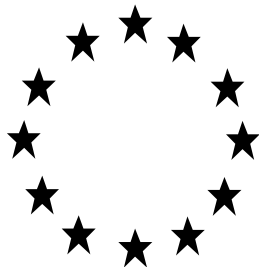
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



[Saniblanc QM]

Product type [2 and 3]

[Calcium magnesium oxide as included in the Union list of approved active substances]

Case Number in R4BP: [BC-TR055644-08]

Evaluating Competent Authority: [BE]

Date: [11/04/2022]
Final PAR

Table of Contents

1 CONCLUSION

Overall conclusion on the biocidal product family regarding physical, chemical and technical properties:

The product Saniblanc® QM is a dustable powder (DP) and is the same as the active substance.

The product is a off-white solid without odour. The pH of the product is 12.42 and its alkalinity is 155%. The pour density is 0.83 g/mL and the tap density is 1.15 g/mL. The dusts are within the inhalable/respirable range.

No relevant variations were observed during the accelerated and long term storage stability tests. The product is considered as stable for a period of 24 weeks.

All studies have been performed in accordance with the current requirements. The results of applicable to the formulation type (DP) technical properties are deemed acceptable. However, some restrictions are addressed by storage conditions restriction ("Keep away from acids", "Store in a dry place" and "Do not use aluminium for transport and storage if there is a risk of contact with water")

Implications for labelling:
"Keep away from acids"
"Store in a dry place"
"Do not use aluminium for transport and storage if there is a risk of contact with water"

Shelf-life:
24 weeks

Overall conclusion on the biocidal product family regarding physical hazards and respective characteristics:

Based on the evaluation of different physical hazards of biocidal product Saniblanc® QM, it can be concluded that it does not have explosive and oxidising properties. The product is not flammable solid and has a relative self-ignition temperature below 400 °C.
The product Saniblanc® QM is not corrosive to metals.

Overall conclusion on the biocidal product family regarding methods of detection and identification:

The product Saniblanc® QM is the same as the active substance. All analytical methods for detection and indentification are based on the CAR of the active substance. The analytical methods for all lime and dolime variants are applicable to the biocidal product.
The ISO method for detection of the substance in air is applicable to monitor workplace exposures.

Overall conclusion on the biocidal product family regarding EFFICACY

Considering all the data provided by the Applicant, efficacy of the product is proved enough for disinfection procedures of sewage sludges (use #1) and non-porous floors inside animal accommodations & animal transportation vehicles.

Disinfection of sewage sludges :
The relevant efficacy tests provided by the Applicant showed that the product ***SANIBLANC QM*** mixed at application rates from 0.26 to 2.6 kg of CaO.MgO/kg dry sludge is effective to control all the target organisms i.e. Bacteria, yeasts, fungi, viruses and nematode eggs.
The efficacy of the product is mainly due to the high temperature above +60°C, the increase of the pH above 12 and a relevant contact time from 1 to 24h (but up to 4-8 weeks for eggs of *Ascaris suum)*.

Disinfection procedures of non-porous floors inside animal accommodations & animal transportation vehicles :
The relevant efficacy tests provided by the Applicant showed that the product ***SANIBLANC QM*** used at 1300 g/m^2 with pre- and post-humidation with water at 0.5 L/m^2 is bactericidal, fungicidal/yeasticidal and virucidal in minimum 24h (preferably 48h) on non-porous floors inside animal accommodations/animal transportation vehicles, without prior cleaning (even if cleaning by brushing the floors before the desinfection procedure is highly recommended).
The disinfection procedure should be performed only without the presence of animals (i.e. between two productions, prophylactic quarantine…).
Monitoring of the temperature > +55°C and of the pH > 12 should be mandatorily put in place in order to achieve the good activation of the product.

Overall conclusion on the biocidal product family regarding human health

All the uses proposed offer safe use for the users and the general public, under the conditions that some RMM (including the use of PPE) are applied. Many of the uses are similar to what was proposed in the CAR of the active substance.
It is to be noted that the active substance present both a risk for systemic exposure (thought the UL of calcium) and for local effects (due to a classification as skin irritant and eye damage). For those reason, the assessment of most scenario contains both a tier 2 and a tier 3 side. The tier 2 involves the use of gloves and coverall, and is needed to remain below the UL of clalcium for the users and, when possible, an increased ventilation. The tier 3 involves only the wearing of a mask.
The mask present in the tier 3 is not necessary for a safe use from a systemic point of view, the use of a good ventilation, gloves and coverall being enough. However, the active substance having an AEC, and being a powder that can generate dust requires the use of RPE in order to offer sufficient protection to the respiratory tract. To remain below the AEC and guarantee a safe use from a local risk assessment, the use of RPE is necessary for some of the scenario used for the assessment.
Given the uses involved, exposure through food to calcium is possible, this risk for consumer is therefore assessed and demonstrate that exposure through food remains below the UL. Calcium being a nutrient that is essential for a good health, it's presence in food is not an issue, as long as the total amount to which the general public and the

workers do not exceed the UL. Given the mode of action of the active substance, no other risk (notably local risks) are expected regarding the exposure through food.

Overall conclusion on the biocidal product family regarding environnement

The product Saniblanc® QM is the same as the active substance. All proposed used of the product were evaluated following the same qualitative methodology. According to this, no unacceptable risk for the environment is expected following the use of Saniblanc® QM.

Overall conclusion on the biocidal product family regarding endocrine disrupting properties

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product Saniblanc QM was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product Saniblanc QM.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country**
Saniblanc® QM Neutralac® QM	Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Carrières et Fours à Chaux Dumont-Wautier S.A.
	Address	28, rue Charles Dubois 1342 Ottignies - Louvain-la-Neuve Belgium
Authorisation number	BE2022-0010	
Date of the authorisation	11/04/2022	
Expiry date of the authorisation	11/04/2032	

2.1.1.3 Manufacturer of the products

Name of manufacturer	Carrières et Fours à Chaux Dumont-Wautier S.A.
Address of manufacturer	Rue Charles Dubois, 28 1342 Ottignies - Louvain-la-Neuve Belgium
Location of manufacturing sites	Rue la Mallieue, 95 4470 Saint-Georges-sur-Meuse Belgium

2.1.1.4 Manufacturer of the active substance

Active substance	*Calcium magnesium oxide*
Name of manufacturer	Carrières et Fours à Chaux Dumont-Wautier S.A.
Address of manufacturer	Rue Charles Dubois, 28 1342 Ottignies - Louvain-la-Neuve Belgium
Location of manufacturing sites	Rue la Mallieue, 95 4470 Saint-Georges-sur-Meuse Belgium

1 Please fill in here the identifying product name from R4BP.

2.1.2 Product composition and formulation

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	
ISO name	*Calcium magnesium oxide*
IUPAC or EC name	*Calcium magnesium oxide*
EC number	253-425-0
CAS number	37247-91-9
Index number in Annex VI of CLP	N/A
Minimum purity / content	800 g/kg The value provides the content of Ca and Mg expressed as the sum of CaO and MgO. Minimum value for MgO in Burnt dolomitic lime is 30 % based on Magnesium content.
Structural formula	CaO.MgO

2.1.2.2 Candidate for substitution

Not applicable

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Calcium magnesium oxide	Calcium magnesium oxide	Active substance	37247-91-9	253-425-0	100 (TECH) ≥ 97 (PURE)

The product has the same composition as the approved active substance and is in compliance with the active substance Reference Specification.

2.1.2.4 Information on technical equivalence

Not applicable. The active substance is supplied from approved supply sources evaluated as part of the Reference Source specification.

2.1.2.5 Information on the substance of concern

The products are the same as the active substance. There are no impurities in the active substance that qualify for definition as a substance of concern.

2.1.2.6 Type of formulation

DP: Dustable powder

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Irrit. 2
Hazard statement	H315: Causes skin irritation
Hazard category	Eye Dam. 1
Hazard statement	H318: Causes serious eye damage
Hazard category	STOT SE 3
Hazard statement	H335: May cause respiratory irritation
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Precautionary statements	P102 Keep out of reach of children P264: Wash skin thouroughly after handling P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 Immediately call a POISON CENTER or doctor/physician. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P261 Avoid breathing dust P362 take off contaminated clothes and wash before reuse P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P501 Dispose of contents/container in accordance with national regulation.
Note	

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. 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. The application rate is 0.26 – 2.6 kg of CaO.MgO / kg of dry matter in the sludge (DM). The application dose should be set to achieve a rate of 20 - 90% of the dry solids weight of sludge, and must be high enough to achieve a pH of > 12 for a minimum of 24 hours (up to 8 weeks for nematode eggs). - The rate may vary between applications. The user should ensure efficacy of the treatment with laboratory trials. - Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use[2]

See general directions for use

2.1.4.3 Use-specific risk mitigation measures

Appropriate engineering controls: If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust levels below recommended exposure limits. Individual protection measures Respiratory protection: Provide sufficient air exchange and/or exhaust in work

[2] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

rooms. Respirator with a particle filter (EN 143) See also the exposure scenario.
Hand protection: Protective gloves: Nitrile rubber.
Eye/face protection: Tightly fitting safety goggles. Do not wear contact lenses.
Skin protection: Long sleeved clothing, close fittings at openings. Footwear protecting against chemicals.

Hygiene measures:
Wash hands and face before breaks and immediately after handling the product. If needed: Use protective skin cream before handling the product. When using, do not eat, drink or smoke.

Environmental exposure controls: Exhaust ventilation equipped with filters. Do not flush into surface water or sanitary sewer system.

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

First aid measures: If symptoms persist or in case of doubt seek medical advice
Inhalation: If inhaled move to fresh air. Call a doctor.
Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation develops, get medical attention.
Eye contact: Rinse immediately with plenty of water, also under eyelids for at least 15 minutes.
Remove contact lenses. Get medical attention.
Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.
Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

Environmental precautions: Do not flush into surface water or sanitary sewer system. Protect from moisture. If the product contaminates rivers and lakes or drains inform respective authorities.

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

Empty containers: Can be landfilled or incinerated, when in compliance with local regulations. After usage, empty the packing completely.

Waste from residues / unused products: Dispose of in compliance with local and national regulations.

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

"Keep away from acids"

"Store in a dry place" "Do not use aluminium for transport and storage if there is a risk of contact with water" Shelf-life: 24 weeks

Table 2. Use # 2 – Disinfection procedures of non-porous floors inside animal accommodations and of inside floors of animal transportation vehicles

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts Fungi Virus
Field of use	Indoor – in animal accommodations and animal transportation vehicles - only without the presence of animals (i.e. between two productions, prophylactic quarantine…): Disinfection of non-porous floors, without prior cleaning
Application method(s)	Direct application
Application rate(s) and frequency	1. Wash the installation with running water 2. Spray 0.5 L water/m^2 3. Apply ***SANIBLANC QM*** : 1300 g pure powder/m^2 4. Spray again 0.5 L water/m^2 5. Leave to act for at least 24 h Monitoring of the temperature > +55°C and of the pH > 12 should be mandatorily put in place in order to achive the good activation of the product.
Category of users	Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.7 Use-specific instructions for use[3]

See general directions for use

[3] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.8 Use-specific risk mitigation measures

Appropriate engineering controls:
If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust levels below recommended exposure limits.

Individual protection measures
Respiratory protection: Provide sufficient air exchange and/or exhaust in work rooms. Respirator with a particle filter (EN 143) See also the exposure scenario.
Hand protection: Protective gloves: Nitrile rubber.
Eye/face protection: Tightly fitting safety goggles. Do not wear contact lenses.
Skin protection: Long sleeved clothing, close fittings at openings. Footwear protecting against chemicals.

Hygiene measures:
Wash hands and face before breaks and immediately after handling the product. If needed: Use protective skin cream before handling the product. When using, do not eat, drink or smoke.

Environmental exposure controls: Exhaust ventilation equipped with filters. Do not flush into surface water or sanitary sewer system.

2.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid measures: If symptoms persist or in case of doubt seek medical advice
Inhalation: If inhaled move to fresh air. Call a doctor.
Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation develops, get medical attention.
Eye contact: Rinse immediately with plenty of water, also under eyelids for at least 15 minutes.
Remove contact lenses. Get medical attention.
Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.
Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

Environmental precautions: Do not flush into surface water or sanitary sewer system. Protect from moisture. If the product contaminates rivers and lakes or drains inform respective authorities.

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

Empty containers: Can be landfilled or incinerated, when in compliance with local

regulations. After usage, empty the packing completely.

Waste from residues / unused products: Dispose of in compliance with local and national regulations.

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

"Keep away from acids"
"Store in a dry place"
"Do not use aluminium for transport and storage if there is a risk of contact with water"

Shelf-life: 24 weeks

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please refer to the authorised use with use conditions.

2.1.5.2 Risk mitigation measures

Appropriate engineering controls:
If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust levels below recommended exposure limits.

Individual protection measures
Respiratory protection: Provide sufficient air exchange and/or exhaust in work rooms. Respirator with a particle filter (EN 143) See also the exposure scenario.
Hand protection: Protective gloves: Nitrile rubber.
Eye/face protection: Tightly fitting safety goggles. Do not wear contact lenses.
Skin protection: Long sleeved clothing, close fittings at openings. Footwear protecting against chemicals.

Hygiene measures:
Wash hands and face before breaks and immediately after handling the product. If needed: Use protective skin cream before handling the product. When using, do not eat, drink or smoke.
Environmental exposure controls: Exhaust ventilation equipped with filters. Do not flush into surface water or sanitary sewer system.

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

First aid measures: If symptoms persist or in case of doubt seek medical advice
Inhalation: If inhaled move to fresh air. Call a doctor.
Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation

develops, get medical attention.
Eye contact: Rinse immediately with plenty of water, also under eyelids for at least 15 minutes.
Remove contact lenses. Get medical attention.
Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.
Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

Environmental precautions: Do not flush into surface water or sanitary sewer system. Protect from moisture. If the product contaminates rivers and lakes or drains inform respective authorities.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers: Can be landfilled or incinerated, when in compliance with local regulations. After usage, empty the packing completely.
Waste from residues / unused products: Dispose of in compliance with local and national regulations.

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

"Keep away from acids"
"Store in a dry place"
"Do not use aluminium for transport and storage if there is a risk of contact with water"

Shelf-life: 24 weeks

2.1.6 Other information

/

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)
Bulk	30 tonnes	Stainless steel closed powder tanker	N/A	Professional	Yes
Big bag/sack	1000 kg	Body cover: Polypropylene white Anti-UV	No specific closure material	Professional	Yes

		treatment according to ISO 21898 : 2004; or paper Lining: Type: Polyethylene			
Sack	25 kg	Body cover: Polypropylene or paper Lining (if included): Type: Polyethylene	No specific closure material	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

Carrières et Fours à Chaux Dumont-Wautier S.A.is the applicant supporting the active substance. A letter of access to the active substance dossier is required.

2.2 Assessment of the biocidal product

The uses below are the ones applied for by the applicant, without any changes by the eCA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

2.2.1 Intended uses as applied for by the applicant

Table 1. 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. The application rate is 0.26 – 2.6 kg of CaO.MgO / kg of dry matter in the sludge (DM). The application dose should be set to achieve a rate of 20 - 90% of the dry solids weight of sludge, and must be high enough to achieve a pH of > 12 for a minimum of 3 hours.
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper / plastic sacks: 25 kg

Table 2. Use # 2 – Disinfection of manure

Product Type	3
Where relevant, an exact description of the authorised use	The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use.
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor, outdoor
Application method(s)	Direct application
Application rate(s) and frequency	Application to manure/litter outside animal houses Remove the manure or litter from the animal house. 1. For prevention: Add approximately 17 kg dolime/m³ of

	litter or manure. 2. For treatment: Add approx. 171 kg dolime/m³ of litter or manure 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water. 4. Stockpile the lime treated manure. 5. After at least 24h, dispose of the dolime treated manure according to local legislation. Application of dolime to litter or manure inside animal houses 1. For Prevention: Spread approx. 17 kg/m³ (3.4 kg of dolime /m² for 20 cm litter) on the litter or manure inside the poultry house 2. For treatment: Spread approx. 171 kg/m³ (34 kg of dolime /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 dolime/manure or dolime/litter mixture from the animal house 5. Homogenise the dolime/manure or litter mixture 6. Stockpile the dolime treated manure 7. After at least 24 h, dispose the dolime treated manure according to the local legislation
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper /plastic sacks: 25 kg

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

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto the floors of animal accomodations (poultry, cattle, sheep)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor
Application method(s)	Direct application
Application rate(s) and frequency	a. On concrete floors 1. Wash the installation with running water 2. Sprinkle sufficient product to cover the damp ground (e.g. 1.4 kg of dolime/m²) 3. Spray sufficient water to quench the steaming reaction with the product (e.g. 1 litre of water per m² of dolime) 4. Leave to act for at least 2 h 5. Brush and remove the hydrated dolime which may be recycled as agricultural liming material as described in the European standard EN/ TS15084:2007 (Liming materials –

	Determination of the lime requirement – Guidelines, principles and parameters) B. On mud floors 1. Brush the floor 2. Sprinkle approx. 1400 g of product per m² on the damp ground 3. Spray 2 litre of water per m² or sufficient water to quench the steaming reaction with the quick dolime 4. Leave to act for at least 24 h 5. Brush and remove the hydrated dolime powder which may be recycled as agricultural liming material as described in the European standard EN/TS15084:2007 (Liming materials – Determination of the lime requirement – Guidelines, principles and parameters)
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper / plastic sacks: 25 kg

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

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto the surface of animal enclosures (poultry)
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Outdoor
Application method(s)	Direct application
Application rate(s) and frequency	At the beginning of a production cycle it is recommended to spread 1000-1400 g/m² of the product onto the ground and apply water to the soil. At the end of the production cycle it is recommended to remove any remaining material from the soil. Leave to act for at least 24 hours before bringing in poultry When the flock is in place, reapply if the ground becomes muddy or unstable. The animals should be removed from the area being treated. Re-entry is allowed at least 12 hours after application.
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper / plastic sacks: 25 kg

2.2.2 Physical, chemical and technical properties

The products are the same as the active substance. The main physico-chemical endpoints have been addressed in the active substance dossier and to which the applicant has access. **The biocidal products Neutralac® QM (representative product in the AS dossier) and Saniblanc® QM are both composed of 100% of burnt dolomitic lime (CaO.MgO).**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
Physical state at 20 °C and 101.3 kPa	No Guideline followed	Neutralac® QM: 100% CaO.MgO	Solid	AS dossier: A3.3.1	Acceptable
Colour at 20 °C and 101.3 kPa	No Guideline followed	Neutralac® QM: 100% CaO.MgO	Off-white	AS dossier: A3.3.2	Acceptable
Odour at 20 °C and 101.3 kPa	No Guideline followed	Neutralac® QM: 100% CaO.MgO	Due to low volatility no odour is expected.	AS dossier: A3.3.3	Acceptable
Acidity / alkalinity	CIPAC MT 31 and CIPAC 75.3	Saniblanc® QM: 100% CaO.MgO	The test conditions (test sample mass and [HCl]) were adapted to limit the titration volume to 25 mL of HCl. Moreover, for the determination of the pH, it was shown that reducing the test sample to 0.5 g had no impact on the pH value. Indeed, given the low solubility of dolomitic quicklime, a test sample of 0.5g/100ml remains well above saturation. pH: 12.42 Alkalinity: 155%	P. Tihon, 2021, "pH and alkalinity test report on Saniblanc® QM", report PHT/NH	Acceptable
Relative density / bulk density	OECD 106 EC Method A3	Neutralac® QM: 100%	Relative density: 3.28 Pour density: 0.83 g/mL	AS dossier: Doc. No. 113-006. A3.1.3/07	Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>CIPAC MT 186</td><td>CaO.MgO</td><td>Tap density: 1.15 g/mL</td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>OECD DRAFT GUIDANCE DOCUMENT FOR STORAGE STABILITY TESTING" (dated : 21 May 2014)

Content : XRF Chemical Analysis

pH and alkalinity : CIPAC MT 31 and CIPAC 75.3

Granulometry: Particle size ≥ 2 mm shall be determined by dry sieving in accordance with EN 459–2:2010, 6.1 and particle size < 2 mm by air-jet sieving in</td><td>Saniblanc® QM: 100% CaO.MgO</td><td>At 54°C with 50% RH for 14 days.
Packaging:An industrial polypropylene bag of 25kg

<table>
<tr><td></td><td>T0</td><td>T0+14D</td></tr>
<tr><td>AS content (%)</td><td>96.4</td><td>94.7</td></tr>
<tr><td>CO2 content (%)</td><td>0.88</td><td>0.94</td></tr>
<tr><td>LOI 1000°C content (%)</td><td>1.44</td><td>3.14</td></tr>
<tr><td>Appearance of packaging</td><td>An industrial polypropylene bag of 25kg</td><td>No change in the integrity of the package</td></tr>
<tr><td>pH</td><td>12.4</td><td>12.5</td></tr>
<tr><td>Alkalinity (%)</td><td>154.5</td><td>151.4</td></tr>
<tr><td>Granulometry</td><td></td><td></td></tr>
<tr><td>Residue at 3.15 mm (%)</td><td>1</td><td>1.2</td></tr>
<tr><td>Residue at 2 mm (%)</td><td>7</td><td>5.9</td></tr>
<tr><td>Residue at 90µm (%)</td><td>47</td><td>38.5</td></tr>
<tr><td>Residue at 63µm (%)</td><td>56.3</td><td>47.2</td></tr>
<tr><td>Residue at 50µm (%)</td><td>62</td><td>50.6</td></tr>
<tr><td>Residue at 45µm (%)</td><td>64.2</td><td>51.9</td></tr>
</table>

Note : After 14 days of accelerated storage in a 25kg plastic bag :</td><td>P. Tihon, 2021,"Storage stability test report on Saniblanc® QM", report PHT/NH</td><td>Acceptable

As stated in the Guidance on the Biocide products regulation, Vol I Parts A+B+C (Version 2.0 May 2018), for the solid preparation, an extrapolation based on results of an industrial polypropylene bag of 25kg is acceptable for polypropylene 1.5T big bag.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	accordance with EN 459–2:2010, 6.2		☐☐the water content (difference between LOI and CO2) of the product raised from 0.6 to 2.2% (w/w), which indicates that a small part of the burnt dolomitic lime was transformed into hydrated lime ☐☐consequently, a loss of 2% is observed in the active substance CaO+MgO content ☐☐the product was getting a bit finer due to partial hydration. With around 50% of the product passing at 50 µm, the product is still defined as a dusty powder, which remains far above the 80% indicated in the assessment reports Those difference are insignificant and have no influence on the use of the product as a biocide. Similar storage stability test can not be conducted on polypropylene 1,5T big bags, which could also be alternatively used as commercial packaging for Saniblanc® QM. Nevertheless, as a big bag limits the surface area of the product in contact with the bag and as furthermore, big bags are fitted with damp proof polyethylene liner, the above observations can reasonably be extrapolated to this packaging.		
Storage stability test – **long term storage at ambient temperature**	No Guideline followed	Please refer to the confidential PAR.	Please refer to the confidential PAR.	Please refer to the confidential PAR.	Acceptable Shelf-life of 24 weeks is authorized for Saniblanc® QM.
Storage stability test – **low**	Test waiver - The product is a dustable powder, meaning that the stability test on liquid is not relevant.				Not applicable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
temperature stability test for liquids					
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Test waived - Photodegradation implies the action of some radicals on the substance. In CaO.MgO, Calcium, Magnesium and Oxygen are in their respective preferred oxidation state and are not expected to be further oxidised.				Accceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	During the accelerated storage stability test, during 14 days at 54°C and 50% of relative humidity, one part of the calcium oxide is hydrated into calcium hydroxide which is another active substance. As dolomitic lime CaO.MgO is hygroscopic, it is always recommended, in a preventive mode, to store bagged material under dry conditions.				The humidity of the ambient air has an effect on the reactivity of the product. A restriction should be added on the label: "Store in a dry place"
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer the accelerated storage test. After 14 days of accelerated storage in a 25kg plastic bag, *no change in the integrity of the package was observed.* Similar storage stability test can not be conducted on polypropylene 1,5T big bags, which could also be alternatively used as commercial packaging for Saniblanc® QM. Nevertheless, as a big bag limits the surface area of the product in contact with the bag and as furthermore, big bags are fitted with damp proof polyethylene liner, the above observations can reasonably be extrapolated to this packaging.				Acceptable As stated in the Guidance on the Biocide products regulation, Vol I Parts A+B+C (Version 2.0 May 2018), for the solid preparation, an extrapolation based on results

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
					of an industrial polypropylene bag of 25kg is acceptable for polypropylene 1.5T big bag.
Wettability	Test waived - The product is used as a dry powder				Not applicable
Suspensibility, spontaneity and dispersion stability	Test waived - The product is used as a dry powder				Not applicable

<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>BE remark</th></tr>
<tr><td>Dry sieve test</td><td>Particle size ≥ 2 mm shall be determined by dry sieving in accordance with EN 459–2:2010, 6.1 and particle size < 2 mm by air-jet sieving in accordance with EN 459–2:2010, 6.2</td><td>Neutralac QM: 97% CaO.MgO

And

Saniblanc® QM: 100% CaO.MgO</td><td>
<table>
<tr><td>Residue at 3.15 mm (%)</td><td>2.2</td></tr>
<tr><td>Residue at 2 mm (%)</td><td>13.8</td></tr>
<tr><td>Residue at 1 mm (%)</td><td>30.8</td></tr>
<tr><td>Residue at 500µm (%)</td><td>42</td></tr>
<tr><td>Residue at 250µm (%)</td><td>55.8</td></tr>
<tr><td>Residue at 150µm (%)</td><td>65.2</td></tr>
<tr><td>Residue at 90 µm (%)</td><td>71.6</td></tr>
<tr><td>Residue at 63 µm (%)</td><td>77.6</td></tr>
<tr><td>Residue at 50 µm (%)</td><td>84.4</td></tr>
<tr><td>Residue at 32 µm (%)</td><td>88.8</td></tr>
</table>
The products are defined as being dusty powders.

The substance is therefore considered to be in the inhalable/respirable range.

Moreover, before accelerated storage (54°C, 50% of relative humidity, 14 days):
<table>
<tr><td>Granulometry</td><td>T0</td></tr>
<tr><td>Residue at 3.15 mm (%)</td><td>1</td></tr>
<tr><td>Residue at 2 mm (%)</td><td>7</td></tr>
<tr><td>Residue at 90µm (%)</td><td>47</td></tr>
<tr><td>Residue at 63µm (%)</td><td>56.3</td></tr>
<tr><td>Residue at 50µm (%)</td><td>62</td></tr>
<tr><td>Residue at 45µm (%)</td><td>64.2</td></tr>
</table>
</td><td>M. Pelletier, 2007, Ref: BE1107.5.

And

P. Tihon, 2021,"Storage stability test report on Saniblanc® QM", report PHT/NH</td><td>Acceptable</td></tr>
<tr><td>Wet sieve analysis</td><td colspan="4">Test waiver - The product is a dustable powder reacting with water therefore the wet sieve analysis is not relevant.</td><td>Not applicable</td></tr>
<tr><td>Emulsifiability, re-emulsifiability and emulsion stability</td><td colspan="4">Test waiver - The product is used as a dry powder and not applied as a emulsifiable concentrate or ready to use emulsion.</td><td>Not applicable</td></tr>
<tr><td>Disintegration time</td><td colspan="4">Test waiver - The product is used as a dry powder and not applied as a tablet</td><td>Not applicable</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>BE remark</th></tr>
<tr><td>Particle size distribution, content of dust/fines, attrition, friability</td><td>Particle size ≥ 2 mm shall be determined by dry sieving in accordance with EN 459–2:2010, 6.1 and particle size < 2 mm by air-jet sieving in accordance with EN 459–2:2010, 6.2</td><td>Neutralac QM: 97% CaO.MgO

And

Saniblanc® QM: 100% CaO.MgO</td><td>
<table>
<tr><td>Residue at 3.15 mm (%)</td><td>2.2</td></tr>
<tr><td>Residue at 2 mm (%)</td><td>13.8</td></tr>
<tr><td>Residue at 1 mm (%)</td><td>30.8</td></tr>
<tr><td>Residue at 500µm (%)</td><td>42</td></tr>
<tr><td>Residue at 250µm (%)</td><td>55.8</td></tr>
<tr><td>Residue at 150µm (%)</td><td>65.2</td></tr>
<tr><td>Residue at 90 µm (%)</td><td>71.6</td></tr>
<tr><td>Residue at 63 µm (%)</td><td>77.6</td></tr>
<tr><td>Residue at 50 µm (%)</td><td>84.4</td></tr>
<tr><td>Residue at 32 µm (%)</td><td>88.8</td></tr>
</table>
The products are defined as being dusty powders.

The substance is therefore considered to be in the inhalable/respirable range.

Moreover, before accelerated storage (54°C, 50% of relative humidity, 14 days):
<table>
<tr><td>Granulometry</td><td>T0</td></tr>
<tr><td>Residue at 3.15 mm (%)</td><td>1</td></tr>
<tr><td>Residue at 2 mm (%)</td><td>7</td></tr>
<tr><td>Residue at 90µm (%)</td><td>47</td></tr>
<tr><td>Residue at 63µm (%)</td><td>56.3</td></tr>
<tr><td>Residue at 50µm (%)</td><td>62</td></tr>
<tr><td>Residue at 45µm (%)</td><td>64.2</td></tr>
</table>
</td><td>M. Pelletier, 2007, Ref: BE1107.5.

And

P. Tihon, 2021,"Storage stability test report on Saniblanc® QM", report PHT/NH</td><td>Acceptable</td></tr>
<tr><td>Persistent foaming</td><td colspan="3">Test waived - Although CIPAC method MT 47.2 was standardised for the determination of persistent foam in suspension concentrates it is also applicable to other preparations which are dispersed in water, in our case the product is used as a dry powder, therefore this parameter is not relevant.</td><td></td><td>Not applicable</td></tr>
<tr><td>Flowability</td><td colspan="3">Test waived - Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat. The product is not granular, it is a dry powder.</td><td></td><td>Not applicable</td></tr>
<tr><td>Pourability</td><td>Internal method</td><td>Saniblanc® QM:</td><td>By experience and as shown in the document "Bunrt dolomitic lime – storage", when unloading a bag of 25 kg,</td><td>"Burnt dolomitic lime – storage",</td><td>Acceptable</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>BE remark</th></tr>
<tr><td></td><td></td><td>100% CaO.MgO</td><td>around 50 g of material can stick on the bag. Less than 0.2% of the material remains in the packaging.

<table>
<tr><th colspan="3">Accelerated Storage Stability with Industrial Polypropylene bag</th><th colspan="2">Comment</th></tr>
<tr><td></td><td>T0</td><td>T0 + 14D</td><td colspan="2">At 54°C with 50% Relative Humidity for 14 days</td></tr>
<tr><td><u>Unloading of bag</u></td><td colspan="4"></td></tr>
<tr><td>Amount of material (g) remaining after emptying a 25 kg bag</td><td>31</td><td>50</td><td></td><td rowspan="2">Even after the accelerated storage, only 0.2% of the material remains in the packaging.</td></tr>
<tr><td>Amount of material (%) remaining after emptying a 25 kg bag</td><td>0.1</td><td>0.2</td><td></td></tr>
</table></td><td>Lhoist report</td><td></td></tr>
<tr><td>Dustability</td><td colspan="3">Test waived - Under standard conditions of handling and storage, the product remains a dry powder. The application method of the product is direct application.</td><td>Not applicable</td></tr>
<tr><td>Burning rate — smoke generators</td><td colspan="3">Test waived - The product is used as a dry powder and not applied as a smoke.</td><td>Not applicable</td></tr>
<tr><td>Burning completeness — smoke generators</td><td colspan="3">Test waived - The product is used as a dry powder and not applied as a smoke.</td><td>Not applicable</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td colspan="3">Test waived - The product is used as a dry powder and not applied as a smoke.</td><td>Not applicable</td></tr>
<tr><td>Spraying pattern — aerosols</td><td colspan="3">Test waived - The product is used as a dry powder and not applied as an aerosol.</td><td>Not applicable</td></tr>
<tr><td>Physical compatibility</td><td colspan="3">The biocidal product is the same as the active substance. It is not meant to be mixed with any other substances or mixture except water as described in the application.</td><td>Not applicable</td></tr>
<tr><td>Chemical compatibility</td><td colspan="3">When mixed with water, the substance will react exothermically into $Ca(OH)_2$ by such, increasing the pH. The increase of the temperature and of the pH are precisely the biocidal effects of CaO.MgO.
Calcium magnesium oxide reacts exothermically with water to form calcium dihydroxide.
$CaO.MgO + H_2O \rightarrow Ca(OH)_2 + MgO + 1155$ kJ/kg

The product reacts exothermically with acids to form salts.
CaO and MgO being Lewis bases by their chemical nature, they will react with acid compounds according to an acid/base chemical reaction.</td><td>Restrictions should be added on the label: “Store in a dry place”, “Do not use aluminium for transport and storage if there is</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	Reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen. $CaOMgO + 2Al + 7H_2O \rightarrow MgO + Ca(Al(OH)_4)_2 + 3H_2$. In the presence of water or moisture, CaO.MgO will react exothermically to form Ca(OH)2 that will further react with aluminum.				a risk of contact with water" and "Keep away from acids"
Degree of dissolution and dilution stability	Test waived - The product is used as a dry powder and isn't diluted.				Not applicable
Surface tension	Test waived - The product is a solid				Not applicable
Viscosity	Test waived - The product is a solid				Not applicable

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

The product Saniblanc® QM is a dustable powder (DP) and is the same as the active substance.

The product is a off-white solid without odour. The pH of the product is 12.42 and its alkalinity is 155%. The pour density is 0.83 g/mL and the tap density is 1.15 g/mL. The dusts are within the inhalable/respirable range.

No relevant variations were observed during the accelerated and long term storage stability tests. The product is considered as stable for a period of 24 weeks.

All studies have been performed in accordance with the current requirements. The results of applicable to the formulation type (DP) technical properties are deemed acceptable. However, some restrictions are addressed by storage conditions restriction ("Keep away from acids", "Store in a dry place" and "Do not use aluminium for transport and storage if there is a risk of contact with water")

Implications for labelling:
"Keep away from acids"
"Store in a dry place"
"Do not use aluminium for transport and storage if there is a risk of contact with water"

Shelf-life:
24 weeks

2.2.3 Physical hazards and respective characteristics

The products are the same as the active substance. The main physico-chemical endpoints have been addressed in the active substance dossier and to which the applicant has access. **The biocidal products Neutralac® QM (representative product in the AS dossier) and Saniblanc® QM are both composed of 100% of burnt dolomitic lime (CaO.MgO).**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
Explosives	EU Method A.14	CaO.MgO Batch: BE1110.144 .2	There are no chemical groups within the structure that would imply explosive properties	Atwal, S.S et al. 2010, report 2937/0008	Acceptable
Flammable gases	Test waived - The product is a solid				Not applicable
Flammable aerosols	Test waived - The product is a solid				Not applicable
Oxidising gases	Test waived - The product is a solid				Not applicable
Gases under pressure	Test waived - The product is a solid				Not applicable
Flammable liquids	Test waived - The product is a solid				Not applicable
Flammable solids	EU Method A.10	CaO.MgO Batch: BE1110.144 .2	The ple failed to ignite during the two minutes that the Bunsen flame was applied. The test material has been determined to be not hight flammable as it failed to ignite in the preliminary screening trest. In CaO.MgO, Calcium, Magnesium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded.	Atwal, S.S et al. 2010, report 2937/0008	Acceptable
Self-reactive substances and mixtures	Test waived – Calcium, Magnesium and Oxygen are in their respective preferred oxidation state. The biocidal product is not self-reactive				Acceptable
Pyrophoric liquids	Test waived - The product is used as a dry powder				Not applicable
Pyrophoric solids	Test waived - In CaO.MgO, Calcium, Magnesium and Oxygen are in their respective preferred oxidation state. The active substance and hence the products are not pyrophoric.				Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td>Self-heating substances and mixtures</td><td>UN Class 4 - Division 4.2 – Test N.4</td><td>Saniblanc® QM: 100% CaO.MgO</td><td>Negative test result in a 100 mm basket at 140°C:
The sample Saniblanc® QM should not be classified as a self-heating substance of Class 4, Division 4.2.</td><td>A. Jennings, 2021, report S3016010150R1/2021</td><td>Acceptable</td></tr>
<tr><td>Substances and mixtures which in contact with water emit flammable gases</td><td colspan="4">Test waived - Calcium magnesium oxide will react exothermically with water but it is a simple inorganic salt so it will not emit flammable gases.
$CaO.MgO + H_2O \rightarrow Ca(OH)_2 + MgO + 1155$ kJ/kg</td><td>Acceptable</td></tr>
<tr><td>Oxidising liquids</td><td colspan="4">Test waived - The product is a solid</td><td>Not applicable</td></tr>
<tr><td>Oxidising solids</td><td>EU Method A.17</td><td>CaO.MgO Batch: BE1110.144.2</td><td>The biocidal product is inorganic and does not contain oxygen of halogens. Therefore, the result for oxidising properties was predicted negative.</td><td>Atwal, S.S et al. 2010, report 2937/0008</td><td>Acceptable</td></tr>
<tr><td>Organic peroxides</td><td colspan="4">Test waived - By definition given in the CLP: "Organic peroxides means liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide."
Burnt dolime does not comply with this definition since it is an inorganic salt without the bivalent -O-O- structure.</td><td>Acceptable</td></tr>
<tr><td>Corrosive to metals</td><td>WI COR.09</td><td>Saniblanc QM Batch: 1C120</td><td>Determination of the loss of mass (%) during 7 days at 55°C
<table>
<tr><th>Material</th><th>Position</th><th>Mass loss (%)</th></tr>
<tr><td>Steel</td><td>100% vapour</td><td>0</td></tr>
<tr><td></td><td>50%/50%</td><td>0</td></tr>
<tr><td></td><td>100% product</td><td>0</td></tr>
<tr><td>Aluminium</td><td>100% vapour</td><td>0</td></tr>
<tr><td></td><td>50%/50%</td><td>0</td></tr>
<tr><td></td><td>100% product</td><td>0</td></tr>
</table></td><td>B. Verstraeten , 2021
Report No: 21/120</td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
			For steel, the maximum loss of mass is attained for the sample which was hanged in the vapour phase. For aluminium, no mass loss is observed. The loss of mass does not exceed the maximum of 13.5% during 7 days of exposure.		
Auto-ignition temperatures of products (liquids and gases)	Test waived - The product is a solid				Not applicable
Relative self-ignition temperature for solids	EU Method A.16	CaO.MgO Batch: BE1110.144 .2	The biocidal product has been determined not to have a relative self-ignition temperature below 400 °C.	Atwal, S.S et al. 2010, report 2937/0008	Acceptable
Dust explosion hazard	Test waived - The product is powder but will not be a dust explosion hazard as the substance is a mineral.				Acceptable

Conclusion on the physical hazards and respective characteristics of the product
Based on the evaluation of different physical hazards of biocidal product Saniblanc® QM, it can be concluded that it does not have explosive and oxidising properties. The product is not flammable solid and has a relative self-ignition temperature below 400 °C. The product Saniblanc® QM is not corrosive to metals.

2.2.4 Methods for detection and identification

According to the "Doc I_2_Attachment 1_Dossier structure-Lime" of the AS dossier:

• *For each lime type, one individual dossier has been prepared. The dossier on Hydrated lime is the key (master) dossier and the source for read-across to the other 3 dossiers.*
• *Any studies, publications or other documents, unless they are of relevance only for particular lime types, have been submitted with and described in the dossier on "Hydrated lime". For several dossier parts, General chapters have been included in the "Hydrated lime" dossier. In the dossiers on "Burnt lime", "Burnt dolomitic lime" and "Hydrated dolomitic lime", reference is made to*

these general chapters. In addition, substantial read across is applied between the different dossiers concerning Doc III and Doc II. This is justified because the four lime types are chemically closely related. In particular, the dossier on "Burnt dolomitic lime" is based on read across to "Burnt lime", and the dossier on "Hydrated dolomitic lime is based on read across to "Hydrated lime".

This structure has been accepted and approved by the e-CA of the AS (UK).

The product Saniblanc® QM is the same as the active substance. Analytical methods employed for the active substance are applicable. Justifications for non-submission of data for the active substance are appropriate for products. **The biocidal products Neutralac® QM (representative product in the AS dossier) and Saniblanc® QM are both composed of 100% of burnt dolomitic lime (CaO.MgO).**

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 Ca as % CaO Purity of $CaCO_3$ (%)	5			 53,347 53,683 54,304 55,599 55,837 95-99		 0,28 % 0,30 % 0,23 % 0,20 % 0,26 %		ASTM C1271-99 (1999)

	Mg as % MgO Si as % SiO_2 Fe as % Fe_2O_3 Al as % Al_2O_3 *Mn as % Mn*				0,176 0,216 0,637 0,919 1,406 0,054 0,156 0,627 0,875 1,866 0,0244 0,0359 0,1357 0,1917 0,8792 0,0463 0,0736 0,1142 0,1159 0,4404 0,0024 0,0035 0,017 0,0248 *0,09*		8,52 % 2,78 % 1,10 % 1,09 % 3,49 % 22,22 % 5,77 % 1,75 % 2,97 % 3,32 % 5,33 % 5,01 % 1,69 % 1,10 % 1,56 % 3,24 % 5,43 % 2,63 % 3,11 % 3,70 % 12,50 % 8,57 % 21,18 % 1,21 % 0,44 %		
Active substance (calcium, magnesium, oxide and hydroxide. *Impurities minerals of silicon (silicates),*	ICP AA	Duplicate							ASTM CC 1301 – 95 (1995) (Reapproved 2001)

aluminium, iron (pyrite), manganese, carbon (carbonates), sulphur (sulphates, pyrite) and water.)									
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 dolime 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 dolime 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 dolime 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 – Agitation method"". However, given that these ions will occur naturally in soil and dolime 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 dolime allows for application of the treated sewage or manure to agricultural land (as a replacement for agricultural liming). Given this, the normal requirement for more detailed analysis of the active/residues in soil would seem unnecessary.

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

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

Analytical methods for animal and human body fluids and tisues
The determination of analytical methods for human body fluids and tissues is not justified as dolime 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 dolime 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 product Saniblanc® QM is the same as the active substance. All analytical methods for detection and indentification are based on the CAR of the active substance. The analytical methods for all lime and dolime variants are applicable to the biocidal 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 (organisms to be controlled) and field of use (organisms or objects to be protected)

Main group 01: DISINFECTANTS
Product types :

- PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*)
- PT3 (*Veterinary Hygiene*)

The biocidal product ***Saniblanc® QM*** does contain one active substance i.e. Calcium magnesium oxide/DOLIME/ dolomitic lime (CaO.MgO with CAS N° 37247-91-9) as dustable powder.

The biocidal product ***Saniblanc® QM*** is intended to be used by professional users only for disinfection of sewage sludge (PT2) and for disinfection of liquid and dry sludge manures/litter inside and outside animal houses, disinfection of indoor/outdoor floor surfaces in animal accommodations/enclosures (poultry, cattle, sheep) And in aminal transportation vehicles (PT3).

The biocidal product ***Saniblanc® QM*** is intended to be used to control bacteria, yeasts, fungi, viruses and nemadode eggs.

2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Calcium magnesium oxide/DOLIME/ dolomitic lime (CaO.MgO) is a powder, result of the chemical transformation of double carbonate of calcium and magnesium by heating it above +900°C.
Calcium magnesium oxide does react with water through an exothermic reaction to produce 67 % HYDRATED LIME & 33 % Magnesium hydroxide.

This addition of water serves the purpose of "*activation of the product"* for the pH shift (increase in alkalinity), the temperature increase and for a decrease in water availability. Advanced treatment requires the rise in temperature (> 55°C) and pH (> 12) for at least 24 hours.
Indeed, four effects of dolime are known and further explained thereafter :

1) Increased alkalinity - Addition of sufficient quantities of dolime 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 (NH3) - Proteolytic activity in biodegrading organic matter results in high concentrations of nitrogenous compounds. The high pH associated with dolime 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) and Burnt dolomitic lime (CaO·MgO) react with water to form Calcium hydroxide and half-hydrated dolomitic lime ($Ca(OH)_2$·MgO in an exothermic reaction. A typical initial temperature following addition of Burnt dolime 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, Doc. No., 381-011, Document IIIA, Section A5, Point 5.3.1/09), a 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 dolomitic 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 pH and exothermic reaction of Calcium magnesium oxide (CaO.MgO) in contact with moisture disrupt the cell wall of the target organisms.

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 3 months for the most pH resistant parasites.

2.2.5.3 Efficacy data

In accordance with the active substance assessments, Calcium Magnesium Oxide/DOLIME/ dolomitic lime (CaO.MgO) at 1030 g/m² is considered to be equivalent with the 3 following active substance lime variants:

- Burnt lime ⇔ Quickline ⇔ Calcium Oxide CaO at 600 g/m²
- Hydrated dolomitic lime
- Hydrated lime ⇔ $Ca(OH)_2$ at 800 g/m²

, so data may be read-acrossed to the various forms.

Experimental data on the efficacy of the biocidal product against target organisms				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Calcium Oxide CaO 100% White powder	*Salmonella senftenberg* *Streptococci* *E.coli* *Bovine parvovirus* *Nematode eggs*	**Simulated study** Direct mixing of sewage sludge with the biocidal product The principle employed was one of simulated use. The test was applied on two diffrent scales - one to simulate small scale use and the second to simulate industrial scale treatment. Sewage substrate was combined, in one of two mixer types respective to the scale of use under study, with a range of inocula and the biocidal product. Samples were taken at time points and survivors recovered. Application rate : 0.7 to 1.2 kg CaO/kg total dried solids ⇔ 0.26 to 2.6 kg/kg Dried Matter (according to information provided by the Applicant) Contact time : up to 24h Temperature : +50-55°C	5log reduction bacteria 4log reduction viruses 3log reduction nematode eggs Greater than 5 log reduction in bacteria, greater than 4 log reduction in viruses and a 3 log reduction in Ascaris eggs were observed. It was noted that pH and temperature were important parameters and had an impact on efficacy. pH above 12 was preferred and efficacy was seen to increase with a rise in temperature.	Doc. 6.7-1 " Schim *and al.* – 2003 – "Hygienisation of biowaste" - 840002_NR_336 -0201 copy (1)" (Doc. in German from 2003) + UICLID document in English. **R.I. 2**
Calcium Oxide 100% White powder	*Nematode eggs :* *Ascaris suum* eggs	**Ascaris eggs inactivation kinetics in naturally contaminated sludge treated with quick lime :** The two naturally contaminated sludges were treated with quick lime in order to reach, respectively, temperatures of +50; 55 or 60°C. The quick lime dosages required to obtain the target temperatures were calculated by means of Eq. (1). hese lime dosages ranged from 32.4% to 96.3%. In these three situations the sludge pH exceeded 12 throughout the experiment. The sludge treatments were carried out according the following procedure in a 5 L batch mixer (planetary motion) equipped with a flat stirrer. An amount of sludge that corresponds to 300 g of dry matter and the quick lime was introduced into the blender and mixed for 1 min at a mixing rate of 140 revolutions per minute. A sample of the treated sludge was taken after the treatment times presented according to the target temperature, cooled down and neutralised with 0.1N sulphuric acid. The analysis was performed in triplicate. The resultant sample was pretreated according to US EPA before determination of the Ascaris eggs viability percentages.	**Full-scale study :** at +51°C after 60 min, 40% of the Ascaris eggs were still viable. at +55°C after 75 min, all the Ascaris eggs are killed. at +58°C after 5 min, all the Ascaris eggs are killed. It can be concluded that in order to be an advanced sludge sanitisation treatment, liming must produce a homogeneous mixture at a pH of 12 or more and must maintain this mixture in a time/temperature regime leading to a negligible level of viable Ascaris eggs. 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.	Scientific article : Doc. 6.7-2 "6.7-2 - Capizzi Banas et al (2004) "*Liming as an advanced treatment for sludge sanitisation: helminth eggs elimination—Ascaris eggs as model*" ONLY AS SUPPORTIVE INFORMATION, since very old document

<table>
<tr>
<td></td>
<td></td>
<td>Full-scale study :
Sludge A was treated with quick lime using a plough mixer with a capacity of 18 wet tonnes of sludge per hour. The mixing was performed by the rotation, at a rate of around 80 revolutions per minute, of a shaft equipped with 10 ploughs and the residence time of the sludge in the mixer was around 2 min. The lime dose ranged from 22% to 26% CaO/TS (Table 3) and was adjusted according to the dry matter of the raw sludge in order to reach a temperature range from +50 to 60°C
The percentage viability of the Ascaris eggs was determined by counting the larvae that developed out of 100 eggs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium hydroxide (10% Ca(OH)2 in water: milk of lime)</td>
<td>Salmonella senftenberg 10^8/mL sludge</td>
<td>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 daya).
Step One:The sludge was fed through the digesters for 20 days.
Step Two: Days 21-39 Digester 1 was fed with 10% milk of lime to pH12.8 and given 3 hours agitation.
Step Three: From day 30 to day 50 raw sludge was inoculated with Salmonella, only Digester 1 was treated with lime.
Step Four: Days 51 -60. Raw sludge from both dogesters inoculated with Salmonella. Digester 1 is treated with decreasing amounts of Lime, Digester Two is also treated with Lime.
10% milk of lime mixed to give a final pH >12 in the mixed sludge (dry solids 3.63% or 5.18% w/w):
17.5, 19.0, 22.0 mL
160-180 minutes contact time</td>
<td>Contact time 180 mins:
>log2<log S. senftenberg

Contact time: 180 mins:
>log5<log6 naturally occuring coliforms</td>
<td>Scientific article : Doc. 6.7-3 "Influence of lime treatment of raw sludge on the survival of pathogens, on the digestibility of the sludge and on the production of methane" from 1990.

ONLY AS SUPPORTIVE INFORMATION, since very old document</td>
</tr>
<tr>
<td>Calcium Oxide
Calcium Hydroxide</td>
<td>Salmonella senftenberg as representative for moderate thermo-chemical resistant bacteria and viruses

Enterococcus faecium

Ascaris suum eggs, representative for nematode eggs</td>
<td>"Evaluation of liming in liquid and solid manure"

For the evaluation of liming in liquid and solid manure only <u>for curative treatment (not preventive treatment)</u>, two different methods were used :

<u>Treatment of solid manure</u> (pig and poultry) with dry matter content below 15% :
with Calcium oxide – CaO :

Mixed in a variety of mixers (ploughshare, ribbon, paddle, double screw etc.)</td>
<td>In SOLID pig and poultry manure with Calcium oxide :

<table>
<tr><th></th><th>T°C</th><th>CT (min)</th><th>Results</th></tr>
<tr><td rowspan="4">A. suum eggs</td><td rowspan="2">+70°C</td><td>30</td><td rowspan="4">100% developp mental inhibition , 0% Rel. embryon</td></tr>
<tr><td>60</td></tr>
<tr><td rowspan="2">+60°C</td><td>60</td></tr>
<tr><td>120</td></tr>
</table>
</td>
<td>Doc. "6.7-6 Uni_Leipzig Liming_in_manure EuLA-report-final_2008 copy" - Evaluation of liming in liquid and solid manure.

R.I. 3</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Bovine Parvovirus
as a representative for thermos-resistant viruses</td>
<td>At +60 or 70°C
With 30 or 60 min (up to 120 min for Ascaris suum eggs) incubation/contact time

<u>Treatment of liquid manure</u> (pig and cattle) :
with Calcium Hydroxide – $Ca(OH)_2$ (Hydrated lime).
At +60°C in 60 min for A. suum eggs. But NO T°C reported for the other target organisms
72 or 96h contact time.</td>
<td>
<table>
<tr><td></td><td></td><td></td><td>ating ratio and 100% reduction</td></tr>
</table>
<table>
<tr><th></th><th>T°C</th><th>CT (min)</th><th>% red.</th></tr>
<tr><td rowspan="4">Bovine parvovirus</td><td rowspan="2">+70°C</td><td>30</td><td rowspan="4">> 5 Log_{10}</td></tr>
<tr><td>60</td></tr>
<tr><td rowspan="2">+60°C</td><td>60</td></tr>
<tr><td>120</td></tr>
</table>
<table>
<tr><th></th><th>T°C</th><th>CT (min)</th><th>% red.</th></tr>
<tr><td rowspan="4">Salmonella senftenberg</td><td rowspan="2">+70°C</td><td>30</td><td rowspan="4">> 7 Log_{10}</td></tr>
<tr><td>60</td></tr>
<tr><td rowspan="2">+60°C</td><td>60</td></tr>
<tr><td>120</td></tr>
</table>
<table>
<tr><th></th><th>T°C</th><th>CT (min)</th><th>% red.</th></tr>
<tr><td rowspan="4">E. faecium</td><td rowspan="2">+70°C</td><td>30</td><td rowspan="4">> 7 Log_{10}</td></tr>
<tr><td>60</td></tr>
<tr><td rowspan="2">+60°C</td><td>60</td></tr>
<tr><td>120</td></tr>
</table>
NO differences noted btw pig and poultry manure.

In LIQUID pig and cattle manure with Calcium Hydroxide :
<table>
<tr><th></th><th>T°C</th><th>CT (min)</th><th>Results</th></tr>
<tr><td>A. suum eggs</td><td>+60°C</td><td>60</td><td>100% developmental inhibition, 0% Rel. embryonating ratio and 100%</td></tr>
</table>
</td>
<td>Caracteristics of the products and Application Rates used NOT REPORTED.

On p.2 of the report, it's clearly mentioned that "both methods are based on the "Draft Protocols for Liming of Liquid and Solid Manure" of the European Lime Association (EuLA)."
=> "EuLA Draft Protocols for Liming of Liquid and Solid Manure" : Caracteristics of the products and Application Rates used NOT more REPORTED.

=> In thedoc. "Dolime-dosages_EuLA_trials_Dec-2007-Lhoist-report_210918_», only AR with CaO reported.
STILL CONFUSING</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><td></td><td></td><td></td><td>reduction</td></tr>
</table>
<table>
<tr><td></td><td>CT (h)</td><td>% red.</td></tr>
<tr><td rowspan="2">Bovine parvovirus</td><td>72</td><td rowspan="2">> 5 Log_{10}</td></tr>
<tr><td>96</td></tr>
</table>
<table>
<tr><td></td><td>CT (h)</td><td>% red.</td></tr>
<tr><td rowspan="2">Salmonella senftenberg</td><td>72</td><td rowspan="2">> 7 Log_{10}</td></tr>
<tr><td>96</td></tr>
</table>
<table>
<tr><td></td><td>CT (h)</td><td>% red.</td></tr>
<tr><td rowspan="2">E. faecium</td><td>72</td><td rowspan="2">> 7 Log_{10}</td></tr>
<tr><td>96</td></tr>
</table>
NO differences noted btw pig and cattle manure.
</td>
<td>Info.</td>
</tr>
<tr>
<td>Calcium Oxide 100%
White powder</td>
<td>Bactericidal activity
Enterococcus hirae
Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus</td>
<td>EN 14349 (2012)
Quantitative carrier test – hard & non-porous surfaces

• Temperature : +10 ± 1°C
• Contact time : 30 min
• I.S. :
3g/L BSA (clean conditions)
10g/L yeast extract + 10g/L BSA (dirty conditions)

<u>With some adaptations of the method</u> in order to investigate the efficacy of the product used in the form of a powder applied to a surface:
Application rate : 600g/m2 with 2000 mL/m2 water</td>
<td>Bactericidal activity
RTU in 30 min at +10°C on hard/non-porous CLEAN surfaces

Bactericidal activity
RTU in 30 min at +10°C on hard/non-porous DIRTY surfaces</td>
<td>Doc. "6.7-7 J000714-1 BS EN 14349 Calcium oxide Clean"

Doc. "6.7-8 J000714-1 BS EN 14349 Calcium oxide dirty"

R.I. 1</td>
</tr>
<tr>
<td>Calcium Hydroxide

No information about the application rate

Draft Protocols for Liming of</td>
<td>Ascaris suum eggs,
representative for nematode eggs</td>
<td>"Evaluation of the effect of liming in liquid pig and cattle manure on Ascaris suum eggs" – Activity after 90 days

<u>Liming of liquid manure</u> (pig and cattle) with Calcium Hydroxide (Hydrated lime).</td>
<td>Ascaris suum eggs : > 96% developmental inhibition
Very small differences noted btw pig and cattle manure. Treatment seems to be more efficacious/reliable on cattle manure.</td>
<td>Doc. "6.7-13 Leipzeig liquid results copy"

R.I. 3
(+ Residual</td>
</tr>
</table>

<table>
<tr><td>Liquid and Solid Manure</td><td></td><td>Both methods are based on the "Draft Protocols for Liming of Liquid and Solid Manure" of the European Lime Association (EuLA).</td><td></td><td>activity not proven enough)</td></tr>
<tr><td>Calcium Oxide 100%
White powder
(product EULA OXI-LIME 23)</td><td>Virucidal activity
Porcine Parvovirus</td><td>NF T 72-281 (2014)
Quantitative Surface Test
On stone carriers

- Temperature : +15-22 °C
- Contact time : 120 min

- Dosage: in 3 steps
0.45 L water/m^2
600 g CaO/m^2
0.45 L water/m^2

- I.S. : 10g/L BSA + 10g/L yeast extract (dirty conditions)</td><td>Virucidal activity (Log↓ = 4.67) in 120 min contact time at +20°C on hard/non-porous surfaces without prior cleaning.</td><td>Doc. "6.7-14 : B Oxi- Lime Virus NF T 72 281 (1)"

R.I. 1</td></tr>
<tr><td>Calcium Oxide 100%
White powder
(product EULA OXI-LIME 23)</td><td>Bactericidal & fungicidal/yeasticidal activity

Staphylococcus aureus
Enterococcus hirae
Pseudomonas aeruginosa

Candida albicans
Aspergillus brasiliensis</td><td>NF T 72-281 (2014)
Quantitative Surface Test
On stone carriers

- Temperature : +15-22 °C
- Contact time : 2h or 24h

- Dosage: in 3 steps
0.45 L water/m^2
600 g CaO/m^2
0.45 L water/m^2

- I.S. : 10g/L BSA + 10g/L yeast extract (dirty conditions)</td><td><table><tr><th></th><th>CT</th><th>Log↓</th></tr><tr><td>S. aureus</td><td>24h</td><td>6.85</td></tr><tr><td>E. hirae</td><td>24h</td><td>6.95</td></tr><tr><td>P. aeruginosa</td><td>2h</td><td>6.52</td></tr><tr><td>C. albicans</td><td>2h</td><td>5.83</td></tr><tr><td>A. brasiliensis</td><td>24h</td><td>2.30</td></tr></table>
NO conclusion since mandatory target organisms (E. coli & Proteus vulgaris) are missing.

Under the tested conditions, efficacy against A. brasiliensis is not proven (also confirmed with another test i.e. Doc. "6.7-14A Oxi-Lime Aspergillus simulated use, Clean13020919-A (1)" not reported)</td><td>Doc. "6.7-14 Oxi-Lime NF T 72-281 IRM Final 09 2019 1 (1)"

R.I. 3
E. coli & Proteus vulgaris missing</td></tr>
<tr><td>SANIBLANC QM</td><td>Bactericidal, fungicidal/yeasticidal and virucidal activity

Staphylococcus aureus
Enterococcus hirae
Pseudomonas aeruginosa
E. coli
Proteus vulgaris</td><td>NF T 72-281 (2014)
Quantitative Surface Test
On stone carriers

- Temperature : +15-22 °C
- Contact time : 2h or 24h

- Dosage: in 3 steps
0.5 L water/m^2</td><td><table><tr><th></th><th>CT</th><th>Log↓</th></tr><tr><td>P. aeruginosa</td><td>2h</td><td>5.08</td></tr><tr><td>E. hirae</td><td>24h</td><td>5.90</td></tr><tr><td>E. coli</td><td>2h</td><td>5.88</td></tr><tr><td>S. aureus</td><td>24h</td><td>6.04</td></tr><tr><td>P. hauserii</td><td>2h</td><td>6.23</td></tr><tr><td>E. faecium</td><td>24h</td><td>5.51</td></tr><tr><td>S. enterica</td><td>2h</td><td>5.38</td></tr><tr><td>C. albicans</td><td>2h</td><td>4.60</td></tr></table></td><td>Docs. "1293-0721-1" and "1293-0721-2"

R.I. 1</td></tr>
</table>

	Candida albicans *Aspergillus brasiliensis* Porcine parvovirus	1300 g ***SANIBLANC QM*** /m^2 0.5 L water/m^2 - I.S. : 10g/L BSA + 10g/L yeast extract (dirty conditions)	<table><tr><td>***A. brasiliensis***</td><td>24h</td><td>3.29</td></tr><tr><td>**Porcine parvovirus**</td><td>2h</td><td>3.72</td></tr></table> The product ***SANIBLANC QM***, used at 1300 g/m^2 with 1L water/m^2, has bactericidal, fungicidal/yeasticidal and virucidal activity in 24h on hard/non-porous surfaces wo prior cleaning.	
Calcium Oxide 100% White powder	Aerobic microorganisms Presumed *Enterobacteriaceae* Intestinal Enterococcus Moulds + Yeasts *E. coli* *Pseudomonas spp*	***Efficacy study of a biocidal product for the treatment of poultry housing*** **:** **FARM TRIAL – with *Calcium Oxide 100%*** (at 800g/m^2) **Contact time after treatment :** 48h **The soil is moistened with Karcher before treatment.**	***Calcium Oxide 100%*** at 800g/m^2 **Aerobic microorganisms :** ↓Log 6 **Intestinal Enterococcus :** ↓Log 5.3 **Moulds + Yeasts :** ↓Log 4.3 ***E. coli*** **:** ↓Log 4.7 ***Pseudomonas spp*** **:** ↓Log 6.2 These tests demonstrated that lime (100% CaO) used at a feed rate of 800g / m^2 applied to the soil as a biocidal product for the treatment of poultry farm building soils allows for satisfactory disinfection with high rates. Abatement greater than 4 Log for microorganisms monitored with high initial concentrations (greater than 4 Log10).	Doc. "6.7-16 Calcium oxide - 18-445R Essai Avicide 1 Rapport Final" **R.I. 2**
Calcium Oxide 100% White powder	Aerobic microorganisms Presumed *Enterobacteriaceae* Intestinal Enterococcus Moulds + Yeasts *E. coli* *Pseudomonas spp*	***Efficacy study of a biocidal product for the treatment of poultry housing*** **:** **FARM TRIAL – with *Calcium Oxide 100%*** (at 600g/m^2) **Contact time after treatment :** 48h **The soil is moistened with Karcher before treatment.**	***Calcium Oxide 100%*** at 600g/m^2 **Aerobic microorganisms :** ↓Log 3.4 **Intestinal Enterococcus :** ↓Log 3 **Moulds + Yeasts :** ↓Log 1.7 ***E. coli*** **:** ↓Log 2.4 ***Pseudomonas spp*** **:** ↓Log 3.7 These tests demonstrated that lime (100% CaO) used at a feed rate of 600g / m^2 applied to the soil as a biocidal product for the treatment of poultry farm building soils does **NOT** allow for satisfactory disinfection with high rates enough.	Doc. " 6.7-16 Calcium oxide - 18-445R Essai Avicide 1 Rapport Final" **R.I. 3**
Calcium Oxide 100% White powder	Aerobic microorganisms Presumed *Enterobacteriaceae* Intestinal Enterococcus Moulds + Yeasts *E. coli* *Pseudomonas spp*	***Efficacy study of a biocidal product for the treatment of*** **swine husbandry :** **FARM TRIAL – with *Calcium Oxide 100%*** (at 800g/m^2) **Contact time after treatment :** 40h **The soil is moistened with Karcher before treatment.**	**Aerobic microorganisms; Moulds + Yeasts; *E. coli; Pseudomonas spp* :** 90% decrease **Intestinal Enterococcus :** 70% decrease	Doc. " 19-413R - Piggs final_ ENG" **R.I. 3**
SANIBLANC QM	Aerobic microorganisms Presumed *Enterobacteriaceae*	**Efficacy study of a biocidal product for the treatment of poultry housing :** **FARM TRIAL**	**Aerobic microorganisms :** ↓Log 5 **Intestinal Enterococcus *;* Yeasts*, E. coli*** :	Doc. "6.7-19 Calcium magnesium

	Intestinal Enterococcus Yeasts *E. coli* (NO initial contamination by *Pseudomonas spp, Aspergillus sp or Staphylococcus sp)*	**with *SANIBLANC QM 100%*** 1030g/m^2 with 900 mL/m^2 water 1370g/m^2 with 1200 mL/m^2 water Contact time after treatment : 48h The soil is moistened with Karcher before treatment. Initial pH of the soil : 7 Increse of the pH of the soil during treatment : 12.3	↓Log < 3 These tests demonstrated that lime (100% CaO) used at a feed rate of 800g / m^2 applied to the soil as a biocidal product for the treatment of poultry farm building soils allows for satisfactory disinfection. Abatement greater than 3 Log for AEROBIC microorganisms.	oxide - 19-446R - Rapport final V1.2-Saniblanc QM" + "6.7-19 Calcium magnesium oxide - 19-446R - Rapport final V1.1 annexes" **Supportive information**

1- Desinfection procedures of sewage sludges (uses #1):

Three reports from simulated-use tests have been provided in order to demonstrate efficacy of lime to disinfect sewage sludge :
One of them (study in Doc. 6.7-3) with results for simulated tests performed in 1990 is quite old and is definitively considered as supportive information only.
The Doc. 6.7-1, although provided only in German (with IUCLID file in support), showed that mixture of burnt lime (at application rates from 0.7 to 1.2 kg of CaO/kg dry sludge ⇔ 0.26 to 2.6 kg of CaO.MgO/kg dry sludge) with sewage sludge contamined with a range of microorganisms (*Salmonella senftenberg*, *Streptococcus sp, E. coli, Clostridium perfringens*, Bovine parvovirus, ECBO and eggs of *Ascaris suum*) is effective to control all the target organisms. No results provided about the efficacy against fungi and yeasts. However, since eggs of *Ascaris suum* (frequently used as hygienic indicators) are known to be the most resistant to lime, we consider that efficacy against fungi/yeasts is demonstrated enough.
As already mentioned, it's confirmed that the efficacy of the product is mainly due to the high temperature, the increase of the pH above 12 and a relevant contact time from 1 to 24h but up to 4-8 weeks for eggs of *Ascaris suum*.

2- **Desinfection procedures of litter/manure** (use #2):

Considering the use "Disinfection of litter/manure" claimed by the applicant, it should be noted that both preventive and curative treatments have to be considered for the evaluation of the efficacy of the product.
First of all, no efficacy data with challenge over the time has been provided to support the doses for preventive tretaments. The claim "disinfection of litter/manure via preventive treatment is rejected.

In order to demonstrate efficacy of lime to disinfect manure via a curative treatment, the doc. "*6.7-6 Uni_Leipzig Liming_in_manure EuLA-report-final_2008 copy*" has been provided by the Applicant. However, this report has been scored with R.I.3 due to lack of crucial information about the application rate (expressed in Kg/m^3 of CaO or $Ca(OH)_2$) used during the trials.
On p.2 of the "*6.7-6"* report, it's clearly mentioned that "*both methods are based on the "Draft Protocols for Liming of Liquid and Solid Manure" of the European Lime Association (EuLA)."* Looking at this doc., the caracteristics of the products and Application Rates used are not more reported. Furthermore, it seems that information is only reported about both solid and liquid manures treated with CaO. No reference is reported about $Ca(OH)_2$ and the claim "disinfection of liquid litter/manure" is unsupported by robust efficacy data and as the consequence is rejected.

The Applicant has mentioned another doc. "*Dolime-dosages_EuLA_trials_Dec-2007-Lhoist-report_210918_* » : this document (from Sept. 2021) has been provided to fill this information gap about the lack of crucial information about the application rate (expressed in Kg/m^3 of CaO or $Ca(OH)_2$) used during the trials. Here also, unfortunately, this document does not clarify the issue enough.
Furthermore, the AR proposed by the APP do not make a clear distingtion between liquid/solid manure.

Since all this is still highly confusing, as the consequence, the use #2 is all rejected.

3- Desinfection procedures on concrete or mud floors inside animal accommodations (uses #3) and on floors of outdoor animal enclosures (uses #4):

- Considering the disinfection procedures of concrete floors inside animal accommodations, the Applicant has provided robust efficacy tests showing that the product ***SANIBLANC QM*** using at 1300 g/m^2 with pre- and post-humidation with water at 0.5 L/m^2 is bactericidal, fungicidal/yeasticidal and virucidal in preferably 24h to 48h on non-porous floors inside animal accommodations, without prior cleaning (even if cleaning by brushing the floors before the desinfection procedure is highly recommended).
About the disinfection of the inside floors of animal transportation vehicles, we think that the product ***SANIBLANC QM*** is effective under the use conditions described above.
However, the 24-48h Contact Time is not in line with the recommendations mentioned in the ECHA EFF guidance (i.e. 5 min CT). Knowing that, considering that the very specific mode of action of the product that requires an 24h-activation, we tend to grant this use on inside floors of animal transportation vehicles.

The disinfection procedure should be performed only without the presence of animals (i.e. between two productions, prophylactic quarantine…). Monitoring of the temperature > +55°C and of the pH > 12 should be put in place in order to achive the good activation of the product.

- Based on the supporting document "O20170_1" (only available in French), in order to comprehend whether or not there is a difference of disinfection level between non-porous and porous surfaces, it's clearly mentioned on p. 5 that "*En revanche, la désinfection du sol en terre battue par pulvérisation de désinfectant (parquet 4) donne de moins bons résultats, avec un pourcentage de réduction de la FAT inférieur à 99%, et une population de streptocoques fécaux résiduelle encore importante (5.1 02 colonies/cm2 de sol). Cette technique n'est donc pas à recommande*r ».
As the conclusion, even if the results of this study are preliminary results, we can't ignore them and as a precautionary option, the use on mud floors should be rejected.
Since cheaper that concrete, floors of poultry housing are usually made of beaten earth. As already well-known, non-porous surfaces are usually easier to disinfect that porous surfaces.
Considering this dossier, the Applicant has only submitted efficacy trials performed on non-porous surfaces.
This study has been performed in 2000 at AFSSA Ploufragan (France) in poultry houses with floors made of beaten earth or of concrete after removal of litter/manure and cleaning. The disinfection procedure has been performed using 500g CaO/m^2 with efficacy assessment about total aerobic flora, Gram-negative aerobic bacteria, faecal streptococci (major indicator of a good disinfection procedure in breeding houses), thermotolerant coliforms and Sulfite-Reducing anaerobes (seen as very resistant microorganisms in the environment).
The results from this preliminary study clearly showed that a Log 4 reduction is achieved on concrete-made floors and only a Log 2 reduction is achieved on beaten earth-made floors, with the conclusion that the use of floors of poultry housing made of beaten earth would not be recommended to achieve a good disinfection.

The use #3 "*Disinfection of indoor floor surfaces of animal accomodations– on mud floors*" is rejected.

- About the use #4, since we have no precise information about the type of floors to be considered for outdoor animal enclosures and since it seems that a majority of the floors outdoor animal enclosures are made of soil i.e. porous surface, the use #4 should be rejected, based on the remarks expressed above.

Conclusion on the efficacy of the product

Considering all the data provided by the Applicant, efficacy of the product is proved enough for disinfection procedures of sewage sludges (use #1) and non-porous floors inside animal accommodations & animal transportation vehicles.

Disinfection of sewage sludges :
The relevant efficacy tests provided by the Applicant showed that the product ***SANIBLANC QM*** mixed at application rates from 0.26 to 2.6 kg of CaO.MgO/kg dry sludge is effective to control all the target organisms i.e. Bacteria, yeasts, fungi, viruses and nematode eggs.
The efficacy of the product is mainly due to the high temperature above +60°C, the increase of the pH above 12 and a relevant contact time from 1 to 24h (but up to 4-8 weeks for eggs of *Ascaris suum)*.

Disinfection procedures of non-porous floors inside animal accommodations & animal transportation vehicles :
The relevant efficacy tests provided by the Applicant showed that the product ***SANIBLANC QM*** used at 1300 g/m^2 with pre- and post-humidation with water at 0.5 L/m^2 is bactericidal, fungicidal/yeasticidal and virucidal in minimum 24h (preferably 48h) on non-porous floors inside animal accommodations/animal transportation vehicles, without prior cleaning (even if cleaning by brushing the floors before the desinfection procedure is highly recommended).
The disinfection procedure should be performed only without the presence of animals (i.e. between two productions, prophylactic quarantine…).
Monitoring of the temperature > +55°C and of the pH > 12 should be mandatorily put in place in order to achieve the good activation of the product.

2.2.5.4 Occurrence of resistance and resistance management

Development of resistance of pathogens against dolime treatment has not been observed. For all lime and dolime 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 dolime has been reported.'

Given the non-specific mode of action, the development of resistance to dolime is unlikely to occur.

2.2.5.5 Known limitations

There are no known limitations for the biocidal products.

2.2.5.6 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 products are the same as the active substance. The products have therefore been assessed for human health effects in the evaluation for inclusion of the active substances in the Union List. The summary of the human health effects is copied from the CAR for $Ca(OH)_2$;

Calcium magnesium oxide on contact with water undergoes hydrolysis to form calcium dihydroxide [$Ca(OH)_2$], magnesium oxide [MgO] and magnesium hydroxide [$Mg(OH)_2$]. Calcium hydroxide is an odourless solid, which is highly soluble in water. It is also a strong base; the pH of a saturated calcium hydroxide solution is 12.4. When dissolved in water as occurs on the external surfaces of the body, hydrated lime dissociates into Ca^{2+} and OH^-. As for magnesium oxide and magnesium hydroxide, both are slightly soluble in water but may dissociate into Mg^{2+} and OH^-. The dissociation products Ca^{2+}, Mg^{2+} and OH^- are chemically and biologically not further degradable because they constitute simple basic structures. Therefore, the toxicological properties (local and systemic effects) of dolime are equivalent to those of its dissociation products.

Ca^{2+} is an essential element of the body, which does not possess irritant properties at the initial site of contact. Following absorption into the body, potential adverse systemic effects (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) are only expected when the homeostatic mechanisms, which regulate the levels of calcium in the body, are overwhelmed. The Scientific Committee on Food (SCF) has set an oral Tolerable Upper Intake Level (UL) for calcium of 2500 mg d^{-1} (SCF, 2003; http://ec.europa.eu/food/fs/sc/scf/out194_en.pdf). The UL is defined as the highest level of total (from all sources) chronic daily intake of a nutrient judged unlikely to pose a risk of adverse health effects to humans. It applies to all groups of the general population, including sensitive individuals, throughout the life stage. Therefore, provided exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the UL of 2500 mg d^{-1} (42 mg/kg bw/day for a 60 kg human), adverse effects from excess calcium would not be expected. The UL for calcium applies to adults, including pregnant and lactating women, but not to children.

OH^- is also a natural element of the body produced in situ from water. When released on the external surfaces of the body, because of its alkaline properties, it will exert irritant activity at all the initial sites of contact, with the possible exception of the stomach (following oral uptake) where it is neutralised by the acidic environment. Following absorption into the systemic circulation, it will be neutralised by the tightly controlled pH regulation mechanisms of the body (buffer capacity of extracellular body fluids, respiratory and renal compensation). Although metabolic alkalosis can occur from an excess of OH^- in the body, this will be expected only at very high concentrations of OH^- in the body capable of overwhelming the homeostatic mechanisms, which regulate the blood pH. High concentrations of OH^- in the body are not expected to occur at sub-irritant exposure levels of hydrated lime, as, at these low exposure levels, systemic absorption of OH^- will be limited by the integrity of the body surfaces. Therefore, potential systemic effects of the hydroxide ion (e.g. metabolic alkalosis) are not expected to occur to any significant extent and certainly not until above exposure levels causing irritation. Consequently, the only effects of the hydroxide ion driving the risk characterisation will be the local effects at the initial site of contact.

It should be noted that due to the irritant properties of hydrated lime ($Ca(OH)_2$), the risk characterisation for systemic effects, if any, will differ (e.g. absorption values and conclusions/predictions on some endpoints) depending on whether exposure levels occur below or above the irritation threshold(s) of hydrated lime ($Ca(OH)_2$). Whilst the available

data (see subsequent sections) allow the identification of an irritation threshold of around 1 mg m^{-3} for the inhalation route, there is insufficient evidence for the identification of irritation thresholds for the dermal and oral routes of exposure. For these routes, as risks for local effects cannot be assessed, the implementation of appropriate risk mitigation measures should ensure that exposure is prevented.

Critical endpoints

The lead health effects of dolime (CaO.MgO) are the systemic repeated dose effects caused by excess calcium and the local irritative effects on the external surfaces of the body (skin, eye and respiratory tract) caused by the hydroxide ion.

With regard to systemic effects, the systemic UL value for calcium (42 mg kg^{-1} day^{-1}) will be compared with the calcium internal body burdens arising from dermal and inhalation exposures to dolime. It is important to ensure that the calcium body burden arising from exposure to dolime contributes minimally to the overall calcium UL, as a significant part of the UL depends on other sources of exposure to calcium, mainly through the diet. According to the SCF (2003) Opinion, the calcium UL applies to adults, including pregnant and lactating women, but not to children.

Systemic, short- medium and long-term calcium UL = 42 mg kg^{-1} day^{-1}

With regard to local irritative effects, no threshold/NOAEC/AEC has been identified for the occurrence of such effects on the skin and eye. Therefore, for these routes of exposure, as risks cannot be assessed, exposure needs to be prevented by the implementation of risk mitigation measures. For the inhalation route of exposure, the external hydrated lime ($Ca(OH)_2$) exposure concentrations will be compared with the relevant AEC value. The toxicological studies described in the master dossier for hydrated lime are also relevant for the assessment of the other Lime types. In the hydrated lime evaluation an AEC value for inhalation of 0.3 mg m^{-3} was proposed and derived by dividing the NOAEC of 1 mg m^{-3} by an overall AF of 3.2 (default for dynamic intraspecies differences).
However, based on the adopted Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for Calcium oxide (CaO) and Calcium hydroxide ($Ca(OH)_2$) the European Commission has established an IOELV of 1 mg/m^3 respirable fraction (8h-TWA) for both calcium dihydroxide and calcium oxide. (Commission Directive (EU) 2017/164 of 31 January 2017). This is considered to be protective against adverse effects in case of long-term exposure to calcium dihydroxide and calcium oxide. The IOELV takes precedence over calculated or National limits. The IOELV will be applied for all non-biocidal uses which may also occur in the same facilities. The AEL prescribed in the CAR is therefore precautionary in comparison with the IOELV in place for all other uses.

Inhalation, short- medium- and long-term AEC = 0.3 mg m^{-3}

In accordance with BPR Guidance on the BPR, Vol III Human Health – Assessment and Evaluation (Parts B+C) v 2.1 February 2017, the biocidal products are classified in respect to local effects. The products will not be used at concentrations below which the classification for local effects is not appropriate, therefore systemic exposure is secondary to the local effects. The risk assessment will be qualitative in respect to the dermal exposure as no threshold concentration level has been determined for the dermal hazard and semi-quanitative with respect to inhalation.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Data waiving	
Information requirement	Skin irritation
Justification	No new data on skin irritation/corrosion is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. The available data indicate that CaO.MgO, causes significant skin irritation and that classification with Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is appropriate. Although severe and irreversible scabbing was observed in animals, this is insufficient for corrosivity classification. In addition, in the human cases of alkali burns, the level of skin damage was consistent with irritation rather than corrosion. These findings, however, together with the strong alkaline properties of CaO.MgO should be taken into account in the risk assessment

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	No new data on eye irritation is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. The available data indicate that CaO.MgO is severely irritating to the eye and that classification with Eye Dam.1 H318 is appropriate.

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No new data on irrition in the respiratory tract is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no specific investigation of the ability of CaO.MgO to cause irritation to the respiratory tract in animals. However, two studies in humans involving exposures to $Ca(OH)_2$ or CaO have shown that $Ca(OH)_2$ causes sensory irritation of the nose, eye and throat. Effects considered adverse have been reported starting from a concentration of 2 mg m^{-3} for 20 min, and a NOAEC of 1 mg m^{-3} for a 20-min exposure has been identified. There is no information on the respiratory effects of $Ca(OH)_2$ at exposure concentrations higher than 5 mg m^{-3}; however, based on its severe skin and eye irritant properties and its strong alkaline properties, it is most likely that frank tissue damage would occur at higher concentrations. By read-across,

	these data indicate that classification of CaO.MgO with STOT SE 3 H335 (in accordance with Regulation EC/1272/2008) is appropriate.

Skin sensitization

Data waiving	
Information requirement	Skin sensitisation
Justification	There are no studies, which have specifically investigated the skin sensitisation potential of CaO.MgO. The UK CA agree at active substance evaluation that the irritant properties of the substance prevent a meaningful assessment of its skin sensitising properties at irritant concentrations; however, there remains an uncertainty as to whether at non-irritant concentrations CaO.MgO may possess skin sensitisation potential. Although non-irritant concentrations of CaO.MgO result in physiological concentrations of Ca^{2+}, Mg^{2+} and OH^-, the activity of CaO.MgO at these physiological concentrations on the skin surface (i.e. outside the body) may differ from that inside the body where sophisticated buffer/homeostatic mechanisms or binding processes operate. Therefore, the UK CA disagreed that since Ca^{2+}, Mg^{2+} and OH^- are abundant essential elements of the body, they do not possess skin sensitising potential outside the body. There are no reports of cases of skin sensitisation from workers exposed to CaO.MgO. Overall, it is unclear whether CaO.MgO at non-irritant concentrations may possess skin sensitisation potential. However, given the lack of reports of cases of skin sensitisation from workers exposed to CaO.MgO, and as the recommended risk mitigation measures resulting from failure to identify a threshold for the irritant properties of the substance will prevent skin exposure, testing for skin sensitisation is unnecessary.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Respiratory sensitisation
Justification	No new data on respiratory sensitisation is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. In worker health surveys and epidemiological studies of workers exposed to CaO.MgO there has been no mention of effects related to respiratory sensitisation. No classification is proposed.

Acute toxicity

Data waiving	
Information requirement	Acute toxicity - oral
Justification	No new data on acute toxicity is presented. The products are the same

	as the active substance, therefore data on the active substance is applicable for the products. In a recent oral gavage study in the rat conducted according to current guidelines and GLP the LD_{50} value was greater than the limit dose of 2000 mg kg^{-1} (Arcelin, 2007). No significant systemic effects were observed up to an oral dose of 2000 mg kg^{-1} . Classification for acute toxicity by the oral route is not required.

Acute toxicity by inhalation

Data waiving	
Information requirement	Acute toxicity - inhalation
Justification	No new data on acute toxicity is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There are no data on which to base classification of CaO.MgO for acute toxicity by the inhalation route. A study in human volunteers investigating only the local effects of CaO.MgO on the respiratory tract showed that sensory irritation of the nose and throat occurred at 2 and 5 mg m^{-3} CaO for 20 min, but not at 1 mg m^{-3} for 20 min. Classification for acute toxicity by the inhalation route is not required.

Acute toxicity by dermal route

Data waiving	
Information requirement	Acute toxicity - dermal
Justification	No new data on acute toxicity is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. $Ca(OH)_2$ was applied for 24 hours as supplied at the limit dose of 2500 mg kg^{-1} under semi-occlusive conditions (Kietzmann, 1994). In this study, the LD_{50} value was greater than 2500 mg kg^{-1} No significant systemic effects were observed up to a dermal dose of 2500 mg kg^{-1} . By read-across, classification for acute toxicity by the dermal route is not required.

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption
Justification	No new data on acute toxicity is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. An in vitro dermal penetration study with CaO.MgO has not been conducted, as at irritant concentrations it cannot be performed without affecting skin integrity and at non-irritant concentrations it would be irrelevant to the in vivo situation as the application of non-irritant concentrations of CaO.MgO (on the basis of pH considerations presented) would result in Ca^{2+} concentrations (around 0.05 mmol/L = 2 mg/L) which are lower than the physiological Ca^{2+} blood levels (around 2.5 mmol/L = 100 mg/L) and therefore it is not considered to contribute to the assessment of the dermal absorption CaO.MgO in any significant way. For the purposes of risk characterisation, a dermal absorption value of 100 % of the applied dose of calcium is a reasonable worst-case assumption at irritant concentrations of CaO.MgO. At non-irritant concentrations of CaO.MgO, the default value of 10 % (TGD, 2003) is selected due to the ionic nature of its dissociation products and the well-known barrier functions of the skin. However, as explained above, there is insufficient evidence for the identification of the irritation threshold for the dermal route of exposure. Therefore, as local risks for this route cannot be assessed, the implementation of appropriate risk mitigation measures should ensure that dermal exposure is prevented. However, for the purpose of the systemic risk assessment, a value of 100 % dermal absorption will be used as a worst-case assumption regardless of the exposure concentration.

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

Not applicable, the products are the same as the active substance, therefore data on the active substance is applicable for the products. The active substances, including impurities, have been evaluated for toxicity, therefore there are no additional non-active substances of concern that need to be additionally addressed.

Available toxicological data relating to a mixture

Not applicable, The products are the same as the active substance, therefore data on the active substance is applicable for the products. The active substances, including impurities, have been evaluated for toxicity, there fore there are no additional non-active substances of concern that need to be additionally addressed.

Endocrine Disruption (ED)

Based on the available data on the active substance, there are no indications to suggest that it fulfils any of the criteria to be identified as an ED as described in the guidance on endocrine disruption:

a) It shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

The summary from the CAR for the assessed lime equivalents including calcium magnesium oxide and calcium dihydroxide, specifies;
Overall, the lead health effects of hydrated lime are the systemic repeated dose effects caused by excess calcium (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) in the body and the local irritative effects on the external surfaces of the body (skin, eye, respiratory tract and gastrointestinal tract) caused by the hydroxide ion.

2.2.6.2 It is therefore concluded on the basis of the available information that there is no concern for endocrine disruption.Exposure assessment

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Loading	Primary Manual opening of bags	Professionals
2.	Loading	Primary Tipping of bags into hoppers	Professionals
3.	Mixing/loading	Primary Manual application of product to sewage sludges	Professionals
4.	Mixing/loading	Primary Semi-automated application of product to sewage sludges	Professionals
5.	Mixing/loading	Primary Automated application of product sewage sludges	Professionals
6.	Mixing/loading	Primary Automated application of product to manures	Professionals
7.	Application	Primary Manual spreading of dry product, using a spade/shovel, onto floors, indoors	Professionals
8.	Application	Primary Manual spreading of dry product, using a spade/shovel, onto floors, outdoors	Professionals
9.	Application	Primary Automated spreading of dry product, using a towed spreader, onto floors, indoors	Professionals
10.	Application	Primary Automated spreading of dry product, using a towed spreader, onto floors, outdoors	Professionals
11.	Cleaning and maintenance	Primary Manual cleaning of mixing or spreading equipment.	Professionals
12.	Disposal	Primary Disposal of empty bags	Professionals
13.	Disposal	Primary Manual disposal, using spade/shovel etc, of used product to waste.	Professionals
14.	Disposal	Primary Automated disposal, using tractor etc, of used product to waste.	Professionals
15.	Indirect	Secondary Bystander exposure to products being used in animal accommodations.	Non-professionals General public

Industrial exposure

There are no industrial use scenarios for this product.

Professional exposure

Scenario [1]: Loading – Manual opening of bags

Description of Scenario [1]		
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). The worker cuts open the bag (25 – 50 kg) with a knife. The bag may be on the floor or by the hopper opening. Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product	50 kg (2x25 kg bags)
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	3 x day
	Duration[4]	1 min/bag
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[6]	10 mg/m³
	Hand surface area[5]	820 cm²
Tier 2	Inhalation exposure[3]	1.1 mg/m³
	Dermal exposure – Hand only, inside glove[7]	3.05 mg/min
	Natural Ventilation[5]	30% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)

[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)

[3.] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

[4.] ECHA Recom6_methods_models 2016 No. 10

[5.] Biocides Human Health Exposure Methodology v 1 2015

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

[7.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.

Calculations for Scenario 1

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 1 min/bag x 2 bags x 3 times/day = 1830 mg/day external dose

Internal dose = 1830 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 10.83 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 1 min/bag x 2 bags x 3 times/day = 18.3 mg/day external dose

Internal dose = 18.3 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.11 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 10 x 1.25 m^3/hour x (1 min/bag x 2 bags x 3 times/day)/60 min/hour x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.015 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.1 mg/m^3 x 0.7= 0.77 mg/m^3

Systemic exposure to Ca

Internal dose = 0.77 x 1.25 m^3/hour x (1 min/bag x 2 bags x 3 times/day)/60 min/hour x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.001 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m^3 x 0.1 x 0.7 = 0.077 mg/m^3

Systemic exposure to Ca

Internal dose = 0.077 x 1.25 m^3/hour x (1 min/bag x 2 bags x 3 times/day)/60 min/hour x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0001 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [2]: Loading – Tipping of bags into hoppers

Description of Scenario [2]		
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). To empty the bags the operator opened the hatch and placed the bag on top. The operator then cut open the upper part of the bag. The hatch was then closed (the product then disperses in the hopper). The hatch was reopened, and the empty bag removed and shaken to empty out the remaining product. The empty bag was thrown to the ground. The operation was repeated until the silo is full or until the required quantity of product had been added. Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product	2 x 25 kg bag/min
	Total number of bags/day (average)[6]	60
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	3 x day
	Duration[4]	10 mins
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m³
	Hand surface area[5]	820 cm²
Tier 2	Inhalation exposure[6]	1.07 mg/m³
	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Local Exhaust Ventilation[5]	80% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10
	Inhalation exposure[7]	1.1 mg/m³

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)

[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)

[3.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.

[4.] ECHA Recom6_methods_models 2016 No. 10

[5.] Biocides Human Health Exposure Methodology v 1 2015

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

[7] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

Calculations for Scenario 2

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 10 min x 3 times/day = 9150 mg/day external dose

Internal dose = 9150 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 54.14 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 10 min x 3 times/day = 91.5 mg/day external dose

Internal dose = 91.5 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.541 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 7.2 x 1.25 m^3/hour x (10 min x 3 times/day)/60 (mins/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.053 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m^3 x 0.2= 0.214 mg/m^3

Systemic exposure to Ca

Internal dose = 0.214 x 1.25 m^3/hour x (10 min x 3 times/day)/60 (mins/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0016 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m^3 x 0.1= 0.11 mg/m^3

Systemic exposure to Ca

Internal dose = 0.11 x 1.25 m³/hour x (10 min x 3 times/day)/60 (mins/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0008 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [3]: Mixing and loading – Manual application of product to sewage sludge

Description of Scenario [3]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). A quantity of product equivalent to 20-50 % of the dry solids weight of the sludge is added to the sludge or manure. The product can be provided in 25-50 kg bags that operators manually feed into mobile treatment machines. The operation is conducted outdoors and the bag is opened and then dispensed automatically. 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 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 Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product (Average)	Total: 1500 kg/day 2 x 25 kg bag/min
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	3 x day
	Duration[4]	10 mins
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m³
	Hand surface area[5]	820 cm²

	Natural ventilation[5]	30% protection
Tier 2[2]	Dermal exposure – Hand only, inside glove	3.05 mg/min
	Inhalation exposure[6]	1.07 mg/m³
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10
	Inhalation exposure[7]	1.1 mg/m³

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.

[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014
[7] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

Calculations for Scenario 3

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 10 min x 3 times/day = 9150 mg/day external dose

Internal dose = 9150 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 54.14 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 10 min x 3 times/day = 91.5 mg/day external dose

Internal dose = 91.5 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.541 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 7.2 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.053 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.7 = 0.749 mg/m³

Systemic exposure to Ca

Internal dose = 0.749 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0055 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m³ x 0.1= 0.11 mg/m³

Systemic exposure to Ca

Internal dose = 0.11 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0008 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [4]: Mixing and loading – Semi-automated application of product to sewage sludge

Description of Scenario [4]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). A product quantity equivalent to 20-50 % of the dry solids weight of the sludge is added to the sludge or manure. The product can be supplied in bulk bags, containing typically a half or one tonne. In such cases the product is handled using mechanical equipment, e.g. forklifts or telehanders (sometimes referred to as telehoists or teleporters). This is referred to as a semi-automated process, although the scenario has some manual or non-automatic elements. It is common practice to lift the large bags, using the telehandler, onto a hopper that then automatically cuts the bottom of the bag or to employ a big bag discharging device. Workers using telehandlers are enclosed in the cab of the vehicle and are therefore not directly exposed to any dust emissions. However, forklifts that are also reported to be used do not offer the same degree of separation. When the product is supplied in such bags, it has been reported that a more granular product is used to minimise the risk of occurrence of dust, although attrition of the granules during storage and transport in such bags will generate dust and as can be seen from the table below it is still shown that up to 40 % of the product is <0.09 mm and therefore far from dust free. **Table 3.4 The EuLA statement of typical quicklime (CaO) grading for large bags:**

Sieve (Particle) Size (mm)	Passing (%)
7	100
4	99
0.09	40

Lhoist grading for CaO.MgO

Sieve (Particle) Size (mm)	Passing (%)
3.15	98
0.09	28

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.

Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product (Average)	Total: 1500 kg/day
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	3 x day
	Duration[4]	10 mins/task
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m³
	Hand surface area[5]	820 cm²
	Natural ventilation[5]	30% protection
Tier 2	Inhalation exposure[6]	1.07 mg/m³
	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10
	Inhalation exposure[7]	1.1 mg/m³

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)

[3.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.

[4.] ECHA Recom6_methods_models 2016 No. 10

[5.] Biocides Human Health Exposure Methodology v 1 2015

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

[7] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

Calculations for Scenario 4

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 10 min x 3 times/day = 9150 mg/day external dose

Internal dose = 9150 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 54.14 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 10 min x 3 times/day = 91.5 mg/day external dose

Internal dose = 91.5 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.541 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 7.2 x 1.25 m^3/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.053 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m^3 x 0.7 = 0.749 mg/m^3

Systemic exposure to Ca

Internal dose = 0.749 x 1.25 m^3/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0055 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m³ x 0.1= 0.11 mg/m³

Systemic exposure to Ca

Internal dose = 0.11 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0008 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [5]: Mixing and loading – Automated application of product to sewage sludge

Description of Scenario [5]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indiacted for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). A product quantity equivalent to 20-50 % of the dry solids weight of the sludge is added to the sludge or manure. The products are often supplied as a biocide for stabilisation of manure delivered in bulk powder tankers through automated equipment. Handling of the product under these conditions involves the closed transfer of the product, via a pneumatic pipe connected to the tankers, to the silo. Such silos are reported to be closed systems, and are fitted with filters to prevent dust emission during the pneumatic loading. The speed of transfer to the silo is around 50 tons/hour. 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. Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product (AS) (Average)	Total: 1500 kg/day
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	3 x day
	Duration[4]	10 mins/task

	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m³
	Hand surface area[5]	820 cm²
	Natural ventilation[5]	30% protection
Tier 2	Inhalation exposure[6]	1.07 mg/m³
	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Local Exhaust Ventilation and containment[5]	85% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10
	Inhalation exposure[7]	1.1 mg/m³

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014
[7] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

Calculations for Scenario 5

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 10 min x 3 times/day = 9150 mg/day external dose

Internal dose = 9150 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 54.14 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 10 min x 3 times/day = 91.5 mg/day external dose

Internal dose = 91.5 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.541 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 7.2 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.053 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.15 = 0.1605 mg/m³

Systemic exposure to Ca

Internal dose = 0.1605 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0011 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m³ x 0.1= 0.11 mg/m³

Systemic exposure to Ca

Internal dose = 0.11 x 1.25 m³/hour x (10 min x 3 (times/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0008 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [6]: Mixing and loading – Automated application of product to manures

Description of Scenario [6]
The transfer from the silo to the mixing unit is done through a screw conveyor with a speed between 0.1 and 100 kg/min. The height of the material drop is less than 0.5m. The mixing unit is closed equipment with some access but does not open during the process. 10-40 kg hydrated lime per m³ manure or 25-100 L milk of dolime (40 %) per m³ liquid manure. The product can be applied either before or after dewatering the sludge. In the first case, the product is transferred to the closed agitated conditioning tank through a screw conveyor (closed system), which contains liquid sludge. The liquid sludge-product mixture will be moved in the dewatering tool (wet process). In the second case the product is transferred to a pre-mixer, where the pasty sludge (dewatered) is also added. The sludge-product mixture is then moved to the closed mixing unit (closed system). The system is fully automated and people do not stay always near the equipment or in a 4m area around the mixing equipment.

The product is mixed with the sludge cake at rates of approximately 5–8 % per wet tonne of sludge cake. "Dolime" stabilisation equipment is designed to provide a good mix of product and sludge cake to ensure pathogen destruction, whilst minimising the amount of lime required, leaving no free product dust in the sludge when discharged. Sludge cake is typically 20–30 % dry solids. Therefore, the product particles– typically less than 3mm in size – binds with the sludge and as the exothermic reaction between the dolime (CaO.MgO) and moisture bearing sludge takes place, a stabilised sludge product is produced.

When the product has been mixed with the sludge, the potential for dust emission is reported to be significantly reduced as it is a wet process. The treated product leaves the mixer and is conveyed to the stockpile via a belt conveyor. As the volume of treated product increases under the conveyor the mechanical shovel will be used to push up the stockpile as necessary.

The process is almost exclusively an outdoor activity with the exception of some sites where equipment is housed undercover in open sided agricultural type buildings. The cleaning of equipment (dry process) is done very carefully to reduce dust in suspension. It is reported that vacuum cleaner or exhaust ventilation is used during the cleaning process.

It is reported that various size fractions ranging between a few millimetres up to one or two centimetres are available from suppliers, which users can select, depending on their equipment.

Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

The EuLA statement of typical quicklime (CaO) grading for automated handling

Sieve (Particle) Size (mm)	Passing (%)
12.5	100.00
10	99.98
5	90.6
1	3.4
0.25	1.6

Lhoist grading for CaO.MgO

Sieve (Particle) Size (mm)	Passing (%)
3.15	98
1	69
0.25	44

	Parameters	Value

Tier 1	Body weight[1]	60 kg
	Amount of product (Average)	Total: 1500 kg/day
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	1 x day
	Duration[4]	10 mins/task
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m³
	Hand surface area[5]	820 cm²
Tier 2	Inhalation exposure[6]	1.07 mg/m³
	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Natural ventilation[5]	30% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10
	Inhalation exposure[7]	1.1 mg/m³

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014
[7] MEASE v 1.02.01, EBRC. (ECHA Guidance Human Health Risk Assessment Vol III; Biocides Human Health Exposure Methodology Section 6.3.8 p239)

Calculations for Scenario 6

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 10 min x 1 time/day = 3050 mg/day external dose

Internal dose = 3050 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 18.05 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca

3.05 mg/min x 10 min x 1 time/day = 30.5 mg/day external dose

Internal dose = 91.5 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.181 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca

Internal dose = 7.2 x 1.25 m³/hour x (10 min x 1 (time/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.018 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.7 = 0.749 mg/m³

Systemic exposure to Ca

Internal dose = 0.749 x 1.25 m³/hour x (10 min x 1 (time/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0018 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.1 mg/m³ x 0.1= 0.11 mg/m³

Systemic exposure to Ca

Internal dose = 0.11 x 1.25 m³/hour x (10 min x 1 (time/day)/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0003 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [7]: Application – Manual spreading of dry product - indoors

Description of Scenario [7]
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium oxide). The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into wheelbarrows or onto floors. The product will then be spread using a spade or shovel over the area to be treated. The floors will be damp after cleaning between each use. Accomodations will be cleaned after every change of stock; after animals are sent for slaughter, when the animals are moved out during summer, after the breeding period is completed. Matting or other floor coverings that retain moisture may be present. Manual spreading will take place in smaller animal houses (henhouses, stables,

lambing/calving sheds) and in transportation.
Natural ventilation.
Workers will wear coveralls, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

No model describing the application of powders by shovel/hand is available, therefore, read across from the dust formation model while pouring powders has been used as a worst case. (van Hemmen, 1992)

For Tier 2, the average inhalation exposure concentration from the Operator Exposure measurement study has been used as an indication of potential dust exposure during this task.

Default values for floor area of accomodation are taken from the PT 3 ESD, 2011 Appendices.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate	500 g/m²
	Floor area[7]	160 m²
	Inhalation rate[2]	1.25 m³/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – Hand only[6]	305 mg/min
	Inhalation exposure[3]	12 mg/m³
	Hand surface area[5]	820 cm²
Tier 2[2]	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Natural ventilation[5]	30% protection
	Inhalation exposure[8]	1.07 mg/m³
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] van Hemmen (1992) Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85. Indicative value for mixing and loading of solid pesticides (wettable powders). The indicative 90th percentile of the inhalation exposure is 15 mg formulation per hour, which is considered applicable for about 25 kg active substance applied per day.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping

[7] PT 3 ESD, 2012 Annexes: Default values for accomodation and transport areas. Veal calves

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

Calculations for Scenario 7

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 60 min x 1 time/day = 18300 mg/day external dose

Internal dose = 18300 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 108.28 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca:

3.05 mg/min x 60 min x 1 time/day = 183 mg/day external dose

Internal dose = 183 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 1.08 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 12 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.178 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.7 = 0.749 mg/m³

Systemic exposure to Ca:

Internal dose = 0.749 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.011 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.7 x 0.1 = 0.0749 mg/m³

Systemic exposure to Ca

Internal dose = 0.0749 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca) ÷ 60 (kg bw) = 0.001 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** Using % Ca in CaO

Scenario [8]: Application – Manual spreading of dry product - outdoors

Description of Scenario [8]		
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into wheelbarrows or onto floors. The product will then be spread using a spade or shovel over the area to be treated. The floors may be damp due to weathering Manual spreading will take place in smaller poultry pens Natural ventilation. Workers will wear coveralls, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure. No model describing the application of powders by shovel/hand is available, therefore, read across from the dust formation model while pouring powders has been used as a worst case. (van Hemmen, 1992) For Tier 2, the average inhalation exposure concentration from the Operator Exposure measurement study has been used as an indication of potential dust exposure during this task. There is no information on the size of area outside required per bird. As a worse case, the parameters for floor space inside accomodation will be considered equivalent to the outdoor space required for free-range birds (See Annex 3.2 for values)		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate[8]	224.4 g/m²
	Application area[9]	1430 m²
	Inhalation rate[2]	1.25 m³/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – Hand only[6]	305 mg/min
	Inhalation exposure[3]	12 mg/m³

	Hand surface area[5]	820 cm²
	Natural ventilation – outdoor away from buildings[7]	75%
Tier 2	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Inhalation exposure[10]	1.07 mg/m³
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] van Hemmen (1992) Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85. Indicative value for mixing and loading of solid pesticides (wettable powders). The indicative 90th percentile of the inhalation exposure is 15 mg formulation per hour, which is considered applicable for about 25 kg active substance applied per day.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] HEEG Opinion 1: Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale (TMI 2008) Mixing and loading Model 7; solid (powder) loading and dumping.
[7] Advanced REACH Tool, reduction factor for exposure to product used outdoors, away from buildings. Fransman W et al. Development of a mechanistic model for the Advanced REACH Tool (ART) Version 1.5 TNO Report V9009 18 January 2013. p164.
[8] Maximum application rates to soil from agricultural use: 1700 kg CaO/ha or 2244 kg $Ca(OH)_2$/ha
[9 7] PT 3 ESD, 2012 Annexes: Default values for accomodation and transport areas. Laying hens free range with litter floor.
[10.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014

Calculations for Scenario 8

Tier 1 dermal exposure:

Systemic exposure to Ca

305 mg/min x 60 min x 1 time/day = 18300 mg/day external dose

Internal dose = 18300 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 108.28 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca:

3.05 mg/min x 60 min x 1 time/day = 183 mg/day external dose

Internal dose = 183 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 1.083 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 12 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.178 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.25 = 0.2675 mg/m³

Systemic exposure to Ca:

Internal dose = 0.2675 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.004 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** Using % Ca in CaO

Scenario [9]: Application – Automated spreading of dry product - indoors

Description of Scenario [9]
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into the hopper of a towed spreader (Scenario 2). The spreader will be towed behind a small tractor or quad bike. The floors will be damp after cleaning between each use. Accomodations will be cleaned after every change of stock; after animals are sent for slaughter, when the animals are moved out during summer, after the breeding period is completed. Matting or other floor coverings that retain moisture may be present. Automated spreading will take place in large animal houses and sheds. Natural ventilation or Local Exhaust Ventilation in enclosed pultry sheds. Workers will wear coveralls, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure. Application rates and default values for floor areas of accomodation to ber treated are derived from PT 3 ESD, 2011 Appendices. (See Appendix 3.2). The only models available for determination of exposure from spreading of powders in agricultural areas are for use of plant protection products. The EUROPOEM model (v1.2) has ben used to determine exposure to the operator using the vehicle mounted/draw boom sprayer scenario. As the model assumes outdoor application, no further Protection Factor for ventilation is applied.

A workplace monitoring study for exposure during automated spreading for soil treatment has been performed (Teerlinck and Detry, 2010). The rates and area of application greatly exceed those that would be treated for the biocidal uses. However, the study shows that exposure concentrations for inhalation are below the IOELV.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate	500 g/m²
	Application area[6]	3390 m²
	Inhalation rate[2]	1.25 m³/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – hand only[3]	0.03 mg/min
	Dermal exposure – body[3]	0.00117 mg/min
	Inhalation exposure[3]	0.01 g/h 0.125 mg/m³
	Hand surface area[5]	820 cm²
	Natural ventilation [5]	30 % protection
Tier 2	Inhalation exposure[7]	<1.0 mg/m³
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] EUROPOEM operator exposure model v 1.2
[4.] Biocides Guidance Database; Human Exposure, worst case for ready to use products for spraying.
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] PT 3 ESD, 2012 Annexes: Default values for accomodation and transport areas. Turkeys, free range with litter floor
[7.] Teerlinck M and Detry D (2010) Workplace Dust Monitoring. Carmeuse Research & Technology, Bd de Lauzelle 65, B-1348 Louvain-La-Neuve Report No. 5RM/50/60280555/00/EN/001.

Calculations for Scenario 9

Tier 1 dermal exposure:

Systemic exposure to Ca:

Hand + Body:

0.03117 mg/min x 60 min x 1 time/day = 1.87 mg/day external dose

Internal dose = 1.87 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.011 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 0.125 x 1.25 m^3/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0018 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = <1.0 x 1.25 m^3/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = <0.015 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** Using % Ca in CaO

Scenario [10]: Application – Automated spreading of dry product - outdoors

Description of Scenario [10]
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into the hopper of a towed spreader (Scenario 2). The spreader will be towed behind a small tractor or quad bike. As the product is applied to outdoor enclosures, the wetness of the soil will vary according to weather conditions. Dampening of the soil prior to application is recommended to activate the properties of the substance. Weather conditions, namely wind will have an impact on the potential inhalation exposure, although the outdoor use and natural dispersion of any dust formed will limit exposure. Application rates and default values for floor areas of accomodation to ber treated are derived from PT 3 ESD, 2011 Appendices. (See Appendic 3.2). The only models available for determination of exposure from spreading of powders in agricultural areas are for use of plant protection products. The EUROPOEM model (v1.2) has ben used to determine exposure to the operator using the vehicle mounted/draw boom sprayer scenario. The calculation does not make a distinction between indoor and outdoor use. As the model assumes outdoor application, no further Protection Factor for ventilation is applied. A workplace monitoring study for exposure during automated spreading for soil treatment has been performed (Teerlinck and Detry, 2010). The rates and area of application greatly exceed those that would be treated for the biocidal uses. However, the study shows that exposure concentrations for inhalation are below the IOELV.

There is no information on the size of area outside required per bird. As a worse case, the parameters for floor space inside accomodation will be considered equivalent to the outdoor space required for free-range birds (See Annex 3.2 for values)		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate	500 g/m²
	Application area[6]	3390 m²
	Inhalation rate[2]	1.25 m³/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – hand only[3]	0.03 mg/min
	Dermal exposure – body[3]	0.00117 mg/min
	Inhalation exposure[3]	0.01 g/h 0.125 mg/m³
	Hand surface area[5]	820 cm²
	Natural ventilation – outdoor away from buildings[7]	75%
Tier 2[2]	Inhalation exposure[7]	<1.0 mg/m³
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] EUROPOEM operator exposure model v 1.2
[4.] Biocides Guidance Database; Human Exposure, worst case for ready to use products for spraying.
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] PT 3 ESD, 2012 Annexes: Default values for accomodation and transport areas. Turkeys, free range with litter floor.
[7] Advanced REACH Tool, reduction factor for exposure to product used outdoors, away from buildings. Fransman W et al. Development of a mechanistic model for the Advanced REACH Tool (ART) Version 1.5 TNO Report V9009 18 January 2013. p164.
[8.] Teerlinck M and Detry D (2010) Workplace Dust Monitoring. Carmeuse Research & Technology, Bd de Lauzelle 65, B-1348 Louvain-La-Neuve Report No. 5RM/50/60280555/00/EN/001.

Calculations for Scenario 10

Tier 1 dermal exposure:

Systemic exposure to Ca:

Hand + Body:

0.03117 mg/min x 60 min x 1 time/day = 1.87 mg/day external dose

Internal dose = 1.87 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.011 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 0.125 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0018 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = <1.0 x 1.25 m³/hour x 60 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = <0.015 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** Using % Ca in CaO

Scenario [11]: Cleaning and Maintenance – Manual cleaning of mixing or spreading equipment

Description of Scenario [11]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). Cleaning and maintenance are classed as occasional tasks. Maintaining the compound units and silo mechanisms in the state of operation by doing, at fixed times, visual inspections and repairs, as well as by removing occasional damage. Observations are performed daily. Checking the technical condition of equipment, blockage of electrical vibrators, lubricating lubrication points is performed every 3 months. Hopper cleaning with mechanical tool or pressure washer is performed 2 to 3 times a year. Disassembling and cleaning of equipment and mechanisms, verification of qualification of components for repair or replacement, repair or replacement of parts, assembly of mechanisms and operation test, painting, commissioning and putting into use, only takes place every 3 years. The following tasks were referenced in the exposure measurement study - Changing the skip for treated sludge or transfer to the handling gear for the latter to a storage area - Refilling tanks of the handling gear

- Scraping deposits (leaks/spillages) of sludge off the ground
The assessment in the CAR considered the following maintenance tasks:

Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

None of the available exposure models considers cleaning and maintenance of equipment as a separate measurement for inhalation exposure.

TNsG on Human health Assessment (2002); Dust and soil adhesion model 3 has dermal exposure measurements for a separate task of bag collection and crushing. The values is for dust on gloves only.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	Daily
	Duration[4]	10 mins
	Dermal exposure – hand[3]	228 mg/min
	Inhalation exposure[6]	1.07 mg/m³
	Hand surface area[5]	820 cm²
Tier 2	PPE – gloves[5]	90% Protection
	Local Exhaust Ventilation[5]	80% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] TNsG for Human Health Assessment (2002) Dust and soil adhesion Model 3, 75th Percentile.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014

Calculations for Scenario 11

Tier 1 dermal exposure:

Systemic exposure to Ca:

228 mg/min x 10 min x 1 time/day = 2280 mg/day external dose

Internal dose = 2280 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 13.49 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca:

22.8 mg/min x 10 min x 1 time/day = 228 mg/day external dose

Internal dose = 228 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 1.35 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 1.07 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0026 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.2 = 0.214 mg/m³

Systemic exposure to Ca:

Internal dose = 0.214 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0005 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.1 = 0.107 mg/m³

Systemic exposure to Ca:

Internal dose = 0.107 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0003 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [12]: Disposal – Disposal of empty bags

Description of Scenario [12]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicated for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements

The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide).

Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

None of the available exposure models considers disposal of bags as a separate measurement for inhalation exposure. But the task was included in the Operator Exposure measurement study.

TNsG on Human health Assessment (2002); Dust and soil adhesion model 3 has dermal exposure measurements for a separate task of bag collection and crushing. The values is for dust on gloves only.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Inhalation rate[2]	1.25 m³/hour
	Frequency[6]	Daily
	Duration[4]	10 mins
	Dermal exposure – hand[3]	228 mg/min
	Inhalation exposure[6]	1.07 mg/m³
	Hand surface area[5]	820 cm²
Tier 2	PPE – gloves[5]	90% Protection
	Local Exhaust Ventilation[5]	80% protection
Tier 3	RPE[5] – Filtering half masks (FFP3)	PF = 10

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)
[2] HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)
[3.] TNsG for Human Health Assessment (2002) Dust and soil adhesion Model 3, 75th Percentile.
[4.] ECHA Recom6_methods_models 2016 No. 10
[5.] Biocides Human Health Exposure Methodology v 1 2015
[6.] INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014

Calculations for Scenario 12

Tier 1 dermal exposure:

Systemic exposure to Ca:

228 mg/min x 10 min x 1 time/day = 2280 mg/day external dose

Internal dose = 2280 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 13.49 mg Ca/kg bw/day

Tier 2 dermal exposure:

Systemic exposure to Ca:

22.8 mg/min x 10 min x 1 time/day = 228 mg/day external dose

Internal dose = 228 x 0.5 (fraction absorbed*) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 1.35 mg Ca/kg bw/day

Tier 1 Inhalation exposure:

Systemic exposure to Ca:

Internal dose = 1.07 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.003 mg Ca/kg bw/day

Tier 2 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.2 = 0.214 mg/m³

Systemic exposure to Ca:

Internal dose = 0.214 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0005 mg Ca/kg bw/day

Tier 3 Inhalation exposure:

Local exposure:

1.07 mg/m³ x 0.1 = 0.107 mg/m³

Systemic exposure to Ca:

Internal dose = 0.107 x 1.25 m³/hour x 10 min/60 (min/hour) x 0.71 (fraction Ca**) ÷ 60 (kg bw) = 0.0003 mg Ca/kg bw/day

* BfR Proposal WGII2019_TOX_8-4a

** % Ca in CaO

Scenario [13]: Disposal – Manual disposal, using spade/shovel, to manure waste

Description of Scenario [13]
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide).

The product will be mixed in with used bedding and manure. Frequency of cleaning is dependent upon the accomodation/transportation usage. Due to the nature of the wastes dermal exposure will be negligible.

Exposure to dusts is unlikely as the product has reacted with moisture. According to the model EUROPOEM I, the exposure can be considered as negligible.
Inhalation exposure to residual product dust is considered to be negligible in comparison with exposure to dusts from bedding materials.

Manual disposal will mainly take place in transporation, smaller animal housing or cleaning out of pens.

Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection against inhalatory exposure.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Frequency	Daily
Tier 2	PPE – gloves[5]	90% Protection

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)

Calculations for Scenario 13

Lime-europoem-manual spreading.pdf

Scenario [14]: Disposal – Automated disposal, using tractor, to manure waste

Description of Scenario [14]
The in-use concentration of the product contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). The product will be mixed in with used bedding and manure. Frequency of cleaning is dependent upon the accomodation/transportation usage. Due to the nature of the wastes dermal exposure will be negligible. Exposure to dusts is unlikely as the product has reacted with moisture. According to the model EUROPOEM I, the exposure can be considered as negligible. Inhalation exposure to residual product dust is considered to be negligible in comparison with exposure to dusts from bedding materials. Automated disposal will mainly take place large animal housing. Workers will wear coverall, boots and gloves. The tier 2 step involves the use of gloves and protective clothing. In the tier 3, FFP3 masks are added for additional protection

against inhalatory exposure.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Frequency	Daily
Tier 2	PPE – gloves[5]	90% Protection

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)

Calculations for Scenario 14

Lime-europoem-automated spreading.pdf

In accordance with BPR Guidance on the BPR, Vol III Human Health – Assessment and Evaluation (Parts B+C) v 2.1 February 2017, the biocidal products are classified in respect to local effects. The products will not be used at concentrations below which the classification for local effects is not appropriate, therefore systemic exposure is secondary to the local effects. The risk assessment will be qualitative in respect to the dermal exposure as no threshold concentration level has been determined for the dermal hazard and semi-quanitative with respect to inhalation. Systemic exposure to calcium is assessed against the UL of 42 mg/kg bw/day, as described in the CAR.

Summary table: estimated systemic exposure to calcium from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 1	1 2 3	0.015 0.001 0.0001	10.83 0.11 0.11	10.84 0.111 0.110
Scenario 2	1 2 3	0.053 0.0016 0.0008	54.14 0.541 0.541	54.19 0.543 0.542
Scenario 3	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542
Scenario 4	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542
Scenario 5	1 2 3	0.053 0.001 0.001	54.14 0.541 0.541	54.19 0.542 0.542

Scenario 6	1 2 3	0.018 0.0018 0.0003	18.05 0.181 0.181	18.07 0.183 0.181
Scenario 7	1 2 3	0.178 0.011 0.001	108.28 1.08 1.08	108.46 1.09 1.08
Scenario 8	1 2	0.178 0.004	108.28 1.08	108.46 1.08
Scenario 9	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026
Scenario 10	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026
Scenario 11	1 2 3	0.0026 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35
Scenario 12	1 2 3	0.003 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35
Scenario 13	1	Negligible	Negligible	Negligible
Scenario 14	1	Negligible	Negligible	Negligible

Summary table: estimated local exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal exposure (mg/min)**	**Total Exposure for semi-quantitative assessment (mg/m³)**
Scenario 1	1 2 3	10 0.77 0.077	305 3.05 3.05	10 0.77 0.077
Scenario 2	1 2 3	7.2 0.214 0.11	305 3.05 3.05	7.2 0.214 0.11
Scenario 3	1 2 3	7.2 0.749 0.11	305 3.05 3.05	7.2 0.749 0.11
Scenario 4	1 2 3	7.2 0.749 0.11	305 3.05 3.05	7.2 0.749 0.11
Scenario 5	1 2 3	7.2 0.1605 0.11	305 3.05 3.05	7.2 0.1605 0.11

Scenario 6	1 2 3	7.2 0.749 0.11	305 3.05 3.05	7.2 0.749 0.11
Scenario 7	1 2 3	12 0.749 0.0749	305 3.05 3.05	12 0.749 0.0749
Scenario 8	1 2	12 0.2675	305 3.05	12 0.2675
Scenario 9	1 2	0.125 <1.0	0.03 0.03	0.125 <1.0
Scenario 10	1 2	0.125 <1.0	0.03 0.03	0.125 <1.0
Scenario 11	1 2 3	1.07 0.214 0.107	228 228 228	1.07 0.214 0.107
Scenario 12	1 2 3	1.07 0.214 0.107	228 228 228	1.07 0.214 0.107
Scenario 13	1	Negligible	Negligible	Negligible
Scenario 14	1	Negligible	Negligible	Negligible

Further information and considerations on scenario [1 to 14]
The products are skin irritants and cause serious damage to the eyes. Consequently, wearing of full protective clothing (boots, coverall, protective gloves and goggles) is mandatory.
RPE of at least Filtering half masks (FFP3) should be worn when dust levels are above the AEC of 0.3 mg/m³ respirable fraction and no forced ventialation measures are in place.

Combined scenarios

Workers will be performing several tasks and will also have indirect exposure to the used products so all scenarios are combined:

Scenario 1: Opening of bags
Scenario 2: Tipping of bags into hoppers
Scenarios 3 to 10: Application of the products
Scenario 11: Cleaning and maintenance
Scenarios 12 to 14: Disposal tasks
Scenario 15: Bystander exposure

However the critical factor is inhalation exposure. This measurement is not time dependent or additive. As indicated inthe Operator exposure model referenced in the CAR for the active substance; INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014, dust measurements were made for a worker performing combined tasks and covering each of the scenarios indicated above. The average exposure concentration in this study was 1.07 mg/m³.The application of RMM ensure that the exposure is below the AEC of 0.3 mg/m³.

Non-professional exposure

There are no non-professional uses claimed.

Exposure of the general public

Scenario [15]: Indirect – Bystander exposure to products used in animal accomodation

Description of Scenario [15]		
The in-use concentration of hydrated lime contains 85-95 % w/w of the potential range of component substances (calcium magnesium oxide). Bystanders may be exposed to the products by incidental inhalation exposure to dusts present after spreading. Inhalation exposure: Dusts formed from treated floors. Bystanders may raise dusts from walking in treated floors. As the dusts formed from mixing and loading applications where high levels of dust are expected have been measured to be on average equivalent to the IOELV of 1 mg/m³ respirable fraction (8h-TWA), the exposure from this scenario is considered to be negligible.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Frequency	Daily

[1] ECHA Guidance on BPR. Vol III Human Health Part B Risk Assessment (Oct 2015)

Calculations for Scenario 15

Summary table: Local exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m³)**	**Estimated dermal exposure**	**Estimated oral exposure**	**Estimated total exposure**
Scenario [15]	1	Negligible	Negligible	Not applicable	Negligible

For dermal systemic exposure, a model from EFSA (Guidance on the assessment of exposure of operators, workers, residents 2 and bystanders in risk assessment for plant protection products, 2014, 6.3.2.3 Surface deposits) has been applied in order to provide an estimation.

The final results for systemic exposure for bystanders are:

Dermal (mg/kg bw/day)	**Inhalation (mg/kg bw/day)**	**Total (mg/kg bw/day)**
0.12	Negligible	0.12

The result for dermal systemic exposure for bystanders is at least 350 times lower than the UL = 42 mg/kg bw/day which can be considered as negligible.

Further information and considerations on scenario [15]
The dry products are skin irritants and cause serious damage to the eyes. Care should be taken to prevent bystanders from enetering accomodations when spreading has just taken place. Dusts should be allowed to settle before reentry.
The general public should not handle dry bedding treated with unreacted dolime.

Combined scenarios

No combined scenarios are applicable.

Monitoring data
Teerlinck M and Detry D (2010) Workplace Dust Monitoring
This study is summarised and assessed in the CAR for the active substance.

Dietary exposure
Dolime products are used extensively in agriculture. Dietary exposure will occur mainly through this use, but some indirect exposure may occut from the biocidal use. This biocidal exposure has been indicated in the active substance CAR as being minor in comparison to other uses of these basic substances.

Residue definitions

No dietary MRL has been set in accordance with Regulation 2377/90.
Calcium hydroxide, calcium oxide and magnesium oxide are listed in Regulation No. 37/2010 as pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
16.	Animal husbandry	Indirect exposure from use in bedding, on floors and walls of accomodations. Incidental oral exposure from licking, dermal exposure. Inhalation will not occur as dolime is spread when accomodation not inhabited.	Poultry, pigs, cattle, sheep.

Information of non-biocidal use of the active substance

Calcium hydroxide is listed as a basic substance (approval date 01/07/2015) in accordance with Regulation (EC) No. 1107/2009. (Implementing Regulation (EU) No 540/2011). It is included in Annex IV to (EC) No. 396/2005
Calcium oxide is listed in Annex II of Regulation 2377/90. The substance has been evaluated and a conclusion has been established that a MRL is not required for the protection of public health.

Calcium hydroxide, calcium oxide and magnesium oxide are listed in Regulation No. 37/2010 as pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.

Residue definitions

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
17.	Plant Protection Products	Application to all types of food and feedstuffs of plant and animal origin. (Reg 2016/143)	No MRL required.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Scenario [18]: Indirect exposure in diet from transfer of substances into meat

Description of Scenario [18]		
Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 Chapter 6		
	Parameters	Value
Tier 1	Application rate of product (worse-case)	800 g/m²
	Calcium content in calcium oxide	71%
	Dermal absorption	10%

Calculations for estimating livestock exposure for Scenario [18]

See Annex 3.2

Internal dose received by the animal and WCCE* - calcium						
Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 Chapter 6 WCCE is determined as 30% of UL. Trigger value is 0.004 mg/kg bw livestock						
	Livestock	Inhalation exposure	Dermal exposure (mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	WCCE (mg/kg bw/day)
Scenario 18	Calf	0	247	227	474	4.0
	Laying hen	0	3034	330	3364	28.0
	Dairy cattle	0	147	0	147	4.9
	Beef cattle	0	191	0	191	6.4
	Fattening pig	0	477	454	932	7.8

	Broiler chicken	0	1336	369	1705	14.2

Further information and considerations on scenario [18]
No further considerations

Conclusion
Based on the model, the estimated exposure to livestock is above the trigger value of 0.004 mg/kg bw/day. However, calcium uptake in animals is homeostatically controlled within the body. When excess calcium is ingested, the amount absorbed by the animal is reduced, thereby maintaining the balance within the body. In addition, it is standard practice to supplement the diet of chickens with additional calcium in order to aid egg shell development.

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

Scenario [18]

See scenario 18 above.

Internal dose received by the animal and WCCE* - calcium						
Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 Chapter 6 WCCE is determined as 30% of UL. Trigger value is 0.004 mg/kg bw livestock						
	Parameters	Inhalation exposure	Dermal exposure (mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	WCCE (mg/kg bw/day)
Scenario 18	Calf	0	247	227	474	4.0
	Laying hen	0	3034	330	3364	28.0
	Dairy cattle	0	147	0	147	4.9
	Beef cattle	0	191	0	191	6.4
	Fattening pig	0	477	454	932	7.8
	Broiler chicken	0	1336	369	1705	14.2

The WCCE ranges from 4.0 to 7.8 mg/kg bw/day (9.4 – 18.5 % of the UL for calcium) for livestock excluding chickens. The values obtained for laying hens and broiler chickens are 28.0 and 14.2 mg/kg bw/day (66.8 and 33.8 % of UL) respectively. There values are above the 30% that requires further investigation. However, calcium uptake is homeostatically controlled in animals, meaning that in practice, the amount of calcium available in meat should be maintained in a close range, regardless of actual exposure of the animals. In addition, it should be noted that the diet of chickens is regularly supplemented with addition calcium in order to aid with the development of strong eggshells. Finally, the calculations represent a worse case since they assume that animals

are exposed to the total amount of calcium oxide applied, without taking into account any removal prior to animals being reintroduced to the accommodation.

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

There are no non-professional use applications claimed.

Furthermore, as the concentrations used for biocide application are minor in comparison with those used in agriculture, the determination of EFSA that an MRL for the substance is not applicable, is considered to be appppropriate for the biocide use and no further assessment of exposure to livestock and to food is required.

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

The biocidal product is the same as the active substance. The substance does not undergo any further formulation steps before use.
The substances are registered up to Annex X under REACH under calcium magnesium oxide EC No. 253-425-0.
Exposure to the substance during manufacturing is already addressed through Regulation 793/93/EEC and information is not required under Regulation 528/2012.

Summary of exposure assessment

Scenarios and values to be used in risk assessment - systemic exposure to calcium					
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
1.	Professional	1 2 3	0.015 0.001 0.0001	10.83 0.11 0.11	10.84 0.111 0.110
2.	Professional	1 2 3	0.053 0.0016 0.0008	54.14 0.541 0.541	54.19 0.543 0.542
3.	Professional	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542
4.	Professional	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542
5.	Professional	1 2 3	0.053 0.001 0.001	54.14 0.541 0.541	54.19 0.542 0.542
6.	Professional	1 2 3	0.018 0.0018 0.0003	18.05 0.181 0.181	18.07 0.183 0.181
7.	Professional	1 2 3	0.178 0.011 0.001	108.28 1.08 1.08	108.46 1.09 1.08
8.	Professional	1 2	0.178 0.004	108.28 1.08	108.46 1.08
9.	Professional	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026
10.	Professional	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026
11.	Professional	1 2 3	0.0026 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35
12.	Professional	1 2 3	0.003 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35
13.	Professional	1	Negligible	Negligible	Negligible
14.	Professional	1	Negligible	Negligible	Negligible
15	Bystander, General public	1	Negligible	Negligible	Negligible

Scenarios and values to be used in risk assessment – Local effects				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Inhalation exposure (mg/m³)**	**Estimated total exposure (mg/m³)**
1.	Professional	1 2 3	10 0.77 0.077	10 0.77 0.077
2.	Professional	1 2 3	7.2 0.214 0.11	7.2 0.214 0.11
3.	Professional	1 2 3	7.2 0.749 0.11	7.2 0.749 0.11
4.	Professional	1 2 3	7.2 0.749 0.11	7.2 0.749 0.11
5.	Professional	1 2 3	7.2 0.1605 0.11	7.2 0.1605 0.11
6.	Professional	1 2 3	7.2 0.749 0.11	7.2 0.749 0.11
7.	Professional	1 2 3	12 0.749 0.0749	12 0.749 0.0749
8.	Professional	1 2	12 0.2675	12 0.2675
9.	Professional	1 2	0.125 <1.0	0.125 <1.0
10.	Professional	1 2	0.125 <1.0	0.125 <1.0
11.	Professional	1 2 3	1.07 0.214 0.107	1.07 0.214 0.107
12.	Professional	1 2 3	1.07 0.214 0.107	1.07 0.214 0.107
13.	Professional	1	Negligible	Negligible
14.	Professional	1	Negligible	Negligible
15.	Bystander, General Public	1	Negligible	Negligible

Risk characterisation for human health
In accordance with BPR Guidance on the BPR, Vol III Huan Health – Assessment and Evaluation (Parts B+C) v 2.1 February 2017, the biocidal products are classified in respect to local effects. The products will not be used at concentrations below which the classification for local effects is not appropriate, therefore systemic exposure is secondary to the local effects. The risk assessment will be qualitative in respect to the dermal exposure as no threshold concentration level has been determined for the dermal hazard and semi-quanitative with respect to inhalation. Systemic exposure to calcium is assessed against the UL of 42 mg/kg bw/day, as described in the CAR.

Reference values to be used in Risk Characterisation

Reference	Reference	Value
AECshort-term	BPR CAR IOELV	0.3 mg/m³ 1 mg/m³
AECmedium-term	BPR CAR IOELV	0.3 mg/m³ 1 mg/m³
AEClong-term	BPR CAR IOELV	0.3 mg/m³ 1 mg/m³
AELshort, medium & long-term (calcium)	UL	42 mg/kg bw/day
ARfD		Not applicable
ADI		Not applicable

There is no AEC defined for dermal local effects. Assessment will be qualitative only.

Maximum residue limits or equivalent

Residue definitions

Calcium hydroxide is listed as a basic substance (approval date 01/07/2015) in accordance with Regulation (EC) No. 1107/2009. (Implementing Regulation (EU) No 540/2011). It is included in Annex IV to (EC) No. 396/2005
Calcium oxide is listed in Annex II of Regulation 2377/90. The substance has been evaluated and a conclusion has been established that a MRL is not required for the protection of public health.
Calcium hydroxide, calcium oxide and magnesium oxide are listed in Regulation No. 37/2010 as pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.

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

No industrial uses have been identified.

Risk for professional users

Systemic effects

No systemic effects have been identified.

In accordance with BPR Guidance on the BPR, Vol III Human Health – Assessment and Evaluation (Parts B+C) v 2.1 February 2017, the biocidal products are classified in respect to local effects. The products will not be used at concentrations below which the classification for local effects is not appropriate, therefore systemic exposure is secondary to the local effects. The risk assessment will be qualitative in respect to the dermal exposure as no threshold concentration level has been determined for the dermal hazard and semi-quanitative with respect to inhalation. Systemic exposure to calcium is assessed against the UL of 42 mg/kg bw/day, as described in the CAR.

Systemic exposure to calcium						
Scenario number	**Tier/PPE**	**Inhalation uptake (mg/kg bw/day)**	**Dermal uptake (mg/kg bw/day)**	**Total uptake (mg/kg bw/day)**	**Total uptake (% UL)**	**Acceptable (Yes/No)**
1: Opening bags	1 2 3	0.015 0.001 0.0001	10.83 0.11 0.11	10.84 0.111 0.110	24.95 0.26 0.26	No **Yes** **Yes**
2: Tipping bags into hopper	1 2 3	0.053 0.0016 0.0008	54.14 0.541 0.541	54.19 0.543 0.542	129 1.29 1.29	No **Yes** **Yes**
3: Manual application of product to sewage sludge	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542	129 1.29 1.29	No **Yes** **Yes**
4: Semi-automated application of product to sewage sludge	1 2 3	0.053 0.0055 0.0008	54.14 0.541 0.541	54.19 0.547 0.542	129 1.29 1.29	No **Yes** **Yes**

5: Automated application of product to sewage sludge	1 2 3	0.053 0.001 0.001	54.14 0.541 0.541	54.19 0.542 0.542	129 1.29 1.29	No **Yes** **Yes**
6: Automated application of product to manures	1 2 3	0.018 0.0018 0.0003	18.05 0.181 0.181	18.07 0.183 0.181	43 0.44 0.43	No **Yes** **Yes**
7: Manual spreading of dry product onto floors, indoors	1 2 3	0.178 0.011 0.001	108.28 1.08 1.08	108.46 1.09 1.08	258 2.58 2.58	No **Yes** **Yes**
8: Manual spreading of dry product onto floors, outdoors	1 2	0.178 0.004	108.28 1.08	108.46 1.08	258 2.58	No **Yes**
9: Automated spreading of dry product onto floors, indoors	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026	0.03 <0.06	**Yes** **Yes**
10: Automated spreading of dry product onto floors, outdoors	1 2	0.0018 <0.015	0.011 0.011	0.013 <0.026	0.03 <0.06	**Yes** **Yes**
11: Manual cleaning of mixing equipment	1 2 3	0.0026 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35	32.12 3.21 3.21	No **Yes** **Yes**
12: Disposal of empty bags	1 2 3	0.003 0.0005 0.0003	13.49 1.35 1.35	13.49 1.35 1.35	32.12 3.21 3.21	No **Yes** **Yes**
13: Manual disposal, using spade/shovel, to manure waste	1	Negligible	Negligible	Negligible	Negligible	**Yes**

14: Automated disposal, using tractor, to manure waste	1	Negligible	Negligible	Negligible	Negligible	**Yes**
15: Bystander, General public	1	Negligible	Negligible	Negligible	Negligible	**Yes**

Local effects

The biocidal product is a dusty powder used for the treatment of sewage sludge (PT2) as Neutralac® QM and the disinfection of animal accomodations and manure treatment (PT3) as Saniblanc® QM. The local effects resulting from the use of the biocidal products may be due to the direct contact of the worker with the product during the different application steps, in the absence of an adequate ventilation system (when indoor) and/or appropriate PPE.
There are two potential exposure routes that have been identified for the Neutralac® QM / Saniblanc® QM which are skin and inhalation.
In the presence of water or moisture, dolomitic burnt lime (or CaO.MgO) reacts exothermically to form $Ca(OH)_2$ and MgO. When in contact with the skin, the same reaction may occur at a smaller scale provoking some local effect in the form of skin irritation. The inhalation of dust without any adequate mask or a general ventilation system may as well lead to some respiratory tract irritation due to the nature of the product (dusty powder) and its reaction with moisture.

Hazard	**Exposure**									**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*	*Potential degree of exposure (mg/m³)*	*Relevant RMM & PPE*	*Conclusion on risk*
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	23	Professional	1: Opening bags	Dermal inhalation	60 minutes daily	0.077	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied. - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318	AEC = 0.3 mg/m³	23	Professional	2: Tipping bags into hopper	Dermal inhalation	60 minutes daily	0.11	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are

	STOT single exposure 3: H335								mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	2	Professional	3: Manual application of product to sewage sludge	Dermal inhalation	30 minutes daily	0.11	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	2	Professional	4: Semi-automated application of product to sewage sludge	Dermal inhalation	30 minutes daily	0.11	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	2	Professional	5: Automated application of product to sewage sludge	Dermal inhalation	30 minutes daily	0.1605	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure	AEC = 0.3 mg/m³	3	Professional	6: – Automated application of product to manures	Dermal inhalation	10 minutes daily	0.11	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable

	3: H335								- Filtering half masks (FFP3) - LEV	
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professional	7: Manual spreading of dry product - indoors	Dermal inhalation	60 minutes daily	0.0749	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Sk10in irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professional	8: Manual spreading of dry product - outdoors	Dermal inhalation	60 minutes daily	0.2675	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied: - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professional	9: Automated spreading of dry product - indoors	Dermal inhalation	60 minutes daily	<1.0	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professional	10: Automated spreading of dry product - outdoors	Dermal inhalation	60 minutes daily	<1.0	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin	AEC =	2	Professio	11: Manual cleaning	Dermal	10	0.214	Technical and organisational	Acceptable:

	irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	0.3 mg/m³	3	nal	of mixing or spreading equipment	inhalation	minutes daily		RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	2 3	Professio nal	12: Disposal of empty bags	Dermal inhalation	10 minutes daily	0.214	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professio nal	13: Manual disposal, using spade/shovel, to manure waste	Dermal inhalation	60 minutes daily	Negligible	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m³	3	Professio nal	14: Automated disposal, using tractor, to manure waste	Dermal inhalation	60 minutes daily	Negligible	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied:	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable

Discussion and conclusion

As stated previously, the biocidal product is a dusty powder of dolomitic burnt lime. In the presence of moisture, the product reacts exothermically to form $Ca(OH)_2$ and MgO. When in contact with skin, the product may react with the microscopical sweat droplets provoking skin irritation. In the absence of appropriate PPE and exhausting ventilation system, the inhalation of the product may lead to an irritation of the respiratory tract.

When handling the biocidal products, it is highly advised to wear the appropriate PPEs as described in the safety data sheet of the product or the biocidal product leaflet, in order to reduce the risk during all the steps.

The use scenarios are acceptable in terms of risk from the local effects of the products. Professional users are expected to use technical and organisational RMM adequate for the high hazard category. This includes use of appropriate coverall, gloves and boots were necessary. Use of googles is advised in areas where a high dust concentration is expected. If dust concentration above the AEC of 0.3 mg/m³ may be achieved, users should wear a filtering half mask PPF3 or forced ventilation/LEV should be in place.

Other RMM to reduce dust concentrations may be applied, e.g. dampening of surfaces or performing tasks outside where possible.

It should be noted that there is an IOELV of 1.0 mg/m³ for this CaO. The IOELV will be applied for all non-biocidal uses which may also occur in the same facilities.

Risk for non-professional users

No non-professional uses are claimed.

Risk for the general public

Systemic effects
No systemic effects have been identified.

Local effects

Scenario No	Hazard		Exposure information		
	Hazard category	Effects	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMMs
Scenario 15	Low	AEC = 0.3 mg/m³	Incidental exposure – infrequent, daily	Negligible	None

Conclusion

Bystanders may raise dusts from walking in treated floors. As the dusts formed from mixing and loading applications where high levels of dust are expected have been measured to be on average equivalent to the IOELV of 1 mg/m³ respirable fraction (8h-TWA), but levels of dust from low impact applications are less than the AEC of 0.3 mg/m³ the exposure from this scenario is considered to be negligible.

Risk for consumers via residues in food

Internal dose received by the animal and WCCE* - calcium						
Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 Chapter 6 WCCE is determined as 30% of UL. Trigger value is 0.004 mg/kg bw livestock						
	Parameters	Inhalation exposure	Dermal exposure (mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	WCCE (mg/kg bw/day)
Scenario 18	Calf	0	247	227	474	4.0
	Laying hen	0	3034	330	3364	28.0
	Dairy cattle	0	147	0	147	4.9
	Beef cattle	0	191	0	191	6.4
	Fattening pig	0	477	454	932	7.8
	Broiler chicken	0	1336	369	1705	14.2

The WCCE ranges from 4.0 to 7.8 mg/kg bw/day (9.4 – 18.5 % of the UL for calcium) for livestock excluding chickens. The values obtained for laying hens and broiler chickens are 28.0 and 14.2 mg/kg bw/day (66.8 and 33.8 % of UL) respectively. There values are above the 30% that requires further investigation. However, calcium uptake is homeostatically controlled in animals, meaning that in practice, the amount of calcium available in meat should be maintained in a close range, regardless of actual exposure of the animals. In addition, it should be noted that the diet of chickens is regularly supplemented with addition calcium in order to aid with the development of strong eggshells. Finally, the calculations represent a worse case since they assume that animals are exposed to the total amount of calcium oxide applied, without taking into account any removal prior to animals being reintroduced to the accommodation.

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

The products do not contain any substance of concern or additional active substance.

2.2.7 Risk assessment for animal health

A risk assessment for animal health is not required.

The substance is used extensively in agriculture as a plant protection product and for neutralisation of soil. Maximum application rates to soil from agricultural use: 1700 kg CaO/ha or 2244 kg $Ca(OH)_2$/ha or 1500 kg CaO.MgO/ha. Under these conditions of use, EFSA has determined that the substances are pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.

The hazards attributed to the substance are local effects from contact with the dry product and from inhalation of the dusts. There are no systemic effects identified for livestock from indirect exposure to lime in the quantities proposed for biocidal use, which are substantially lower than those for other agricultural use.

Livestock will not be present during the application of the products and will only be exposured once the product has been in contact with moisture.

2.2.8 Risk assessment for the environment

The products are the same as the active substances. The products have therefore been assessed for environmental effects in the evaluation for inclusion of the active substances in the Union List. The summary of the environmental effects is copied from the CAR for the active substance;

Fate in the Aquatic Compartment

When dissolved in water, dolime (CaO.MgO) dissociates into Ca^{2+}, Mg^{2+} and OH^- ions. The dissociation products Ca^{2+}, Mg^{2+} and OH^- are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. For this reason, the performance of any degradation test with dolime is scientifically unjustified. However, studies that investigated the impact of addition of hydrated lime ($Ca(OH)_2$) on the pH of different test media and on the pH of two water-sediment systems were submitted. These studies and their endpoints have been considered relevant because the main toxic effect of hydrated lime ($Ca(OH)_2$) is likely to be caused by temporal pH changes in the environment. By read across, these results are also applicable to dolime.

The more relevant of the available studies was that of Egeler and Gilberg (2007), in which the pH development of two natural water-sediment systems sampled from Germany was investigated. hydrated lime ($Ca(OH)_2$) was added at concentrations ranging between 14.8 and 100 mg l^{-1} to the water phase and changes in pH were monitored for up to 168 h. Upon addition of hydrated lime ($Ca(OH)_2$) to the overlying water, a dose-dependent transient increase in the pH of the water phase was observed. The relative increase in pH following addition of the test substance was noted to be highest in the system with the lowest total hardness (Unterbach Creek system). The water pH was noted to have returned to levels comparable with control systems (pH 7.60 - 7.73) in test concentrations of ≤ 75 mg l^{-1} by the final 7 d sampling point.

Relating concentrations tested in these studies to actual concentrations arising from the biocidal uses of the lime variants, it should be noted that the maximum PECsw value using the Step 2 FOCUSsw tool was only 2.46 mg l^{-1} (as hydrated lime ($Ca(OH)_2$) equivalents). Note this PECsw value accounts for buffering/degradation occurring in soil/sludge or manure prior to the runoff or drainflow event transporting the lime material to surface water.

Fate in Air

Since dolime ($Ca(OH)_2$) is expected to have a vapour pressure well below 10^{-5} Pa exposure via air is not expected. Whilst an estimation using simple calculations could be used to address this data point (e.g. the estimation methods of the Atmospheric Oxidation Program) irrespective of the vapour pressure. For substances such as dolime (CaO.MgO) , such calculations would be largely meaningless as the potential for exposure via air, and subsequent phototransformation in air would be expected to be negligible.

Fate in the Terrestrial Compartment

Standard aerobic degradation studies in soil are not considered necessary for dolime (CaO.MgO). This is because upon addition to soil, dolime would simply dissociate to its respective ion constituents where they would form part of existing chemical cycles in the natural environment. However, two studies that investigated the impact of addition of

hydrated lime ($Ca(OH)_2$) on the pH of different soil systems were considered relevant because as in the aquatic compartment, the main toxic effect of hydrated lime ($Ca(OH)_2$) is likely to be caused by temporal pH changes in the environment. By read across, these results are also applicable to dolime.

In the first study (Schiffner, 2007a) the pH development of a natural and an artificial soil were investigated. Hydrated lime ($Ca(OH)_2$) was added at concentrations up to 4.44 g kg^{-1} dry soil and the pH was measured for up to 6 weeks. Upon addition of hydrated lime ($Ca(OH)_2$) to the soils, a dose-dependent increase in the pH was observed. The relative increase in pH following addition of the test substance was noted to be marginally higher in the artificial soil system. The soil pH was noted to rise to between 10 and 11 pH units in both soils immediately after addition of the hydrated lime ($Ca(OH)_2$) at the highest test concentration (note that initial pH levels in untreated controls were 5.49 for the natural soil and 5.89 for the artificial soil). A decrease in pH of approximately 2 pH units was observed within 72 h following addition. By the end of the 6 week study the pH in the test soils was noted to be elevated above control levels at all concentrations. However, the final pH was within the normal range for typical agricultural soils at all concentrations tested (pH range from 5.88 to 7.95). The estimated DT_{50} and DT_{90} values were determined assuming hockey stick kinetics to reflect the bi-phasic pattern of pH changes observed in the treated soils. Fits were generally good statistically (chi^2 and t-tests) and visually (classical and residual plots). A DT_{50} of **0.742 h** is proposed up to a break point of 6 h, and a DT_{50} of **372 h** is proposed for the time period after the break point. The kinetic modelling endpoints were considered appropriate for direct use in the environmental exposure assessment.

In general, in the soils tested the pH fell back to within normal levels (*ca.* pH 8) within 1 week of application at all concentrations.

In the second study (Schiffner, 2008), the pH development within mixed natural soil after application with hydrated lime ($Ca(OH)_2$) treated sewage sludge was investigated. Sewage sludge was treated with four concentrations of hydrated lime ($Ca(OH)_2$) ranging from 187.5 to 520 g kg^{-1} wet sludge (dry solids content of sludge was reported to be 25 %). After incubation for 24 h at room temperature, the treated sludge was added to mixed natural soil resulting in nominal hydrated lime ($Ca(OH)_2$) concentrations between 1.25and 3.65 g kg^{-1} dry soil. The pH of the amended soil was also measured for up to 24 h.

As with the previous study, upon addition of hydrated lime ($Ca(OH)_2$) treated sewage sludge to soil, a dose-dependent increase in pH was observed. The relative impact on pH following addition of hydrated lime ($Ca(OH)_2$) direct to soil was noted to be marginally higher than the impact of applying comparable rates of hydrated lime ($Ca(OH)_2$) treated sewage to soil. Even though the lowest rate tested was elevated above that which would be proposed for treating sewage sludge, only a relatively minor impact on the final soil pH was noted at this treatment level. This was in contrast with the more pronounced effect on soil pH that was observed either when testing higher sewage sludge application rates or when testing the effect of direct application of hydrated lime ($Ca(OH)_2$) to soil.

Both the studies submitted did not provide sufficient information on the soils used to allow any comparison with any areas of the EU. However, the results from this study are likely to at least be indicative of the likely behaviour in terms of temporal pH changes when a soil is either directly treated with hydrated lime ($Ca(OH)_2$) or when soil is amended with hydrated lime ($Ca(OH)_2$) treated sewage sludge.

In terms of mobility within the soil compartment standard adsorption/desorption studies in soil were not considered necessary for hydrated lime ($Ca(OH)_2$). This is because upon addition to soil hydrated lime ($Ca(OH)_2$) would simply dissociate to its respective ion constituents, which would then form part of the existing chemical cycles in the natural environment. Nonetheless, a soil column study was conducted to investigate the leaching of hydrated lime ($Ca(OH)_2$) in a soil column as well as investigating the impact on the pH of the soil column. Although the column study was of limited reliability with respect to the risk assessment, the results were noted to be broadly consistent with the other studies conducted in soil with respect to the temporal pH changes recorded.

Theoretically, repeated applications of hydrated lime ($Ca(OH)_2$) variants to soil via treated sewage sludge could lead to accumulation of the respective ion constituents in the environment. This would occur if the application rate exceeded the natural loss rate of any of the ions (e.g. the natural loss rate of Ca^{2+} ions via natural weathering processes such as leaching). However, in reality farmers are likely to ensure that over-liming of their soils does not occur since this would also be associated with increases in soil pH above those required for optimum plant growth conditions. At high soil pH values trace element availability can be drastically reduced which can lead to serious yield and financial losses in many crops. Although accumulation in soil cannot be excluded, since this would not be associated with good agricultural practice no further consideration will be made in this assessment.

In addition to standard endpoints, further background information was provided on the distribution of hydrated lime ($Ca(OH)_2$) in the environment and the use of hydrated lime ($Ca(OH)_2$) in agriculture as a measure to counteract soil acidification. With respect to the distribution in the environment, brief summaries of the basic chemical reactions undertaken by the constituents of lime when they are released to the environment were provided. Since these reactions are all well understood processes of the natural calcium cycles they have not been reproduced in detail here. In summary, the level of calcium in soil is governed by the equilibrium between soluble, exchangeable and solid forms. Weathering is enhanced by carbonic acid (CO_2 produced by respiration of organisms dissolved in water). Exchangeable calcium is the dominant ion on soil colloid surfaces and by replacing H^+ ions in exchange sites it largely determines soil pH. In many soils, the steady downward movement of water leaches Ca^{2+} ions over time, H^+ ions take their place on exchange sites and soils become more acidic. Available information suggests that annual losses of lime ($Ca(OH)_2$/CaO) can be as high as 700 kg ha^{-1} (calculated as CaO). The addition of acidifying nitrogen fertilisers can also enhance the loss of lime along with hydrated lime ($Ca(OH)_2$) removal because of crop harvesting.

Extensive information on the lime requirements of typical agricultural soils has been provided. Hydrated lime ($Ca(OH)_2$) rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and hydrated lime ($Ca(OH)_2$) status of highly deficient soils. Although these figures were derived from a German guidance document, the proposed rates are also consistent with UK guidance issued by the Department of Environment, Food and Rural Affairs. These data suggest that the quantities of hydrated lime ($Ca(OH)_2$) used exceed the maximum quantities applied because of sewage sludge using hydrated lime ($Ca(OH)_2$). However, it should be noted that for agricultural liming, in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via manure or sewage sludge to ensure that the total neutralising value of the material applied remained within the relevant guidelines.
In addition to the key role that agricultural liming plays in counteracting soil acidification, a number of other benefits are highlighted, such as the importance of divalent cations such

as calcium in maintaining good soil physical structure; maintaining optimum nutrient uptake by managing soil pH; adequate soil pH also encourages soil biological activity; calcium and magnesium are also noted to be essential plant nutrients in their own right.

2.2.8.1 Effects assessment on the environment

No new data on environmental effects is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. The summary of the effects assessment from the Assessment Report is replicated below for reference:

Effects assessment

The assessment factors used to define the PNEC for the various environmental compartments of concern have been taken from the TGD on risk assessment in support of Commission Directive 93/67/EEC (new notified substances) and Directive 98/8/EC (biocidal products) (EC 2003).

It should be noted that the endpoints used in deriving the following PNEC values are based on initial nominal or measured concentrations. This is because the toxic effect of dolime (CaO.MgO) is due to the rapid change in pH, sometimes referred to as 'pH shock', hence it is more relevant to use the initial concentration rather the mean measured concentration. Further supporting information on the use of initial concentrations, pH shock and selection of assessment factors is provided below.

If a conventional **mean measured concentration** where the concentration of lime ($Ca(OH)_2$/CaO) at the beginning and at the end of the study was used, it would give an endpoint in terms of mg/L that would in effect be equivalent to the average pH during the course of the study. Adding an assessment factor to this would be overly precautionary, i.e. it would be equivalent to adding an assessment factor to a concentration that would not result in any effects. The measured calcium concentrations were much below the nominal concentrations both at the start and end of the test. This is explained by the high concentration of calcium from calcium chloride already present in the test medium, and by the reaction of the test item with CO_2 to poorly soluble calcium carbonate, thus forming precipitates. However, measurement of calcium after acidification at the end of the test resulted in a mean test item recovery of 98.0 % of the nominal concentration. Therefore, the biological effect concentrations were expressed based on the initial nominal concentrations. Alternative test designs were considered; a flow-through study was the only potential alternative option. However in the light of information on environmental exposure and the fact that the pH returns relatively quickly to normal ranges, a flow-through study was not considered to be appropriate.

pH shock: In the fish studies data were supplied on the survival of fish at 3, 24, 48, 72 and 96 hours. These data indicate that at the top concentration of 75 mg/L (equivalent to a pH of 11) 6 out of 7 fish died within 3 hours of exposure. Fish in all other concentrations were alive at this time interval. At 24 hours all fish were dead at the top concentration and one fish was dead at 50 mg/L (initially pH 10.8 but at 24 hours it was 8.1). At 48 hours, one fish was dead at 33.3 mg/L (initially pH 10.4 but at 48 hours it was 7.8), a further fish died at 50 mg/l (initially pH 10.8, but pH 7.9 at 48 hours). No other mortalities occurred. The pH in all the test concentrations (excluding the top concentration) was 7.7 at the end of the study. These data indicate that the effect is an acute effect and due to initial exposure.

Assessment factor: As can be seen in the summary of the fish study above the pH at the start of the study is high in all concentration (pH 9.6-11.1), however in all but the top concentration the pH is within acceptable limits within 24 hours (i.e. it is between pH 6 – 8 (see OECD 203). Using the available data and calculating a mean measured concentration of lime would result in a concentration of lime ($Ca(OH)_2$/CaO) that would not result in any change in pH. Using such an endpoint in deriving a PNEC would be inappropriate as it would be basing a PNEC on standard test water. In addition, it should be noted that para 14 of OECD203 states that if there is likely to be change in pH then the pH should be adjusted to ensure it is within acceptable limits. If this was done then the study would have involved assessing the toxicity of standard test water.

It is also important to note that throughout all the lime variant CARs toxicity has been expressed in the form of the hydrated lime ($Ca(OH)_2$) equivalents (since this was the only form tested in the fate and effects studies). To ensure consistency in the risk characterisation all lime variant PEC values are expressed as hydrated lime ($Ca(OH)_2$) equivalents. Although weight for weight these variants will have a differential effect on pH, there is no direct exposure of environmental compartments anticipated. Exposure only occurs via the indirect route following sludge or manure application to land. Due to the indirect nature of exposure, it was considered that any differences in short term dynamics in effects between the variants could be largely ignored and the data from the hydrated lime ($Ca(OH)_2$) could be read across to other variants like dolime (CaO.MgO).

Direct exposure of surface water to lime during the application stage is considered unlikely. Exposure will only occur when lime is spread outdoors. Chronic data are not considered necessary due to the fact that applications will only occur intermittently, and thus exposure via subsequent runoff events will also only occur intermittently.

Selection of assessment factors and PNEC setting were agreed at WGV2015.

Predicted No Effects Concentration in STP

The PNEC was calculated from the 3 h EC_{50} of against sewage sludge micro-organisms, in accordance with TGD, Table 17 for $Ca(OH)_2$:

$PNEC_{stp}$ = 300.4/100 mg l^{-1}
$PNEC_{stp}$ = 3.004 mg l^{-1}
$PNEC_{stp}$ = 3004 µg l^{-1}

The PNEC for calcium magnesium oxide is calculated from the corresponding PNEC for $Ca(OH)_2$, corrected for the number of hydroxyl-ions potentially released per unit weight upon complete reaction (worst case scenario). Reliable results are available for an activated sludge respiration inhibition test according to the OECD 209 guideline for $Ca(OH)_2$, resulting in an EC50 of 300.4 mg $Ca(OH)_2$/L. According to the REACH Guidance on information requirements and chemical safety assessment (Table R.10-6), an assessment factor (AF) of 100 is to be applied to the EC50 of a sludge respiration test, reflecting the lower sensitivity of this endpoint as compared to nitrification, as well as the short duration of the test. This results in a PNEC value for micro-organisms in STP of 3.0 mg $Ca(OH)_2$/L. CaO.MgO potentially releases 4.15 mmol OH- per 100g, compared to 2.70 mmol OH- for $Ca(OH)_2$ (factor 1.54 difference), resulting in a PNEC STP of 1.95 mg CaO.MgO /L.

For dolime (CaO.MgO) :

$PNEC_{stp}$ = 1.95 mg l^{-1}

Predicted No Effects Concentration in Surface Waters

Three acute studies have been submitted on the toxicity of hydrated lime ($Ca(OH)_2$) to aquatic organisms. These studies are considered acceptable for risk assessment purposes. The relevant endpoints from the above three studies are:

96 h LC_{50} for *Oncorhynchus mykiss* = 50.3 mg l^{-1}
48 h EC_{50} for *Daphnia magna* = 49.1 mg l^{-1}
72 h EyC_{50} for *Pseudokirchneriella subcapitata* = 99.87 mg l^{-1}

As stated above, the effect of hydrated lime ($Ca(OH)_2$) is due to the rapid change in pH, it is considered that the primary effect will be an acute or mortality effect and not to a long-term or reproductive effect. Alternatively, if an aquatic organism survives a change in pH, it is not considered that there will be any chronic or long-term effects. Therefore, the $PNEC_{water}$ is based on acute data only and only addresses the acute effects.

However, when lime ($Ca(OH)_2$/CaO) is used it is under controlled conditions and hence direct exposure during use has not been considered in the exposure assessment. Surface water and hence aquatic life may be exposed to lime ($Ca(OH)_2$/CaO) once the treated manure is spread on to land. This is only likely to occur intermittently (e.g. once a year), furthermore any runoff event is only likely to occur once and hence the likely exposure is also likely to be intermittent. In addition, due to the mode of action, i.e. pH shock, it is considered that the effect of lime is due to the rapid change in pH, and hence it is considered that the primary effect will be an acute or mortality effect and not to a long-term or reproductive effect. Or put it another way, if an aquatic organism survives a change in pH, it is not considered that there will be any chronic or long-term effects. Therefore, the $PNEC_{water}$ is based on acute data only and only addresses the acute effects. In light of these points, it is proposed to amend the assessment factor from 1000 to 100. The resulting PNEC would be 491 µg l^{-1}.

On the basis of the above an assessment factor (AF) of 100 to the lowest endpoint as suggested by the TGD is applied. It should be noted that it is considered that this PNEC is considered conservative as the available fate data indicates that there will not be significant pH changes at this level.

$PNEC_{water}$ = 49.1/100 mg l^{-1}
$PNEC_{water}$ = 0.491 mg l^{-1}
$PNEC_{water}$ = 491 µg l^{-1}

The $PNEC_{water}$ (freshwater) for calcium magnesium oxide is calculated from the corresponding PNEC for $Ca(OH)_2$, corrected for the number of hydroxyl-ions potentially released per unit weight upon complete reaction (worst case scenario). Reliable short-term toxicity data for $Ca(OH)_2$ are available for freshwater organisms from three trophic levels: aquatic invertebrates, fish and algae. The lowest L(E)C50 value was observed for immobilisation of Daphnia magna: 49.1 mg $Ca(OH)_2$/L. According to the REACH Guidance on information requirements and chemical safety assessment (Table R.10-4), an assessment factor of 1000 applies on the lowest short-term toxicity result. However, testing immediately after application of lime substances without equilibration of the lime in the test medium yields an overestimate of the exposure and hence potentially also results in an overestimation of the effects compared to field conditions. Depending on the properties of the test medium, calcium dihydroxide will be strongly neutralised in the initial period after application. Moreover, test media in standard laboratory toxicity tests are

expected to have lower buffer capacity compared to natural waters (hardness, presence of particles and colloids). Because of the conservative nature of laboratory tests, the standard assessment factor from the REACH guidance was decreased by a factor 10, resulting in a factor 100. This approach agrees with the note a from Table R.10-4 from the REACH guidance. The assessment factor of 100 results in a $PNEC_{water}$, fresh water of 0.49 mg $Ca(OH)_2$/L. CaO.MgO potentially releases 4.15 mmol OH- per 100g, compared to 2.70 mmol OH- for $Ca(OH)_2$ (factor 1.54 difference), resulting in a PNEC aqua (freshwater) of 0.32 mg CaO.MgO /L.

For dolime (CaO.MgO) :

$PNEC_{water}$ = 0.32 mg CaO.MgO /L

Predicted No Effects Concentration in Sediments

No data have been submitted on the toxicity of hydrated lime ($Ca(OH)_2$) to sediment dwelling invertebrates, hence, there is no toxicity endpoint. $CaCO_3$ would be expected to be ubiquitous in the natural aquatic environment and the additional source via the biocidal uses of hydrated lime ($Ca(OH)_2$) would not be expected to increase levels significantly above existing background levels. Therefore, there is no requirement to determine the $PNEC_{sediment}$.

Predicted No Effects Concentration in Soil

For the effects assessment of the soil compartment, endpoints are available for earthworms, plants and terrestrial microorganisms. All the values presented are in terms of mg a.s. kg^{-1} 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.

Acute

- Worm (*E. foetida*): LC_{50} (14 d) = > 5000 mg a.s. kg^{-1} dw
- Terrestrial microorganisms: EC_{50} (28 d) = 9700 mg a.s. kg^{-1} dw
- Terrestrial plant (*Spinacia oleracea*): EC_{50} (21 d) = 2670 mg a.s. kg^{-1} dw
- Terrestrial plant (*Spinacia oleracea*): NOEC (21 d) = 1080 mg a.s. kg^{-1} dw

Chronic

- Worm (*E. foetida*): NOEC (56 d) = 2000 mg a.s. kg^{-1} dw
- Terrestrial microorganisms: NOEC (96 d) = 12000 mg a.s. kg^{-1} dw

The choice of $PNEC_{soil}$ was discussed at WG V 2015. There it was agreed to use the NOEC from the *Spinacia oleracea* study with an Assessment Factor of 10. (It should be noted that it is considered that this PNEC is conservative as the available fate data indicates that there will not be significant pH changes at this level.)

$PNEC_{soil}$ = 1080/10 mg kg^{-1}
$PNEC_{soil}$ = 108 mg kg^{-1}

The $PNEC_{soil}$ for calcium magnesium oxide is calculated from the $PNEC_{soil}$ for $Ca(OH)_2$, corrected for the number of hydroxyl-ions potentially released per unit weight upon complete reaction (worst case scenario). Reliable chronic NOEC values are available for the

effect of $Ca(OH)_2$ on plants, invertebrates and soil microorganisms. The NOEC values range between 1080 and 12000 mg/kg dw. The lowest NOEC was observed for the growth (shoot fresh weight) of Brassica napus. According to the REACH Guidance Table R.10-10), an assessment factor of 10 should be applied if chronic NOEC values are available for 3 species, representing the 3 trophic levels. However, testing immediately after application of lime substances without equilibration of the lime in the test medium yields an overestimate of the exposure and potentially overestimates the effects. Further, the soils used for ecotoxicity testing all had a relative low organic matter and clay content and can be expected to have limited buffer capacity. Because of the conservative nature of laboratory tests, the standard AF was decreased by a factor 10, resulting in a factor 1. This factor 1 was supported in view of the various sources of uncertainty to be taken into account: i) intra- and inter-species variations (biological variance): multiple data are available for the most sensitive taxonomic group (6 plant species, including monocotyledonous and dicotyledonous species); ii) intra- and inter-laboratory variation of toxicity data: considered of minor importance compared to variation across species; iii) short-term to long-term toxicity extrapolation: not applicable because only chronic data available and iv) laboratory data to field impact extrapolation: overestimation of exposure during laboratory toxicity tests immediately after application of $Ca(OH)_2$. CaO.MgO potentially releases 4.15 mmol OH- per 100g, compared to 2.70 mmol OH- for Ca(OH)2 (factor 1.54 difference), resulting in a $PNEC_{soil}$ of 702 mg CaO.MgO /L.

For dolime (CaO.MgO) :

$PNEC_{soil}$ = 702 mg CaO.MgO/L

Predicted No Effects Concentration in Biota

No studies have been submitted on the potential for hydrated lime ($Ca(OH)_2$) to bioaccumulate. It has been agreed that no assessment is required as the dissociation products of hydrated lime ($Ca(OH)_2$), ($Ca^{2+,}$ and OH^-) occur naturally in any surface water and in any plant and animal species. Based on the common knowledge of their physiological role, uptake, distribution and excretion in animals and plants, it can be concluded that there is no risk of bioconcentration due to biocidal uses of hydrated lime ($Ca(OH)_2$). Therefore, there is no need to calculate a $PNEC_{oralpredator}$.

With regard to a $PNEC_{oral}$, whilst it is feasible that birds or mammals could consume invertebrates present in soil where sewage sludge that has been treated with hydrated lime ($Ca(OH)_2$) has been applied, the exposure will be minimal due to the fate and behaviour profile of hydrated lime ($Ca(OH)_2$) and the subsequent changes in pH, hence it has not been considered necessary to determine a $PNEC_{oral}$.

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

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No new data on environmental effects is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	Effects on other specific, non-target organisms.
Justification	No new data on non-target organisms is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	Trials on non-target organisms.
Justification	No new data on non-target organisms is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	Ingestion of biocidal product by non-target organisms.
Justification	No new data on non-target organisms is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No new data is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products.
As stated in the summary of the fate assessment from the Assessment Report above hydrated lime ($Ca(OH)_2$) and dolime (CaO.MgO) are widely used as a measure to counteract soil acidification. Hydrated lime ($Ca(OH)_2$) rates as high as 16 tons ha^{-1}

(expressed as CaO) can be required to adjust the pH and hydrated lime ($Ca(OH)_2$) status of highly deficient soils. These data suggest that the quantities of hydrated lime ($Ca(OH)_2$) used exceed the maximum quantities applied due to the biocidal uses. However, it should be noted that for agricultural liming ($Ca(OH)_2$/CaO), in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via biocidal use to ensure that the total neutralising value of the material applied remained within the relevant guidelines.
Further information on the secondary ecological effect is not therefore required to address the biocidal uses.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Indirect routes: to soil and surface water from use in maure and sewage sludge
Direct routes: STP, soil, air and surface water from direct application to indoor and outdoor surfaces.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment.
Justification	No new data on fate and behaviour is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

Leaching behaviour (ADS)

Data waiving	
Information requirement	Leaching behaviour
Justification	No new data on leaching is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for leaching studies to be performed based on the natural occurrence of limestone.

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

Data waiving	
Information requirement	Distribution and dissipation in water
Justification	No new data on distribution and dissipation is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+}, Mg^{2+} and OH^- ions in

	nature.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Distribution and dissipation in air
Justification	No new data on distribution and dissipation is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+}, Mg^{2+} and OH^- ions in nature.

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)

Data waiving	
Information requirement	Overspray study; surface waters
Justification	No new data is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. As stated in the summary of the fate assessment from the Assessment Report above hydrated lime ($Ca(OH)_2$) and dolime (CaO.MgO) are widely used as a measure to counteract soil acidification. Hydrated lime ($Ca(OH)_2$) rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and hydrated lime ($Ca(OH)_2$) status of highly deficient soils. These data suggest that the quantities of hydrated lime ($Ca(OH)_2$) used exceed the maximum quantities applied due to the biocidal uses. However, it should be noted that for agricultural liming ($Ca(OH)_2$/CaO), in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via biocidal use to ensure that the total neutralising value of the material applied remained within the relevant guidelines. As the use of lime ($Ca(OH)_2$/CaO) sprayed onto fields for agricultural purposes far out weighs the intermittent biocidal use in well defined areas, an over spray study is not scientifically justified.

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)

Data waiving

Information requirement	Overspray study; bees and non-target arthropods
Justification	No new data is presented. The products are the same as the active substance, therefore data on the active substance is applicable for the products. As stated in the summary of the fate assessment from the Assessment Report above hydrated lime ($Ca(OH)_2$) and dolime (CaO.MgO) are widely used as a measure to counteract soil acidification. Hydrated lime ($Ca(OH)_2$) rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and hydrated lime ($Ca(OH)_2$) status of highly deficient soils. These data suggest that the quantities of hydrated lime ($Ca(OH)_2$) used exceed the maximum quantities applied due to the biocidal uses. However, it should be noted that for agricultural liming ($Ca(OH)_2$/CaO), in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via biocidal use to ensure that the total neutralising value of the material applied remained within the relevant guidelines. As the use of lime ($Ca(OH)_2$/CaO) sprayed onto fields for agricultural purposes far out weighs the intermittent biocidal use in well defined areas, an over spray study is not scientifically justified.

2.2.8.2 Exposure assessment (As proposed by the applicant)

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Application to sewage sludges
ESD(s) used	Not applicable. Qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Approach	Scenario 1: Total tonnage
Distribution in the environment	Qualitative
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	Not applicable. Qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Approach	Scenario 2: Total tonnage
Distribution in the environment	Qualitative
Groundwater simulation	No
Confidential Annexes	NO
Life cycle steps assessed	Scenario 2: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

As all proposed uses result in the products being mixed with either sewage sludge or manure, with subsequent application to land, the qualitative approach for environmental risk assessment used in the active substance dossier (CAR) is applicable to these products. For application in transport vehicles, main emissions are directed to stp. The active being not an organic substance, the agreed methodology is not applicable since Fwater is 0 for a mineral substance. Therefore its was considered that the evaluation performed in the CAR is enough for the authorisation of this product. It should be noted that authorised used as supported by efficacy (see section 2.1.4) differs to the initial uses as proposed by the applicant. It was however considered the the qualitative approach proposed in the CAR are stil valid and cover the use in section 2.1.4.

The summary of the assessment is reproduced below:

Based on the quantitative assessment in soil, the maximum tier 1 PEC_{soil} value was 2667 mg kg^{-1} (as hydrated lime equivalents). Note this PEC_{soil} value assumes no time lapse between the application of lime and spreading of treated material onto agricultural soil. In a refined tier 2 assessment, conservatively assuming a 1 d time period between lime application and subsequent application to land, the PEC_{soil} reduced to 9.49 mg kg^{-1}. An indication of the possible impact on environmental pH can be estimated based on the laboratory studies. In those studies, an application of 2230 mg kg^{-1} (i.e. comparable to the tier 1 and in excess of the tier 2 PEC_{soil} value) direct to soil did not result in an increase in the pH of natural soil outside of the typical environmental range (pH increased from control levels of 5.49 to 9.08 at time 0 and declined to 7.81 within 24 h). At the lowest dose tested (444 mg kg^{-1}) the maximum initial pH was 7.52, declining to 6.41 within 24 h. Although these perturbations cannot be described as negligible (as was the case for hydrochloric acid) it can at least be stated that these changes would be within the typical range of agricultural soils encountered across the EU and no significant effect on non-target organisms would be expected as a result of pH changes in this range. Agricultural soils may be routinely lime treated to amend the pH within these ranges as part of good agricultural practice. In addition, it should be noted that the quantitative assessment has been based on a $PNEC_{soil}$ value of 108 mg kg^{-1}. Again based on the data provided for effects of lime on soil, no significant adverse effect on soil pH would be expected at a concentration level of 108 mg kg^{-1}. This further highlights the likely conservativism of the standard quantitative risk assessment presented.

Further supporting information is available from tests performed where lime treated sewage sludge was applied to soil. At the lowest concentration tested (1.25 g kg^{-1} sludge), which was in excess of the proposed target application rate, negligible changes in the pH of the treated soil were observed. This suggests that the qualitative approach taken for the hydrochloric acid assessment based on negligible perturbations of environmental pH levels may also be applied in the case of the lime variants.

Further supporting information on the agricultural use of lime stated lime rates as high as 16 tons ha^{-1} expressed as CaO) can be required to adjust the pH and lime status of highly deficient soils. In comparison, the application of burnt or burnt dolomitic lime would equate to only around 3 tons ha^{-1} (as hydrated lime). The contribution via agricultural liming, outside of the scope of the BPR, is therefore likely to be far in excess of the lime added to soil via the biocidal uses in many soils.

Finally additional information has been included considering the likely natural background levels of the key constituents of the lime variants in soil, surface water and ground water. Information on background concentrations in soil and surface waters in the EU are available in the Statistical Data of Analytical Results Annexed to the Geochemical Atlas of Europe (part 1) as downloaded from http://weppi.gtk.fi/publ/foregsatlas/index.php. The mean topsoil calcium concentration (measured as CaO) in this survey is reported to be 3.54%, equivalent to 35.5g/kg (minimum and maximum values ranged from 0.026 to 470.7%). For surface water the mean calcium concentration was reported to be 55.2mg/l (minimum and maximum values ranged from 0.226 to 592 mg/l). For magnesium (measured as MgO), the mean topsoil concentration was 1.18%, equivalent to 11.8 g/kg (minimum and maximum values ranged from <0.01 to 24.6%). For surface water the mean magnesium concentration was reported to be 11.5mg/l (minimum and maximum values ranged from 0.048 to 230mg/l). Calcium and magnesium are the major ion constituents of groundwater along with Na+, Cl-, HCO3- and SO42-. These major constituents are typically found at levels in excess of 5mg/l. Actual levels are largely dependent on the surrounding rock formations from which Ca2+ and Mg2+ may dissolve but vary from low mg/l levels up to hundreds of mg/l in areas where the surrounding rock formations contain high levels of calcium or magnesium (e.g. chalk, limestone, dolomite etc.). Water hardness is often expressed in units of equivalent mg/l of CaCO3 (Ca2+ and Mg2+ are the two most prevalent divalent cations responsible for hardness). Various scales exist, but water is often described as hard above around 200 mg/l (equivalent to around 80 mg/l calcium). In contrast soft water generally contains the equivalent of less than 30mg/l calcium. Based on widespread evidence over the ubiquitous nature of calcium and magnesium in the environment at levels in excess of those arising from the biocidal use, no further detailed specific references have been included here.

The biocidal application rates to soil from the PT2 and 3 rates can be shown to be lower than the expected agricultural rate of 16 tonnes/ha. Soil treatment will take place at least once per year:

See calculations in Annex 3.2
NB. On application of water, CaO.MgO will form $Ca(OH)_2$, MgO. All calculations are therefore performed in amounts of $Ca(OH)_2$ application. 536 g/m² of CaO.MgO is equivalent to 800 g/m² $Ca(OH)_2$.

<u>PT 3: Manure application</u>
Calculated on the worst case of 100 kg active substance/m³ manure
Total applied per ha/year = 5.4 tonnes

<u>PT3: Animal accommodations:</u>
Using the accommodation areas as stated in the Human Health exposure assessment:
Manual spreading: 0.8 kg $Ca(OH)_2$/m² x 160 m² = 128 kg $Ca(OH)_2$
Automated spreading: 0.8 kg/m² $Ca(OH)_2$ x 3390 m² = 2712 kg $Ca(OH)_2$
The use of $Ca(OH)_2$ for treatment of manure is covered in the CAR; 10-40 kg /m³ manure.

The product remains on the floors of accommodation so will mix with manure. It is removed with manure on cleaning of accommodations, with the spent $Ca(OH)_2$/manure mix either sent to manure storage or for disposal, normally incineration. It will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Manure mixed with $Ca(OH)_2$ can also be left in storage for use on fields.
Manure spreading is considered in ESD PT3 to take place once per year on arable land or 4 times a year on grassland.

Working to a similar calculation used in the CAR (see attached spreadsheet in Annex 3.2) it can be seen that the weekly application of 2712 kg lime into cattle barns:
Total applied per ha/year = 1.009 tonnes

The total of the amounts from treatment of manure and from the use in animal accommodations result in a lower release to soil than from the agricultural application

Overall, based on the qualitative arguments above, the biocidal uses of the product are not expected to have an adverse affect on environmental pH and no unacceptable impacts on non-target organisms is predicted.

2.2.8.3 Risk characterisation

Atmosphere

Exposure via air (and subsequent phototransformation in air) would be negligible based on the structure of the active substance and its expected low vapour pressure.

Conclusion:There is no concern for the atmosphere from the proposed uses

Sewage treatment plant (STP)

The main route of environmental exposure resulting from the biocidal use of dolime (CaO.MgO) is expected to arise following the broad scale application of treated manure to agricultural land. There is theoretically the potential for point source contamination of sewage treatment plants to occur following runoff from individual contaminated farmyards entering drainage systems connected to local treatment plants. However, widespread contamination of farmyards with dolime (CaO.MgO) would not be expected to be significant in farming operations of a high standard where best practice is routinely followed. In addition, this route of exposure would not be expected to form part of the normal use of the dolime (CaO.MgO) based products and therefore should not form part of the routine exposure assessment.
In the event that such point source contamination did occur, it is not expected that the risk would be any higher than already predicted to occur in surface water via runoff following the broad scale use on agricultural land

Conclusion:There is no concern for the STP from the proposed uses

Aquatic compartment

The proposed use patterns for the products is the treatment of manure or other digestive tract contents. Following application of dolime (CaO.MgO) treated animal manure to soil the most likely route of entry to adjacent surface water bodies would be expected to be via surface runoff. Surface water exposure via spray drift would not be anticipated since farmers would not be expected to allow applications to result in direct contamination of water bodies with animal manure due to the obvious environmental pollution issues this would cause.
The surface water exposure assessment for application of hydrated lime ($Ca(OH)_2$) in animal manures is based on the same assumptions of maximum application rate of 50 m^3 ha^{-1} of liquid manure, which equates to a hydrated lime ($Ca(OH)_2$) application rate of 2000 kg ha^{-1}.

Overall, the natural reactions of the lime ($Ca(OH)_2$/CaO) components in treated manure or sewage sludge and subsequently in amended soil would be expected to significantly reduce the exposure levels following treatment and thus reduce the potential for significant levels of lime in runoff from treated fields. At 1030 µg l^{-1} significant long-term pH changes because of this level of lime ($Ca(OH)_2$/CaO) treatment would not be expected, noting that in studies, the pH in reconstituted water returned to control levels within 24 h when dosed at concentrations of 14.8 mg l^{-1} hydrated lime ($Ca(OH)_2$) .

Conclusion:There is no concern for the aquatic compartment from the proposed uses

Terrestrial compartment

At application levels comparable to the worst case application level assumed for uses of lime on animal manures (i.e. 2230 mg $Ca(OH)_2$) kg^{-1} equivalent to an application rate of 1672 kg ha^{-1} over 5 cm) the soil pH returned to normal levels (ca. pH 8) within 12 h (Schiffner, 2008). The natural reactions of the hydrated lime ($Ca(OH)_2$) and other lime variants components in treated manure and subsequently in amended soil would therefore be expected to significantly reduce the exposure levels following treatment and thus reduce the potential for significant effects in treated fields. Based on the above information, the application concentration of 9.49 mg kg^{-1} is appropriate for $Ca(OH)_2$. Significant long-term pH changes because of this level of treatment would therefore not be expected.

Liming is also used to reduce the bioavailability of metals from sludge via pH amendment. However the risk is effectively compensated for as pH is monitored in soils receiving this sludge as part of directive 86/278/EEC. Therefore lasting effects on pH by liming will be detected and only if desired, the lime ($Ca(OH)_2$/CaO) amended sludge will be applied to that soil. The risk to soil organisms by lime ($Ca(OH)_2$/CaO) is after all an acute one, and despite an increase in background pH, the effect is in the shock –increase. Therefore the interaction between this risk assessment and the Directive 86/278/EEC should be noted.

Conclusion:There is no concern for the terrestrial compartment from the proposed uses

Groundwater

When dissolved in water, dolime (CaO.MgO) dissociates into Ca^{2+}, Mg^{2+} and OH^- ions. 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 would be expected to simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, Ca^{2+} ions would be expected to be a major constituent in many groundwater zones. They would be expected to be present at concentrations greater than 1 mg l^{-1} 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 dolime (CaO.MgO) residues, it would not be expected that these processes would lead to any significant increase in the background groundwater concentrations of these major ions.

Conclusion:There is no concern for groundwater from the proposed uses

Primary and secondary poisoning

As agreed in the active substance CAR this point is not relevant because Lime and its variants 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.

The justification is a general statement to cover hydrated lime ($Ca(OH)_2$) and its variants, including the dolimitic forms); hence there is no need to consider this point further.

Mixture toxicity

Not applicable

Aggregated exposure (combined for relevant emmission sources)

Not applicable

Overall conclusion on the risk assessment for the environment of the product
There is no concern for the proposed biocidal uses. Users should take care to ensure that no unaaceptable long-term pH changes in soil occur from spreading of manures or sewage sludges containing lime products.

2.2.9 Measures to protect man, animals and the environment

Appropriate engineering controls:
If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust levels below recommended exposure limits.

Individual protection measures
Respiratory protection: Provide sufficient air exchange and/or exhaust in work rooms. Respirator with a particle filter (EN 143) See also the exposure scenario.
Hand protection: Protective gloves: Nitrile rubber.
Eye/face protection: Tightly fitting safety goggles. Do not wear contact lenses.
Skin protection: Long sleeved clothing, close fittings at openings. Footwear protecting against chemicals.

Hygiene measures:
Wash hands and face before breaks and immediately after handling the product. If needed: Use protective skin cream before handling the product. When using, do not eat, drink or smoke.
Environmental exposure controls: Exhaust ventilation equipped with filters. Do not flush into surface water or sanitary sewer system.

First aid measures: If systems persist or in case of doubt seek medical advice
Inhalation: If inhaled move to fresh air. Call a doctor.
Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation develops, get medical attention.
Eye contact: Rinse immediately with plenty of water, also under eyelids for at least 15 minutes.
Remove contact lenses. Get medical attention.
Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.
Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

Environmental precautions Do not flush into surface water or sanitary sewer system. Protect from moisture. If the product contaminates rivers and lakes or drains inform respective authorities.

Empty containers: Can be landfilled or incinerated, when in compliance with local regulations. After usage, empty the packing completely.
Waste from residues / unused products: Dispose of in compliance with local and national regulations.

2.2.10 Assessment of endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in the product Saniblanc QM:

1. Assessment of the ED properties of the active substances in Saniblanc QM:
   - According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Calcium magnesium oxide is not part of the list[4] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
   - Therefore, BE eCA considers that there are no concerns regarding ED properties of Calcium magnesium oxide.

2. Assessment of the ED properties of non-active substances (co-formulants) in Saniblanc QM:
   - After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product Saniblanc QM.
If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.11 Assessment of a combination of biocidal products

The products are not claimed for use in combination with other biocidal products.

2.2.12 Comparative assessment

The substance has neither been identified as a Candidate for Substitution nor does it fulfill any of the Exclusion criteria. A comparative assessment is not therefore required.

[4] Please refer to CA-September18.Doc.7.5.a-final .

3 ANNEXES

3.1 List of studies for the biocidal product

Type		Section information		Annex II/III requirement		Open IUCLID document	
Biocidal product		**Section No.** 3.1 **Section Name:** Appearance (at 20°C and 101.3 kPa) **Name given to the Document:** Appearance (at 20°C and 101.3 kPa) - active substance reference		Appearance (at 20°C and 101.3 kPa)		Document UUID: cddcea88-0033-49a7-aeef-44f74da74f20 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.GeneralInformation/cddcea88-0033-49a7-aeef-44f74da74f20 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: review article or handbook	Title: CD Römpp Chemie Lexikon – Version 1.0	Author: Georg Thieme	Bibliographic source: CD Römpp Chemie Lexikon – Version 1.0, Stuttgart/New York: Georg Thieme Verlag 1995 Year: 1995	Testing facility: No testing laboratory provided	Report no.: No report number provided	Study sponsor: No company owner provided Study number: No company study number provided	Report date: No report date provided
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.2 **Section Name:** Acidity, alkalinity **Name given to the Document:** Acidity, alkalinity - active substace reference		Acidity, alkalinity		Document UUID: f8e08a82-bbe7-4152-879f-e76fa326c1a1 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-	

						8ea26f7afb9a/ENDPOINT_STUDY_RECORD.Ph/f8e08a82-bbe7-4152-879f-e76fa326c1a1 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Hydrated Lime active substance dossier: Doc. No.: 215-001; CB3.5/01	Author:No author provided	Bibliographic source: No bibliographic source provided Year: No year provided	Testing facility: No testing laboratory provided	Report no.: No report number provided	Study sponsor: No company owner provided Study number: No company study number provided	Report date: No report date provided
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.4.1 **Section Name:** Storage stability tests **Name given to the Document:** Storage stability tests- active substance reference		Storage stability tests		Document UUID: 9179c4d2-feb5-4988-9ac7-6514607601bb Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.StorageStability/9179c4d2-feb5-4988-9ac7-6514607601bb or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Burnt Lime active substance dossier: Doc. No.: 245-001; CB3.7/01	Author:No author provided	Bibliographic source: No bibliographic source provided Year: No year provided	Testing facility: No testing laboratory provided	Report no.: No report number provided	Study sponsor: No company owner provided Study number: No company study number provided	Report date: No report date provided
Remarks: no remarks in literature reference							

<table>
<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 3.4.2.1
Section Name: Light
Name given to the Document:
Reactivity towards container material - active substance reference</td><td colspan="2">Light</td><td colspan="2">Document UUID: a7f9a77f-6ede-473d-af70-6f3b0db8eb35
Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.StabilityThermal/a7f9a77f-6ede-473d-af70-6f3b0db8eb35 or, if you have a server version of IUCLID running, open the IUCLID document in the server version of IUCLID</td></tr>
<tr><td>Reference type: study report</td><td>Title: Burnt Lime active substance dossier: Doc. No.: 245-001; CB3.7/01</td><td>Author:No author provided</td><td>Bibliographic source: No bibliographic source provided

Year: No year provided</td><td>Testing facility: No testing laboratory provided</td><td>Report no.: No report number provided</td><td>Study sponsor: No company owner provided

Study number: No company study number provided</td><td>Report date: No report date provided</td></tr>
<tr><td colspan="8">Remarks: no remarks in literature reference</td></tr>
<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 3.5
Section Name: Technical characteristics of the representative biocidal products
Name given to the Document:
Particle size distribution (gran ulometry).001</td><td colspan="2">Technical characteristics of the representative biocidal products</td><td colspan="2">Document UUID: 1c387b60-b72f-41f7-bc48-fced5482d40a
Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.TechnicalCharacteristics/1c387b60-b72f-41f7-bc48-fced5482d40a?submissionType=COMPLETE#Technical%20characteristics%20of%20the%20biocidal%20product-EU%20BPR or, if you have a server version of IUCLID running, open the IUCLID document in the server version</td></tr>
</table>

						of IUCLID	
Reference type: study report	Title: Final-report on the determination of the dust generation tendency ("dustiness") of Calcium magnesium oxide Neutralac QM³	Author: Parr, H.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: DMT GmbH & Co. KG, Am Technologiepark 1, 45307 Essen, Germany	Report no.: GS 3-0006410	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date : Jun 17, 2010
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.5 **Section Name:** Technical characteristics of the representative biocidal products **Name given to the Document:** Particle size distribution (gran ulometry).001		Technical characteristics of the representative biocidal products		Document UUID: 1c387b60-b72f-41f7-bc48-fced5482d40a Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.TechnicalCharacteristics/1c387b60-b72f-41f7-bc48-fced5482d40a?submissionType=COMPLETE#Technical%20characteristics%20of%20the%20biocidal%20product-EU%20BPR or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Dustiness and particle size testing of nine different lime substances and qualities.	Author: Grewe, T.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: EBRC Consulting GmbH, Raffaelstr. 4, 30177 Hannover, Germany	Report no.: No report number provided	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.5 **Section Name:** Technical characteristics		Technical characteristics of the representative biocidal products		Document UUID: c363a377-b965-429e-a3f8-22cfdbedf507	

		of the representative biocidal products **Name given to the Document:** Particle size distribution (gran ulometry).002				Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.TechnicalCharacteristics/c363a377-b965-429e-a3f8-22cfdbedf507?submissionType=COMPLETE#Technical%20characteristics%20of%20the%20biocidal%20product-EU%20BPR or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Calcium magnesium oxide: Determination of general physico-chemical properties	Author: Fox, J.M.; Walker J.A.; White, D.F.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shardlow, Derbyshire, DE72 2 GD, UK	Report no.: 2937/0007	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date: Aug 11, 2010
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.5 **Section Name:** Technical characteristics of the representative biocidal products **Name given to the Document:** Particle size distribution (gran ulometry).003		Technical characteristics of the representative biocidal products		Document UUID: e11ba4c9-52d9-47ba-aebd-88d18219ec9b Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.TechnicalCharacteristics/e11ba4c9-52d9-47ba-aebd-88d18219ec9b?submissionType=COMPLETE#Technical%20characteristics%20of%20the%20biocidal%20product-	

						EU%20BPR or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Dustiness and particle size testing of nine different lime substances and qualities.	Author: Grewe, T.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: EBRC Consulting GmbH, Raffaelstr. 4, 30177 Hannover, Germany	Report no.: No report number provided	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.1 **Section Name:** Explosiveness **Name given to the Document:** Explosiveness – waiver		Explosiveness		Document UUID: c6587bc8-814f-4b4e-a200-40b0321428ec Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.Explosiveness/c6587bc8-814f-4b4e-a200-40b0321428ec?submissionType=COMPLETE#14-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Calcium magnesium oxide: Determination of hazardous physico-chemical properties	Author: Atwal, S.S.; Tremain, S.P.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shardlow, Derbyshire, DE72 2 GD, UK	Report no.: 2937/0008	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date: Jun 17, 2010
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.2 **Section Name:** Flammability **Name given to the Document:**		Flammability		Document UUID: 5d31e27e-1b7c-46a7-ad82-1e2a1407f12f Open this IUCLID document in your web	

		Flammability – waiver				browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.Flammability/5d31e27e-1b7c-46a7-ad82-1e2a1407f12f?submissionType=COMPLETE#13-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Calcium magnesium oxide: Determination of hazardous physico-chemical properties	Author: Atwal, S.S.; Tremain, S.P.	Bibliographic source: No bibliographic source provided Year: 2010	Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shardlow, Derbyshire, DE72 2 GD, UK	Report no.: 2937/0008	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date: Jun 17, 2010
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.4 **Section Name:** Oxidising properties **Name given to the Document:** Oxidising properties - solids - waiver		Oxidising properties		Document UUID: 0d891a91-c369-4a76-8844-4f85cd2a51e6 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.OxidisingProperties/9ac778b9-6ff4-4509-b251-08ea47583173?submissionType=COMPLETE#15-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Calcium magnesium oxide: Determination of	Author: Atwal, S.S.; Tremain, S.P.	Bibliographic source: No bibliographic source	Testing laboratory: Harlan Laboratories Ltd., Shardlow	Report no.: 2937/0008	Company owner: EuLA, Rue des deux Eglises 26 Box	Report date: Jun 17, 2010

	hazardous physico-chemical properties		provided Year: 2010	Business Park, Shardlow, Derbyshire, DE72 2 GD, UK		2, 1000 Bruxelles, Belgium	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.16 **Section Name:** Corrosive to metals **Name given to the Document:** Corrosive to metals_ BAM 1999		Corrosive to metals		Document UUID: 0e2fd22f-14fb-48e2-926f-4146dfffa809 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.CorrosiveToMetals/0e2fd22f-14fb-48e2-926f-4146dfffa809 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Beurteilung der korrosion von kalkmilch hinsichtlich ihrer einstufung als atzender stoff der Klasse 8 “atzende stoffe” im sinne der transportlichen vorschriften.	Author: Ruckert J and Hopfner W	Bibliographic source: No bibliographic source provided Year: 1999	Testing laboratory: Bundessanstalt fur Materialforschung und - prufung (BAM) 12200 Berlin, Germany	Report no.: No report number provided	Company owner: Bundesverband der Deutschen Kalkindustrie e.V. Postfach 51 05 50, 50 941 Koln Germany Company study number: VII.41/13514	Report date: Jan 11, 2000
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.16 **Section Name:** Corrosive to metals **Name given to the Document:** Corrosive to metals_ CTL 2012		Corrosive to metals		Document UUID: ba3c437c-b2ad-469e-b5f3-a64cba0f6576 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f331	

						2e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.CorrosiveToMetals/ba3c437c-b2ad-469e-b5f3-a64cba0f6576 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Corrosion Testing per OSHA Regulations CFR 1910.1200 Appendix B	Author: Ownsby RL and Krantz BD	Bibliographic source: No bibliographic source provided Year: 2012	Testing laboratory: Corrosion Testing Laboratories, Inc (CTL) 60 Blue Hen Drive, Newark, DE 19713 USA	Report no.: No report number provided	Company owner: Corrosion Probe, Inc. 12 Industrial Park Rd. P.O. BOX 178 Centerbrook, CT 06409-0178 Company study number: 29392-1R	Report date: Aug 27, 2012
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.17.1 **Section Name:** Auto-ignition temperature (liquids and gases) **Name given to the Document:** Relative self-ignition temperature for solids - Waiver				Document UUID: 30c96de9-d358-42eb-872f-3941d5f275e7 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.AutoFlammability/30c96de9-d358-42eb-872f-3941d5f275e7?submissionType=COMPLETE#12-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Calcium magnesium oxide: Determination of hazardous physico-chemical properties	Author: Atwal, S.S.; Tremain, S.P.	Bibliographic source: No bibliographic source provided	Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shardlow,	Report no.: 2937/0008	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date: Jun 17, 2010

			Year: 2010	Derbyshire, DE72 2 GD, UK			
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 4.17 **Section Name:** Additional physical indicators for hazards **Name given to the Document:** Self-heating substances and mixtures				Document UUID: 0cfa59b1-ca8b-4176-9dff-a3c23c11e333 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/dossier/7fe54869-82d7-44e4-bedc-d30ba54cc28c?content_uri=iuclid6:%2F7fe54869-82d7-44e4-bedc-d30ba54cc28c%2FMIXTURE%2Fa9a51b4a-0b34-47f5-bd17-7eab876f4189%2FENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical%2F0cfa59b1-ca8b-4176-9dff-a3c23c11e333&node=0cfa59b1-ca8b-4176-9dff-a3c23c11e333&treeId=BIOC_BIOCIDAL_PRODUCT or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Saniblanc QM UN Test N.4: Self-heating Substances	Author:	Bibliographic source: No bibliographic source provided Year: 2021	Testing laboratory: DEKRA Organisational and Process Safety, Phi House, Southampton Science Park, Southampton, Hampshire, SO16 7NS, UK	Report no.: S3016010150R1/2021	Company owner: Lhoist S.A	Report date:17th of August, 2021
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials		Document UUID: c3149e87-7add-4871-a4da-e095f5b5f257 Open this IUCLID document in your web	

		Name given to the Document: 6.7-1 from AS A5.10.01 Schirm et al. Hygienisation of biowaste. 2003 (Phase 3 - PT 2 - simulated use)		used including performance standards where appropriate and relevant		browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/c3149e87-7add-4871-a4da-e095f5b5f257 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Development of a safe method to hygienise bio-waste with lime	Author: Schirm V. et al	Bibliographic source: Forschungsgemainschaft Kalk, 1/03/ C 023 Jan 2003 Year: 2003	Testing laboratory: NA	Report no. 336-0201	Company owner: NA Company study number: NA	Report date: Jan 1, 2003
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-2 from AS A5 10.02 Capizzi-Banas et al Liming as an advanced treatment for sludge sanitisation. 2004 (Phase 3 - PT 2)		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 35a8e49c-a238-43bb-ad2a-15b156859b9d Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/35a8e49c-a238-43bb-ad2a-15b156859b9d or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Liming as an advanced treatment for sludge sanitisation: helminth eggs	Author: Capizzi-Banas S.	Bibliographic source: Water Research 38: 3251-3258: Doc. No. 392-024	Testing laboratory: NA	Report no. NA	Company owner: NA Company study number: NA	Report date: Dec 31, 2004

	elimination - Ascaris as a model		Year: 2004				
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-3 From AS A5 10.03 Pfuderer G Hygenic aspects related to the treatment and use of sewage sludge. 1985 (Phase 2 - PT 2)		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: a2f6ccd5-9330-4dc8-977f-9697ba12c1d1 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/a2f6ccd5-9330-4dc8-977f-9697ba12c1d1 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Hygenic aspects related to treatment and use of sewage sludge	Author: Pfuderer G.	Bibliographic source: Ed P. L'Hermite, Elsevier, pp 85-97; Doc No 392-035 Year: 1984	Testing laboratory: NA	Report no. NA	Company owner: NA Company study number: NA	Report date: Dec 31, 1985
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-6 - Evaluation of Liming in liquid and solid manure (Phase 2 - PT 2 and 3), Daugshies, 2008		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 9622d657-8d10-401a-bb18-13cd27665fb9 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/9622d657-8d10-401a-bb18-13cd27665fb9 or, if you have a server version of IUCLID running, open the IUCLID document in the **server**	

						version of IUCLID	
Reference type: study report	Title: Evaluation of limingin liquid and solid manure	Author: Prof. Dr. A. Daugshies	Bibliographic source: NA Year: 2008	Testing laboratory: VMF, Leipig, Germany	Report no. not assigned	Company owner: EuLA Company study number: not assigned	Report date: Feb 6, 2008
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-7 Calcium oxide, Clean conditions, EN 14349 Phase 2 Step 2 (non porous surface test), MSL, 2018		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: beef5a48-ccbb-40e2-ab6f-382d0aca55a8 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/beef5a48-ccbb-40e2-ab6f-382d0aca55a8 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action (Phase 2 Step 2)	Author: Crane D., Burney C.,	Bibliographic source: NA Year: 2018	Testing laboratory: MLS. Bury, UK	Report no. J000714-1	Company owner: EuLA, Brussels, Belgium Company study number: J000714-1	Report date: Mar 19, 2018
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support		Efficacy data to support these claims, including any available standard		Document UUID: 6685b765-244d-4488-9acf-f1c56b57db9e	

		these claims **Name given to the Document:** 6.7-8 Calcium oxide, Dirty conditions EN 14349 Phase 2 Step 2 (non porous surface test, MSL, 2018		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/6685b765-244d-4488-9acf-f1c56b57db9e or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action, dirty conditions (Phase 2 Step 2)	Author: Crane D., Burney C.	Bibliographic source: NA Year: 2018	Testing laboratory: MSL Bury, UK	Report no. J000714-1	Company owner: EuLA, Brussels, Belgium Company study number: J000714-1	Report date: Mar 19, 2018
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-13 - Evaluation of Liming in liquid manure - 90 day - Phase 2 (PT 3), Daugshies, May 2008		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: cb1a7969-af34-4ee1-ba4d-69bac5659019 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/cb1a7969-af34-4ee1-ba4d-69bac5659019 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	

Reference type: study report	Title: Evaluation of the effect of liming in liquid pig and cattle manure on Ascaris suum eggs	Author: Prof. Dr. Daugschies	Bibliographic source: NA Year: 2008	Testing laboratory: VMF Leipzig	Report no. NA	Company owner: EuLA Brussels Belgium Company study number: NA	Report date: Apr 10, 2008
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-14 Calcium Oxide_Simulated test_ Modified NF T 72-281, (PT 3) Bacteria, Yeast Fungi, High Level Soil, Strohl, 2019		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 15e51617-4455-41d5-b170-b42d7a40069e Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/15e51617-4455-41d5-b170-b42d7a40069e or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Test Report No RE-1102/0219 Determination of microbicide activity of 2 powders: hydra-lime and oxi-lime according to a methodology issued to NF T 72-281 - Powder One - Calcium Oxide (oxi-lime)	Author: Amandine Carre and Dr. Philippe Strohl	Bibliographic source: NA Year: 2019	Testing laboratory: IRM, 77290, Mitry-Mory, France	Report no. RE-1102/0219	Company owner: EuLA, Rue Des Deux Eglises 26 box 2, 1000 Bruxelles, Belgium Company study number: RE-1102/0219	Report date: Jul 31, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support		Efficacy data to support these claims, including any available standard		Document UUID: 7b228c5c-94df-4170-85eb-733b7e476649	

		these claims **Name given to the Document:** 6.7-14A Calcium oxide Modified NF T 72-281, Fungi, Aspergillus brasiliensis, Veterinary Low Level Soil, RE-1302/ 0919/A , Carre, Final, 2019		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/dossier/7fe54869-82d7-44e4-bedc-d30ba54cc28c?content_uri=iuclid6:%2F7fe54869-82d7-44e4-bedc-d30ba54cc28c%2FMIXTURE%2Fa9a51b4a-0b34-47f5-bd17-7eab876f4189%2FENDPOINT_STUDY_RECORD.EfficacyData%2F7b228c5c-94df-4170-85eb-733b7e476649&node=7b228c5c-94df-4170-85eb-733b7e476649&treeId=BIOC_BIOCIDAL_PRODUCT or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Test Report No RE-1302/0919/A Determination of microbicide activity of EuLA oxi-lime 23 according to a methodology issued to NF T 72-281 (Fungicidal Only)	Author: Amandine Carre and Dr. Philippe Strohl	Bibliographic source: NA Year: 2019	Testing laboratory: IRM, 77290, Mitry-Mory, France	Report no. RE-1302/919/A	Company owner: EuLA, Rue Des Deux Eglises 26 box 2, 1000 Bruxelles, Belgium Company study number: RE-1302/919/A	Report date: 25th of October 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-14B Calcium oxide Modified NF T 72-281, Virus - Porcine Parvovirus, Veterinary High Level Soil, RE-1297/ 0819, Carre, Final, 2019		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 2287275b-48c7-4c1d-b391-03d1c249cd42 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/dossier/7fe54869-82d7-44e4-bedc-d30ba54cc28c?content_uri=iuclid6:%2F7fe54869-82d7-44e4-bedc-	

						d30ba54cc28c%2FMIXTURE%2Fa9a51b4a-0b34-47f5-bd17-7eab876f4189%2FENDPOINT_STUDY_RECORD.EfficacyData%2F2287275b-48c7-4c1d-b391-03d1c249cd42&node=2287275b-48c7-4c1d-b391-03d1c249cd42&treeId=BIOC_BIOCIDAL_PRODUCT or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Test Report No RE-1297/0819 Determination of microbicide activity of EuLA Oxi-lime 23 according to a methodology issued to NF T 72-281 and prEN 17122 (Virucidal Efficacy)	Author: Amandine Carre and Dr. Philippe Strohl	Bibliographic source: NA Year: 2019	Testing laboratory: IRM, 77290, Mitry-Mory, France	Report no. RE - 1297/0819	Company owner: EuLA, Rue Des Deux Eglises 26 box 2, 1000 Bruxelles, Belgium Company study number: RE - 1297/0819	Report date:4th of November, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-16 Calcium oxide - Phase 3: Field Trial - PT 3 Poultry - RITTMO 18-445R		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: be96ad68-7eea-4123-8144-6eb5c5c4772f Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/be96ad68-7eea-4123-8144-6eb5c5c4772f or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	

Reference type: study report	Title: EFFECTIVENESS STUDY OF A BIOCIDE PRODUCT FOR TREATMENT OF POULTRY (FARM TRIAL)	Author: Nassar N et al	Bibliographic source: No bibliographic source provided Year: 2019	Testing laboratory: RITTMO Agroenvironnement 37, rue de Herrlisheim - Z.A Biopôle - 68000 Colmar France	Report no.: No report number provided	Company owner: Lhoist o behalf of EuLA Company study number: 18-445R	Report date: Apr 16, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-17 Calcium oxide - Phase 3: Field Trial - PT 3 Poultry - RITTMO 19-415R		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: cad9bed5-b7f0-481f-9285-52b0f0cfd5a1 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/cad9bed5-b7f0-481f-9285-52b0f0cfd5a1 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: EFFICACY STUDY OF A BIOCIDAL PRODUCT FOR THE TREATMENT OF POULTRY HOUSING	Author: NassarN et al	Bibliographic source: No bibliographic source provided Year: 2019	Testing laboratory: RITTMO Agroenvironnement 37, rue de Herrlisheim - Z.A Biopôle - 68000 Colmar France	Report no.: No report number provided	Company owner: Lhoist on behalf of EuLA Company study number: 19-415R	Report date: Apr 16, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-18 Calcium oxide - Phase 3: Field Trial - PT 3 Pigs - RITTMO 19-413R		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 31713e94-eeb5-462c-85ad-620480db38d4 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f331	

						2e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/31713e94-eeb5-462c-85ad-620480db38d4 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: EFFICACY STUDY OF A BIOCIDAL PRODUCT Treatment of swine husbandry building	Author: Nassr N et al	Bibliographic source: No bibliographic source provided Year: 2019	Testing laboratory: RITTMO Agroenvironnement 37, rue de Herrlisheim - Z.A Biopôle - 68000 Colmar France	Report no.: No report number provided	Company owner: Lhoist on behalf of EuLA Company study number: 19-413R	Report date: Apr 16, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-19 Calcium magnesium oxide - Phase 3: Field Trial - PT 3 Poultry - RITTMO 19-446R		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 2287275b-48c7-4c1d-b391-03d1c249cd42 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/dossier/7fe54869-82d7-44e4-bedc-d30ba54cc28c?content_uri=iuclid6:%2F7fe54869-82d7-44e4-bedc-d30ba54cc28c%2FMIXTURE%2Fa9a51b4a-0b34-47f5-bd17-7eab876f4189%2FENDPOINT_STUDY_RECORD.EfficacyData%2F2287275b-48c7-4c1d-b391-03d1c249cd42&node=2287275b-48c7-4c1d-b391-03d1c249cd42&treeId=BIOC_BIOCIDAL_PRODUCT or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type:	Title:	Author: Nassr N et	Bibliographic	Testing laboratory:	Report no.: No	Company owner:	Report date: 29th of

study report	EFFICACY STUDY OF A BIOCIDAL PRODUCT FOR THE TREATMENT OF POULTRY HOUSING - Saniblanc QM	al	source: No bibliographic source provided Year: 2019	RITTMO Agroenvironnement 37, rue de Herrlisheim - Z.A Biopôle - 68000 Colmar France	report number provided	Lhoist on behalf of EuLA Company study number: 19-446R	April, 2019
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-22 Calcium magnesium oxide Modified NF T 72-281, Bacteria, Yeast, Fungi, Viruses, Veterinary High Level Soil, Carre (pending final results)		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 1b817fbb-e8b7-4a62-badb-f71a6f661501 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/dossier/7fe54869-82d7-44e4-bedc-d30ba54cc28c?content_uri=iuclid6:%2F7fe54869-82d7-44e4-bedc-d30ba54cc28c%2FMIXTURE%2Fa9a51b4a-0b34-47f5-bd17-7eab876f4189%2FENDPOINT_STUDY_RECORD.EfficacyData%2F1b817fbb-e8b7-4a62-badb-f71a6f661501&node=1b817fbb-e8b7-4a62-badb-f71a6f661501&treeId=BIOC_BIOCIDAL_PRODUCT or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Determination of microbicide activity of lime according to a methodology modelled on NF T 72-281	Author: Amandine Carré	Bibliographic source: No bibliographic source provided Year: 2021	IRM, 77290, Mitry-Mory, France	Report no.: RE-1293/0721-1 and RE-1293/0721-2	Company owner: Lhoist	Report date: 19th of October 2021
Remarks: no remarks in literature reference							

Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** 6.7-23 Calcium oxide - Phase 3: Field Trial - PT 3 Poultry - Comparison of results between mud floors and conce		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		Document UUID: 31713e94-eeb5-462c-85ad-620480db38d4 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/dossier/0/MIXTURE/3f3312e4-2b18-4146-8c9e-8ea26f7afb9a/ENDPOINT_STUDY_RECORD.EfficacyData/31713e94-eeb5-462c-85ad-620480db38d4 or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Comparaison de résultats de décontamination entre un sol en terre battue et un sol cimenté	Author: H. Valancony, F. Humbert, P. Drouin, F. Lalande et L. Balaine	Bibliographic source: No bibliographic source provided Year: 2000	Testing laboratory: AFSSA Ploufagran	Report no.: No report number provided	Company owner: EuLA	Report date: 2000
Remarks: no remarks in literature reference							
Biocidal product		**Section No.**: 8.3 **Section Name:** Sensitisation **Name given to the Document:** Skin sensitisation		Skin sensitisation		Document UUID: 6cd838c4-5f57-4522-a9c1-c48b44f89b3f Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.SkinSensitisation/6cd838c4-5f57-4522-a9c1-c48b44f89b3f?submissionType=COMPLETE#66-1-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type:	Title: Evaluation of	Author: Witte, F. et	Bibliographic				

publication	the skin sensitizing potential of biodegradable magnesium alloys	al.	source: J. Biomed. Mater. Res. A. 86, 1041-1047 Year: 2007				
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 8.5.1 **Section Name:** Acute toxicity: oral **Name given to the Document:** Acute toxicity: oral		Acute toxicity: oral		Document UUID: a840e172-d030-42bd-aa14-21975d10a2f7 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.AcuteToxicityOral/a840e172-d030-42bd-aa14-21975d10a2f7?submissionType=COMPLETE#60-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Neutralac QM³, Neutralac HM, PRECAL 30S and PRECAL 50S: Acute oral toxicity study in the rat (up and down procedure)	Author: Arcelin, G.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: RCC Ltd., Wölferstrasse 4, 4414 Füllinsdorf/Switzerland	Report no.: B22151	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date : Jul 17, 2007
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 8.6 **Section Name:** Dermal absorption **Name given to the Document:** Dermal absorption		Dermal absorption		Document UUID: a49a5e86-41a9-46d3-aa05-4867f339111e Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-	

						0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.DermalAbsorption/a49a5e86-41a9-46d3-aa05-4867f339111e?submissionType=COMPLETE#59-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Permeabilty of human skin to selected anions and cations - in vitro studies.	Author: Laudanska, H.; et al.	Bibliographic source: Res. Communications Molecular Pathol. Pharmacol., 16-26				
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.1.1 **Section Name:** Short-term toxicity testing on fish **Name given to the Document:** Short-term toxicity testing on fish.001		Short-term toxicity testing on fish		Document UUID: 8a029885-09d1-4f63-92a1-8312f23b7217 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish/8a029885-09d1-4f63-92a1-8312f23b7217?submissionType=COMPLETE#41-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: PRECAL 50S: a study on the acute toxicity to freshwater fish (rainbow trout).	Author: Egeler P., Weil M., Knoch E.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: ECT Oekotoxicologie GmbH, Flörsheim am Main, Germany	Report no.: AW1FA	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	Report date : Dec 16, 2007

						Company study number : 821-001	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.1.2 **Section Name:** Short-term toxicity testing on aquatic invertebrates **Name given to the Document:** Short-term toxicity testing on aquatic invertebrates.001		Short-term toxicity testing on aquatic invertebrates		Document UUID: 30da0c4b-3a01-4643-9e0a-04e2eefe9dad Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv/30da0c4b-3a01-4643-9e0a-04e2eefe9dad?submissionType=COMPLETE#43-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Preliminary evaluation of effects of invasive tunicate management with acetic acid and calcium hydroxide on non-target marine organisms in Prince Edward Island, Canada	Author: Locke A., Doe K.G., Fairchild W.L., Jackman P.M. and Reese E.J.	Bibliographic source: Aquatic Invasions (2009) Volume 4, Issue 1: 221-236 Year: 2008				
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.1.2 **Section Name:** Short-term toxicity testing on aquatic invertebrates **Name given to the Document:** Short-term toxicity testing on aquatic invertebrates.002		Short-term toxicity testing on aquatic in vertebrates		Document UUID: 8a029885-09d1-4f63-92a1-8312f23b7217 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RE	

						CORD.ShortTermToxicityToAquaInv/c0abd20d-6fca-453b-a36b-fc79886f4104?submissionType=COMPLETE#43-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: PRECAL 50S: a study on the acute toxicity to freshwater fish (rainbow trout).	Author: Egeler P., Weil M., Knoch E.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: ECT Oekotoxicologie GmbH, Flörsheim am Main, Germany	Report no.: AW1FA	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium Company study number : 821-001	Report date : Dec 16, 2007
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.1.5 **Section Name:** Inhibition of microbial activity **Name given to the Document:** Inhibition of microbial activity		Toxicity to microorganisms		Document UUID: 1a7778a1-be78-450c-ae35-af3da4a307a8 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms/1a7778a1-be78-450c-ae35-af3da4a307a8?submissionType=COMPLETE#47-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: PRECAL 50S: a study on the acute toxicity to freshwater fish (rainbow trout).	Author: Egeler P., Weil M., Knoch E.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: ECT Oekotoxicologie GmbH, Flörsheim am Main, Germany	Report no.: AW1FA	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium Company study	Report date : Dec 16, 2007

						number : 821-001	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.1.7 **Section Name:** Bioaccumulation in an appropriate aquatic species **Name given to the Document:** Bioaccumulation in an appropriate aquatic species - waiver		Toxicity to aquatic organisms		Document UUID: cdb1b13d-4ee9-4ec9-8fb0-61fe94781992 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.TechnicalCharacteristics/e11ba4c9-52d9-47ba-aebd-88d18219ec9b?submissionType=COMPLETE#Technical%20characteristics%20of%20the%20biocidal%20product-EU%20BPR or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: publication	Title: Effect of Liming and Gypsum on Soil Chemistry, Yield, and Mineral Composition of Ryegrass Grown in an Acidic Andisol.	Author: Mora, M.L., Schnettler, B., Demanet, R.	Bibliographic source: Communications in Soil Science and Plant Analysis, 30(9&10), 1251-1266				
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.2.1 **Section Name:** Effects on soil microorganisms **Name given to the Document:** Effects on soil microorganisms – dehydrogenase activity		Effects on soil microorganisms		Document UUID: 97cd9166-59bf-43de-989a-f6ae2dbaddc5 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms/9	

						7cd9166-59bf-43de-989a-f6ae2dbaddc5?submissionType=COMPLETE#52-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Effects of calcium dihydroxide (hydrated lime) on the activity of soil microflora (dehydrogenase activity)	Author: Schulz L.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany	Report no.: 07 10 48 030 C	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium Company study number: 841-002	Report date : Dec 11, 2007
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 9.2.2.1 **Section Name:** Effects on soil microorganisms **Name given to the Document:** Effects on soil microorganisms – nitrogen transformation		Effects on soil microorganisms		Document UUID: 97cd9166-59bf-43de-989a-f6ae2dbaddc5 Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms/a9df2a1d-7e82-44ae-9722-6e5d3e878b9e?submissionType=COMPLETE#52-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the **server version** of IUCLID	
Reference type: study report	Title: Effects of calcium dihydroxide (hydrated lime) on the activity of soil microflora (nitrogen transformation test).	Author: Schulz L.	Bibliographic source: No bibliographic source provided Year: 2007	Testing laboratory: BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany	Report no.: 07 10 48 016 N	Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium Company study number: 841-001	Report date : Dec 11, 2007

<table>
<tr><td colspan="8">Remarks: no remarks in literature reference</td></tr>
<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 9.2.2.2
Section Name: Effects on earthworms or other soil-dwelling non-target invertebrates
Name given to the Document: Effects on earthworms - long-term</td><td colspan="2">Terrestrial toxicity, initial tests</td><td colspan="2">Document UUID: 1f7e0d46-abe1-4318-ba7a-0930de60d6d8
Open this IUCLID document in your web browser (the base URL may need adjusting): http://localhost:8080/iuclid6-web/browser/raw/MIXTURE/a9a51b4a-0b34-47f5-bd17-7eab876f4189/ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods/1f7e0d46-abe1-4318-ba7a-0930de60d6d8?submissionType=COMPLETE#50-1-OECD or, if you have a server version of IUCLID running, open the IUCLID document in the server version of IUCLID</td></tr>
<tr><td>Reference type: study report</td><td>Title: Sublethal toxicity of calcium dihydroxide (hydrated lime) to the earthworm eisenia fetida in artificial soil.</td><td>Author: Friedrich S.</td><td>Bibliographic source: No bibliographic source provided

Year: 2007</td><td>Testing laboratory: BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany</td><td>Report no.: 07 10 48 038 S</td><td>Company owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium

Company study number : 833-002</td><td>Report date: Dec 14, 2007</td></tr>
<tr><td colspan="8">Remarks: no remarks in literature reference</td></tr>
</table>

3.2 Output tables from exposure assessment tools

HUMAN HEALTH

SEE SEPARATE SPREADSHEETS FOR HUMAN HEATH EXPOSURES

CaO livestock_v2.xlsx

ENVIRONMENT

CaO_Application rates to soil_3004201

3.3 New information on the active substance

/

3.4 Residue behaviour

/

3.5 Summaries of the efficacy studies

/

3.6 Confidential annex

PLEASE REFER TO THE CONFIDENTIAL PAR

3.7 Other