- Indoor	Tier 1/no RPE	0.3	1.90E+01 (in)	6333.3%
	Tier 2/ RPE (APF40)		4.75E-01 (in)	158.3%
Scenario [5] – Manual disposal of empty bags- Outdoor	Tier 1/no RPE		2.85E+01	9500.0%
	Tier 2/ RPE (APF40)		7.13E-01	237.5%
Scenario [6] –Semi automated	Tier 1/no RPE	0.3	2.00E+00	666.7%

disposal of empty bags-Forklift-Indoor	Tier 2/ RPE (APF10)		2.00E-01	66.7%

- **Qualitative local risk assessment**

The product BIOCALCO QL is classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and is 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 Cleaning	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 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 - 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 RMM: - Wear: - Substance/ task appropriate gloves - Protection coverall - Face shield - Substance/ task appropriate respirator	
Low	STOT RE 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 sewage sludge and manures- Conclusion

For local effects (due to the calcium oxide), the risk is considered acceptable for the scenarios of loading (manual, semi-automated and automated), cleaning and disposal of empty bags (semi-automated) taking into account appropriate RPE.

Regarding the results of the RA for manual disposal of empty bags indoor and outdoor, the % AEC is above 100% even considering a RPE (APF 40).

Based on these results, the risk is deemed not acceptable for the professional during handling of small bags of 25kg of lime powder product.

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

For semi-automated loading and cleaning of the unit treatment:
- gloves;
- protective coverall;
- goggles;
- Respiratory protective equipment at least APF 40.

For fully automated loading and disposal of big bags:
- gloves;
- protective coverall;
- goggles;
- Respiratory protective equipment at least APF 10.

In addition to the above mentioned PPE, the following RMMs are required:
- The loading of burnt lime powder into the treatment unit and the application must be done semi or fully 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).
- Wear protective gloves and protective coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge/manures, wearing RPE specific for air fed ammonia gas or for canisters, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.
- 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 and the disposal of empty bags).
- Use in a well ventilated area.

Risk for non-professional users

Non-professional uses are not claimed.

Risk for the general public

Secondary exposure to the general public is not expected.
The presence of children may be envisaged for uses in agricultural exploitations (treatment of manure).
A RMM must be added in order to prevent indirect exposure of children.

Risk for consumers via residues in food

Considering the intended uses on sludge (TP2) and manure (TP3), no dietary risk is expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not applicable

2.2.7. Risk assessment for animal health

No exposure of animals with lime based product occurs during disinfection of sludge and manures as the application is done in a closed system (unit treatment). Consequently, no unacceptable risk for animal health is expected.

2.2.8. Risk assessment for the environment

BIOCALCO QL is a PT2 and PT3 product containing calcium oxide, Burnt lime (CAS 1305-78-8) that is applied for disinfection of sewage sludge (PT02) and manure (PT03).

The product is a blend of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material used to manufacture the active substance. Both of them are naturally occurring inorganic salts.
No environmental SoCs were identified for the BIOCALCO QL 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 oxide, Burnt lime CAS 1305-78-8, 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 BIOCALCO QL are not available. Therefore, all data pertaining to the active substance are derived from the Calcium oxide CAR, Burnt lime (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 and sewage sludge.

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 adsorption/desorption studies in soil are not considered necessary for burnt lime. This is because upon addition to soil, burnt lime would simply convert to the hydrated form and dissociate to its respective ion constituents which would form part of existing chemical cycles in the natural environment (Doc IIB of calcium oxide, Burnt lime, UK, 2016).

Testing for distribution and dissipation in water and sediment (ADS)

Distribution

Burnt 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

Burnt 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 burnt 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 BIOCALCO QL.

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 BIOCALCO QL.

PNECs

The following table contains a summary of PNECs of the active substance Calcium oxide for the respective compartments (Calcium oxide CAR, Burnt 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 oxide				
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

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: Application to manure
ESD(s) used	Scenario 2: - ESDTP3, Veterinary hygiene biocidal products, 2011 - ESDTP18, Emission scenario document for Insecticides for stables and manure storage systems, 2006
Approach	Semi-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 2: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

Scenario 1 (PT02): disinfection of sewage sludge in an open mixer

For this use a qualitative assessment and a comparison with the CAR assessment is proposed.

The dry 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 Burnt Lime PT2, with the following application rate in comparison with the product BIOCALCO QL:

Application rate of active substance in sewage sludge			
	Representative product of the CAR Burnt Lime, 2016	**BIOCALCO QL product**	**Remarks**
Fraction of a.s in the product (-)	1	0.5	-
Maximum application rate of the product (in % of dry solid weight of sludge)	120	400 (i.e 4.0 kg product/kg dry solid weight of sludge)	-
Application rate of the a.s (in % of dry solid weight of sludge)	120	200	= Fraction of a.s in the product x Maximal application rate of the product

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 BIOCALCO QL (see table below).

Application rate of active substance in agricultural fields		
	Representative product of the CAR Burnt Lime, 2016	**BIOCALCO QL product**
Input		
Application rate of the a.s for the use described in the CAR	120% of dry solid weight of sludge	200% of dry solid weight of sludge
Maximum application rate of sludge in agricultural land per year (as a worst case)	5000 kg dry solid sludge/ha/year	
Output		
Amount of lime added to the sludge during the treatment	6000 kg	10000 kg
Total dry weight of treated sludge after the treatment (considering the dry sludge and the lime treatment)	11000 kg	15000 kg
Application of a.s per ha per year due to the final 5000 kg of actual sludge + lime landed in agricultural field	5000/11000 * 6000 = 2.7 t/ha/year	5000/15000*10000 = 3.3 t/ha/year

As the use of BIOCALCO QL 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 BIOCALCO QL 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 (PT03): disinfection of manure

The dry 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). The mix burnt lime/manure is removed when accommodations are cleaned and sent to manure storage for use in fields or for incineration.
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".
The manure could be spread on fields, therefore the soil compartment is indirectly exposed to the active substance.

All parameters (amount of nitrogen produced per day per animal…) 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.

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	Remarks
		BIOCALCO QL product Scenario 2		
Fraction of a.s in the product	Fbioc	0.5	[-]	-
Maximum application rate of product in manure	-	200	[kg/m^3 of manure]	-
Concentration of a.s in manure after the application of product	**-**	**100**	[kg/m^3 of manure]	**=** Fraction of a.s in the product x Maximum application rate of product in 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.

2) Application rate of manure in arable and grassland					
Parameters	**Symbol from ESDTP3/18**	**Value**		**Unit**	**Remarks**
Input					
		Scenario 2 - 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 application rate of manure on arable land	-	**49.96**	**12.69**	[m^3/year/ha soil]	Maximum emission standard for nitrogen on grassland or arable land / Concentration of nitrogen in the manure

Therefore, the application rate of s.a in agricultural field is calculated as follow:

3) Application rate of active substance in arable land and grassland				
Input				
Parameters	**Value**		**Unit**	**Remarks**
	Scenario 2 - 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]	= Concentration of a.s in manure x Maximum application rate of manure on grassland and arable land x 0.001

As the use of BIOCALCO QL 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 BIOCALCO QL 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.

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	Scenario 2	No	No	No	No	Yes	Yes

manure							

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	56.08	g/mol	(CAR, 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 10°C)	1.31	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 (CAR, 2016)
DT_{50} for biodegradation in surface water	-	d or hr (at 12ºC)	When dissolved in water, Burnt 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, Burnt 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)	0.752	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

As all the uses generate lower emissions than the routine agricultural use of lime applied to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of BIOCALCO QL on soil. A qualitative assessment is deemed sufficient as proposed during the assessment of the active substance at the European level.

Primary and secondary poisoning

Primary poisoning

As the product is a powder 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 burnt 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)

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 or manure/slurry storage areas can be directed to a sewage treatment plant or other aquatic environment".

Terrestrial compartment

All the uses of BIOCALCO QL that lead to emissions to soil will generate application rate of lime on agricultural soil much lower than the routine agricultural use of lime spread to correct soil pH and maintain soil fertility (16T/ha/an, see table below).

Uses	**Emissions to soil (agricultural land, in T/ha/year)**
PT2	
1	3.3

PT3	Veal calves	Turkeys
2	5	1.27

Therefore, the use of BIOCALCO QL leads to acceptable risk to the terrestrial compartment.

Groundwater

Burnt lime is transformed to hydrated lime upon contact with water and dissociates into Ca^{2+} and OH^-.

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 groundwaters.

Primary and secondary poisoning

Primary poisoning

As the product is a powder 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 emission sources)

No aggregated exposure is relevant for this dossier. However, an aggregated risk assessment leads to acceptable risks when all the uses are considered.
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.

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 BIOCALCO QL.

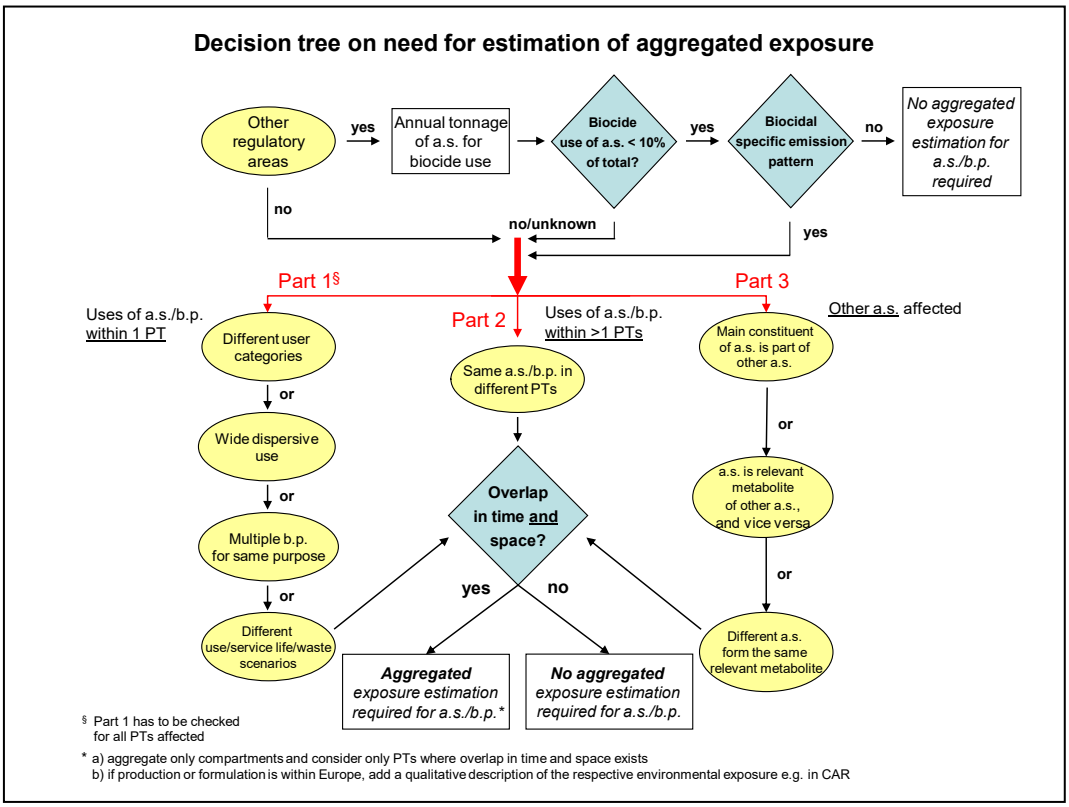


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Acceptable risks are foreseen for the following uses: In PT2: - disinfection of sewage sludge, In PT3: - disinfection of manure, with 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."

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.

3. ANNEXES[7]

3.1. List of studies for the biocidal product

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)_Biocalco QL	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 Section No.** 3.2	IUCLID Document name: pH_Biocalco QL-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_Biocalco QL-Eurofins 2019	Title: Physico-chemical Properties of Biocalco QL 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_Biocalco QL_Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	Yes
[redacted]	Year:	**Annex II/III**	IUCLID	Title: Physico-	Type of	Company	yes	Yes

7 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

[redacted]	2019	**requirement :** Acidity, alkalinity **IUCLID Section No.** 3.2	Document name: Acidity, alkalinity_Biocalco QL_Eurofins 2019	chemical Properties of Biocalco QL before and after Accelerated Storage for 2 weeks at 54 °C No report number provided	publication: study report	Owner: Carmeuse Europe Boulevard de Lauzelle 65 B-1348 Louvain-la-Neuve Belgium		
[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) - Eurofins 2019	Title: Dry Sieve Analysis of Biocalco QL 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 :** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability test_Accelerated_Biocalco QL_ 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_Biocalco QL_ Eurofins 2019	Title: Physico-chemical Properties of Biocalco QL 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 :** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dustibility_Biocalco QL - 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_Biocalco QL - Eurofins 2019	Title: Determination of the Dustiness of Biocalco QL 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 :** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Dry sieve test_Biocalco QL - 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_Biocalco QL - Eurofins 2019	Title: Dry Sieve Analysis of Biocalco QL 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: 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 —	Type of publication: publication			No

				Method by measurement of corresponding cations by suppressed ion chromatography Report no. ISBN 978 0 580 77732 5				
[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: 6.7-01 Biocalco QL, 1200g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Biocalco QL 1200g/m2 Report no. 201800315	Type of publicatio n: study report	Source: NA Company Owner: Carmeuse Europe, Louvain-la-Neuve, Belgium	not specif ied	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.**	IUCLID Document name: 6.7-02 Biocalco QL, 1600g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Biocalco QL 1600g/m2 Report no. 201800315	Type of publicatio n: study report	Source: NA Company Owner: Carmeuse Europe, Louvaiin-la-Neuve	not specif ied	Yes

		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: 6.7-03 Biocalco QL, 2000g/M2 EN 14349 Bactericidal Efficacy, Surface Test Clean (Eise 2018)	Title: Efficacy Test for the Evaluation of Bactericidal Activity (EN 14349, Clean), Biocalco QL 2000g/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, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-04 Biocalco QL, Simulated Use, Placeholder	Title: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281 Report no. N°RE-1106/0220	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	IUCLID Document name: 6.7-04 Biocalco QL, Simulated Use, Placeholder	Title: Determination of microbicide activity of lime according a methodology modelled on NF T 72-281	Type of publication: study report	Company Owner: CARMEUSE EUROPE SA Rue du château 13A 5300 SEILLES		No

		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7		Report no. RE-1437/1119/A		BELGIQUE		
[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: 6.7-05 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: 2004	**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	IUCLID Document name: 6.7-06 from AS A5 10.02 Capizzi-Banas et al Liming as an advanced treatment for sludge sanitisation. 2004	Title: Liming as an advanced treatment for sludge sanitisation: helminth eggs elimination - Ascaris as a model Report no. NA	Type of publication: publication	Source: Water Research 38: 3251-3258: Doc. No. 392-024 Company Owner: NA	not specified	No

		and relevant **IUCLID Section No.** 6.7						
[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: 6.7-07 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	Yes
[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: 6.7-08 - 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
[redacted]	Year: 2008	**Annex II/III requirement :** Efficacy data to support	IUCLID Document name: 6.7-09 - Evaluation	Title: Evaluation of the effect of liming in liquid pig and cattle	Type of publication: study report	Source: NA Company Owner: EuLA	not specified	Yes

		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	of Liming in liquid manure - 90 day, Daugshies, May 2008	manure on Ascaris suum eggs Report no. NA		Brussels Belgium		

3.2. Output tables from exposure assessment tools

HUMAN HEALTH

RISKOFDERM MANURES SLUDGES

ART modélisation-MANURES SLUDGES

Exposure calculations.xlsx

3.3. New information on the active substance

FR position on systemic risk linked t

3.4. Summaries of the efficacy studies (B.5.10.1-xx)

See IUCLID file.

3.5. Confidential annex

See separated annex.