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 UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

EULA OXI-LIME 23

Product type(s) 2 and 3

Calcium oxide

Case Number in R4BP: BC-VJ038509-19

Evaluating Competent Authority: FR

Date: July 2022

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1 CONCLUSION

SUMMARY OF THE EVALUATION AND CONCLUSIONS OF THE RISK ASSESSMENT

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product EULA OXI-LIME 23.

General
France, as e-CA, received an application from European Lime Association aisbl for Union authorisation for the biocidal product EULA OXI-LIME 23.

The biocidal product EULA OXI-LIME 23, containing 100% calcium oxide[1], is a product type (PT) 2 and 3 intended to be used for disinfection of sewage sludge and manures, indoor floor surfaces of animal accommodations and transportation, and outdoor floor surfaces. The biocidal product EULA OXI-LIME 23 is a dustable powder to be used by professional users.

Physical, chemical and technical properties of the product

The product is the same as the active substance.
It is a white dusty solid of naturally occurring origin. The dusts are within the inhalable/respirable range fraction. The solid has an alkalinity of 0.24-0.26% w/w as NaOH.
A 6 months shelf-life was accepted in the CAR of the active substance but based on the new storage study provided by the applicant, a 15 months shelf-life can be accepted for the product.

The product is not classified for any physical hazard properties.

Labelling:
Protect from humidity.
Do not store above 30°C.
EUH014: reacts violently with water.

The product being the same as the active substance, thus analytical methods or justification for non-submission of data, submitted in the frame of the active substance approval, are also applicable and relevant to the product.

Efficacy

The product EULA OXI-LIME 23 has shown a sufficient efficacy:

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

The effective final use concentration and contact time are variable. pH should be > 12 and temperature > 50°C during the exposure time.
The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature and should be calculated by the user based on the dry weight of the substrate.

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

1 COMMISSION IMPLEMENTING REGULATION (EU) 2016/1936 of 4 November 2016 approving calcium oxide (burnt lime) as an existing active substance for use in biocidal products of product-types 2 and 3.

Regarding virus, for the disinfection of sewage sludge, the EFF WG (WG I 2022 meeting) concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study. This target organism is therefore not proposed for authorisation on this use.

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

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

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

✓ For the disinfection of indoor floor surfaces of animal accommodations and transportation, and floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus.

The effective application rate is of 600 g CaO/m².

Human Health

The product EULA OXI-LIME 23 is classified as follow for human health:

H315: Causes skin irritation
H318: Causes serious eye damage
H335: May cause respiratory irritation

Systemic and local quantitative risk assessments have been performed in line with the CAR. No risk for operator is expected considering systemic effects, as intake of Ca^{2+} and Mg^{2+} during application combined with the dietary intake is still below the Upper Limit values set for Ca^{2+} and Mg^{2+} by EFSA. Regarding local effect by inhalation (respiratory irritation), the risk is deemed acceptable based on the experimental data provided in the dossier and a weight of evidence approach.

- **Disinfection of sewage sludge and manures**

The risk for human health is considered acceptable **only for the fully automated process** (including loading and disposal of empty bags) considering the following PPE are worn:
- gloves;
- protective coverall;
- respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter).

Moreover, it is also likely that the addition of calcium oxide to sewage sludge or manure leads to the production of ammonia gas, which may be of concern. During the treatment of sewage sludge, wearing RPE specific for air fed ammonia gas or for canisters, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.

In addition to the above mentioned PPE, the following RMMs are required:
- The pouring of the burnt lime into the treatment unit must be done fully automatically.
- Considering the use of big bags (500-1200 kg), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).

- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including loading, application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

- **Disinfection of indoor and outdoor floor surfaces**

The risk for human health is considered acceptable for the loading, the application and the disposal of empty bags considering the following PPE:

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

In addition to above-mentioned PPE, the following RMM are needed:

- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including loading, application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimize the remaining powder;
- Fold carefully the small bag in order to avoid any spills.
- Considering the use of big bags (500-1200 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- Use in a well ventilated area.

Animal Health

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

- Animals should not be present during all the treatment duration.
- Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals. Collect the resulting dry waste and recycle them as agricultural liming material or dispose the dry waste according to local requirements.
  For animal transportation use only: after brushing, rinse and clean the vehicle.
- Feed and drinking water must be carefully covered or removed during the application of the product.

Consumers via residues in food

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

Environment

The product EULA OXI-LIME 23 is not classified for the environment.

The risks are considered acceptable for the environment for the uses:

In PT2:

- ✓ disinfection of sewage sludge,

In PT3: considering the following RMM "Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water.":

- ✓ disinfection of manure,
- ✓ disinfection of indoor floors of animal accommodations and transportation,

This RMM is necessary for these uses as the risk assessment is conducted for the release to the STP and risks are expected for the STP microorganisms.

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

- ✓ disinfection of floors of outdoor animal enclosures.

PRESENTATION OF THE BIOCIDAL PRODUCT/BIOCIDAL PRODUCT FAMILY INCLUDING CLASSIFICATION AND LABELLING

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

DESCRIPTION OF USES PROPOSED TO BE AUTHORISED

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

COMPARATIVE ASSESSMENT

The active substance calcium oxide contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product was not performed in accordance with Article 23(1) of Regulation (EU) No 528/2012.

OVERALL CONCLUSION OF THE EVALUATION OF THE USES PROPOSED TO BE AUTHORISED

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the product is reported in the table below, for each use.

Uses	Target	Conditions of use	Conclusions
Disinfection of sewage sludge	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Professional The dry product is mixed with the sewage sludge in an open mixer.	**Acceptable except for yeast, fungi and virus**
Disinfection of manure	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Professional The product is mixed with the manure.	**Acceptable except for yeast and fungi**
Disinfection of indoor floor surfaces of animal accommodations and transportation	Bacteria, yeast, fungi, viruses	Indoor Professional Direct application	**Acceptable**
Disinfection of floors of outdoor animal enclosures	Bacteria, yeast, fungi, viruses	Outdoor Professional Direct application	**Acceptable**

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
   - the fate and distribution of the biocidal product in the environment,

- contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
- the impact of the biocidal product on non-target organisms,
- the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[2]	**Country (if relevant)**
EULA OXI-LIME 23	Union Authorisation

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	European Lime Association aisbl (EuLA)
	Address	c/o IMA-Europe aisbl, Rue des Deux Eglises 26, box 2, B-100 Brussels, Belgium
Pre-submission phase started on		
Pre-submission phase concluded on		
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Cal Industrial SL
Address of manufacturer	Pedro I, 19-21 31 007 Pamplona, Spain
Location of manufacturing sites	Pedro I, 19-21 31 007 Pamplona, Spain

Name of manufacturer	Calera de Alzo, S. L.
Address of manufacturer	Postal number: 20.268, Egileor auzoa, 101. Altzo (Guipúzcoa), Spain
Location of manufacturing sites	Egileor auzoa, 101. Altzo (Guipúzcoa), Spain

Name of manufacturer	Caleras de San Cucao, S.A.
Address of manufacturer	Agüera s/n 33425-San Cucao de Llanera, Spain
Location of manufacturing sites	Agüera s/n 33425-San Cucao de Llanera, Spain

Name of manufacturer	Cales Pascual S.L.
Address of manufacturer	C/ Cura Bau, 15. 46112 Valencia, Spain
Location of manufacturing sites	Ctra. Valencia-Ademuz, KM 9.3. Paterna, Valencia, Spain

Name of manufacturer	CalGov

2 Please fill in here the identifying product name from R4BP 3.

Address of manufacturer	Carretera Fuente, Apartado 2, 41 560, Estepa, Spain
Location of manufacturing sites	Carretera Fuente, Apartado 2, 41 560, Estepa, Spain

Name of manufacturer	Carmeuse Chaux
Address of manufacturer	215 route d'Arras, 62320 Bois Bernard, France
Location of manufacturing sites	215 route d'Arras, 62320 Bois Bernard, France

Name of manufacturer	Carmeuse Czech Republic s.r.o.
Address of manufacturer	Mokrá 359,664 04 Mokrá, Czech Republic
Location of manufacturing sites	závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czech Republic

Name of manufacturer	Carmeuse Holding Srl
Address of manufacturer	Str.Carierei Nr.127A, 500047 Brasov, Romania
Location of manufacturing sites	Str Garii 2, 135100 Fieni, Romania. Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Privat, 117805 Campulung, Romania.

Name of manufacturer	Carmeuse Hungaria kft
Address of manufacturer	HRSZ 064/1, 7827 Beremend, Hungary
Location of manufacturing sites	HRSZ 064/1, 7827 Beremend, Hungary

Name of manufacturer	Carmeuse SA
Address of manufacturer	Rue du Château 13a, 5300 Seilles, Belgium
Location of manufacturing sites	Rue de Boudjesse 1, 5070 Aisemont, Belgium. Rue du Val Notre Dame 300, 4520 Moha, Belgium. Rue du Château 13a, 5300 Seilles, Belgium..

Name of manufacturer	Carmeuse Slovakia s.r.o.
Address of manufacturer	Slavec, 049 11 Slavec, Slovakia
Location of manufacturing sites	závod Vápenka Košice, Vstupný areál U.S. Steel, 044 54 Košice, Slovakia. závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia.

Name of manufacturer	Carrières et Chaux Balthazard et Cotte
Address of manufacturer	Rue du Pra Paris, 38 360 Sassenage, France
Location of manufacturing sites	Rue du Pra Paris, 38 360 Sassenage, France

Name of manufacturer	Carrières et fours à chaux de Dugny
Address of manufacturer	B.P.1, 55 100 Dugny-sur-Meuse, France
Location of manufacturing sites	B.P.1, 55 100 Dugny-sur-Meuse, France

Name of manufacturer	Cementos Tudela Veguín, S.A.U.

Address of manufacturer	CL Argüelles 25.33003 Oviedo, Asturias, Spain
Location of manufacturing sites	CL Tino Casal, s/n. 33910, Tudela Veguín, Asturias, Spain.

Name of manufacturer	Chaux de Boran
Address of manufacturer	Route de Boran, 60 640 Précy-Sur-Oise, France
Location of manufacturing sites	Route de Boran, 60 640 Précy-Sur-Oise, France

Name of manufacturer	Chaux de Bretagne
Address of manufacturer	53 600 Evron, France
Location of manufacturing sites	53 600 Evron, France

Name of manufacturer	Chaux de Provence
Address of manufacturer	Ancien Chemin de Martigues, 13 160 Châteauneuf Les Martigues, France
Location of manufacturing sites	Ancien Chemin de Martigues, 13 160 Châteauneuf Les Martigues, France

Name of manufacturer	Chaux et Dolomies du Boulonnais
Address of manufacturer	Rue Jules Guesde, 62 720 Réty, France
Location of manufacturing sites	Rue Jules Guesde, 62 720 Réty, France

Name of manufacturer	Chaux de la Tour
Address of manufacturer	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France
Location of manufacturing sites	1 chemin des Chaux de la Tour 13 820 Ensues La Redonne, France

Name of manufacturer	Clogrennane Lime LTD
Address of manufacturer	Clogrennane Lime LTD, Clogrennane, Carlow, R93 EV26, Ireland
Location of manufacturing sites	Clogrennane, Carlow, R93 EV26, Ireland

Name of manufacturer	Dumont-Wautier
Address of manufacturer	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium
Location of manufacturing sites	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium

Name of manufacturer	Etablissement Leon Lhoist
Address of manufacturer	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium
Location of manufacturing sites	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium

Name of manufacturer	Européenne des Chaux et Liants
Address of manufacturer	2745 route du Bugey, CS22015, 38307 Bourgoin-Jallieu, France
Location of manufacturing sites	Usine de Duin, 38460 TREPT, France

Name of manufacturer	Lhoist Bukowa Sp. z o.o.
Address of manufacturer	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland
Location of manufacturing sites	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland.

Name of manufacturer	Lhoist Central Europe / Lhoist Česká republika a Slovensko Vápenka Čertovy schody a.s
Address of manufacturer	Tmaň 200, 267 21 Tmaň, Czech Republic
Location of manufacturing sites	Tmaň 200, 267 21 Tmaň, Czech Republic

Name of manufacturer	Lhoist Faxe Kalk A/S
Address of manufacturer	Hovedgaden 13, 4654 Faxe Ladeplads, Denmark
Location of manufacturing sites	Nordkajen 17, 7100 Vejle, Denmark Gl. Strandvej 14, 4640 Faxe, Denmark.

Name of manufacturer	Lhoist France Ouest
Address of manufacturer	15 rue Henri Dagallier, 38 100 Grenoble, France
Location of manufacturing sites	15 rue Henri Dagallier 38 100 Grenoble, France

Name of manufacturer	Lhoist UK Ltd
Address of manufacturer	Hindlow, Buxton, Derbyshire, SK17 OEL, UK
Location of manufacturing sites	Hindlow, Buxton, Derbyshire, SK17 OEL, UK

Name of manufacturer	Lusical
Address of manufacturer	Valverde, 2025-201 Alcanede, Portugal
Location of manufacturing sites	Valverde, 2025-201 Alcanede, Portugal

Name of manufacturer	Nordkalk AB
Address of manufacturer	Box 901 SE-731 29 Köping Sweden
Location of manufacturing sites	Nordkalk AB, Köping, Kungsängsvägen 22, SE-731 36 Köping, Sweden Nordkalk AB, KPAB Storugns Lärbro, Lärbro Storugns 2741, SE-624 53, Lärbro, Sweden

Name of manufacturer	Nordkalk AS
Address of manufacturer	Faehlmanni tee 11A, Rakke 46 301, Lääne-Virumaa, Estonia

Location of manufacturing sites	Faehlmanni tee 11A, Rakke 46 301, Lääne-Virumaa, Estonia

Name of manufacturer	Nordkalk Oy Ab
Address of manufacturer	Skräbbölevägen 18, 21600 Pargas, Finland
Location of manufacturing sites	Nordkalk Oy Ab, Louhi, Louhi, Fi-57100, Savonlinna, Finland Nordkalk Oy Ab, Tytyri, Tytyrinkatu 7, Fi-08100, Lohja, Finland. Nordkalk Oy Ab, Pargas, Kalkhamnsvägen 5, Fi-21600, Pargas, Finland

Name of manufacturer	Pigeon Chaux SAS
Address of manufacturer	29 Rue des Ruettes, 53410 Saint-Pierre-la-Cour, France
Location of manufacturing sites	La Hunaudiere - 53480 Vaiges, France

Name of manufacturer	See Bruyeres & Fils
Address of manufacturer	Le Bourg - 47500 Saint Front sur Lémance, France
Location of manufacturing sites	Le Bourg - 47500 Saint Front sur Lémance, France

Name of manufacturer	Singleton Birch
Address of manufacturer	Melton Ross Quarries, Barnetby, N Lincolnshire, DN38 6AE, UK
Location of manufacturing sites	Melton Ross Quarries, Barnetby, N.Lincolnshire, DN38 6AE, UK

Name of manufacturer	SMA Mineral AB
Address of manufacturer	Box 329, SE-682 27 Filipstad, Sweden
Location of manufacturing sites	Luleå lime plant, C/O SSAB Europe SE-971 88 Luleå, Sweden. Boda lime plant, Kärvsåsen Kalkveerksvägen 15 SE-795 96 Boda kyrkby, Sweden. Rättivik lime plant, Kalkvägen 7 SE-795 32 RÄTTVIK, Sweden. SSAB Industriområde, Kalkverket, SE-613 80 Oxelösund, Sweden.

Name of manufacturer	SMA Mineral Burgas Var LTD
Address of manufacturer	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. Nº52
Location of manufacturing sites	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. Nº52

Name of manufacturer	SMA Mineral Oy
Address of manufacturer	Selleenkatu 281, 95450 Torino, Finland
Location of manufacturing sites	SMA Mineral Oy, Röyttä Lime Plant, Selleenkatu 281, 95450 Torino, Finland

Name of manufacturer	Société des fours à chaux de Sorcy
Address of manufacturer	Route de Sorcy B.P.16, 55 190 Void, France
Location of manufacturing sites	Route de Sorcy B.P.16, 55 190 Void, France

Name of manufacturer	Spenner GmbH & Co. KG
Address of manufacturer	Bahnhofstraße 20, D-59597 Erwitte, Germany
Location of manufacturing sites	Hüchtchenweg 2, D-59597 Erwitte, Germany

Name of manufacturer	Tarmac, Lime and Powders
Address of manufacturer	Tunstead House, Wormhill, Buxton, Derbyshire, SK17 8TG, UK
Location of manufacturing sites	Tunstead Quarry, Wormhill, Buxton, Derbyshire, SK17 8TG, UK Hindlow Works, Sterndale Moor, Buxton, Derbyshire, SK17 9QD, UK.

Name of manufacturer	Trzuskawica S.A.
Address of manufacturer	Trzuskawica S.A., Sitkówka 24, 26-052 Nowiny, Poland
Location of manufacturing sites	Trzuskawica S.A., Sitkówka 24, 26-052 Nowiny, Poland

Name of manufacturer	Unicalce S.p.A
Address of manufacturer	Via Tonio da Belledo, 30 l-23900 Lecco (LC), Italy
Location of manufacturing sites	Via Ponti, 18 1-24012 Val Brembilla (BG), Italy. Via Lisso, 12 l-24010 Sedrina (BG) Italy. Strada Amerina Località S.Pellegrino l-05035 Narni (TR) Italy. Via Di S.Vincenzo 21 I-57021 Campiglia Marittima (LI) Italy. S.S.Appia km 134 l-04020 Itri (LT) Italy. Contrada Lupini – C.P.33 l-74019 Palagiano (TA) Italy.

Name of manufacturer	Vápenka Vitošov s.r.o
Address of manufacturer	č.p. 54, 78901 Hrabová, Czech Republic
Location of manufacturing sites	č.p. 54, 78901 Hrabová, Czech Republic

Name of manufacturer	Wietersdorfer & Peggauer Zementwerke GmbH
Address of manufacturer	Wietersdorf 1, 9373 Klein St. Paul, Austria
Location of manufacturing sites	Alois-Kern-Straße 1, 8120 Peggau, Austria

Name of manufacturer	Zakłady Wapiennicze Lhoist S.A.
Address of manufacturer	ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland
Location of manufacturing sites	ul. Fabryczna 22, 47-316 Górażdże, Poland ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland

	ul. Bolesława Chrobrego 77B, 59-550 Wojcieszów, Poland

Name of manufacturer	Zement- und Kalkwerke Otterbein GmbH & Co. KG
Address of manufacturer	Hauptstrasse 50, 36137 Grossenlueder-Mues, Germany
Location of manufacturing sites	Georg-Otterbein-Strasse 123, 36137 Grossenlueder-Mues, Germany

Name of manufacturer	SMA Mineral AS
Address of manufacturer	Postbox 500, NO-8601 Mo I Rana, Norway
Location of manufacturing sites	Mo Industripark, Verkstedsøypa, NO-8626 Mo i Rana, Norway

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

Name of manufacturer	Cal Industrial SL
Address of manufacturer	Pedro I, 19-21 31 007 Pamplona, Spain
Location of manufacturing sites	Pedro I, 19-21 31 007 Pamplona, Spain

Name of manufacturer	Calera de Alzo, S. L.
Address of manufacturer	Postal number: 20.268, Egileor auzoa, 101. Altzo (Guipúzcoa), Spain
Location of manufacturing sites	Egileor auzoa, 101. Altzo (Guipúzcoa), Spain

Name of manufacturer	Caleras de San Cucao, S.A.
Address of manufacturer	Agüera s/n 33425-San Cucao de Llanera, Spain
Location of manufacturing sites	Agüera s/n 33425-San Cucao de Llanera, Spain

Name of manufacturer	CalGov
Address of manufacturer	Carretera Fuente, Apartado 2, 41 560, Estepa, Spain
Location of manufacturing sites	Carretera Fuente, Apartado 2, 41 560, Estepa, Spain

Name of manufacturer	Carmeuse Chaux
Address of manufacturer	215 route d'Arras, 62320 Bois Bernard, France
Location of manufacturing sites	215 route d'Arras, 62320 Bois Bernard, France

Name of manufacturer	Carmeuse Czech Republic s.r.o.
Address of manufacturer	Mokrá 359,664 04 Mokrá, Czech Republic
Location of manufacturing sites	závod Vápenka Mokrá, Mokrá 359, 664 04 Mokrá, Czech Republic

Name of manufacturer	Carmeuse Holding Srl
Address of manufacturer	Str.Carierei Nr.127A, 500047 Brasov, Romania
Location of manufacturing sites	Str Garii 2, 135100 Fieni, Romania. Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Privat, 117805 Campulung, Romania.

Name of manufacturer	Carmeuse Hungaria kft
Address of manufacturer	HRSZ 064/1, 7827 Beremend, Hungary
Location of manufacturing sites	HRSZ 064/1, 7827 Beremend, Hungary

Name of manufacturer	Carmeuse SA
Address of manufacturer	Rue du Château 13a, 5300 Seilles, Belgium
Location of manufacturing sites	Rue de Boudjesse 1, 5070 Aisemont, Belgium. Rue du Val Notre Dame 300, 4520 Moha, Belgium. Rue du Château 13a, 5300 Seilles, Belgium..

Name of manufacturer	Carmeuse Slovakia s.r.o.
Address of manufacturer	Slavec, 049 11 Slavec, Slovakia
Location of manufacturing sites	závod Vápenka Košice, Vstupný areál U.S. Steel, 044 54 Košice, Slovakia. závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia.

Name of manufacturer	Carrières et Chaux Balthazard et Cotte
Address of manufacturer	Rue du Pra Paris, 38 360 Sassenage, France
Location of manufacturing sites	Rue du Pra Paris, 38 360 Sassenage, France

Name of manufacturer	Carrières et fours à chaux de Dugny
Address of manufacturer	B.P.1, 55 100 Dugny-sur-Meuse, France
Location of manufacturing sites	B.P.1, 55 100 Dugny-sur-Meuse, France

Name of manufacturer	Cementos Tudela Veguín, S.A.U.
Address of manufacturer	CL Argüelles 25.33003 Oviedo, Asturias, Spain
Location of manufacturing sites	CL Tino Casal, s/n. 33910, Tudela Veguín, Asturias, Spain.

Name of manufacturer	Chaux de Boran
Address of manufacturer	Route de Boran, 60 640 Précy-Sur-Oise, France
Location of manufacturing sites	Route de Boran, 60 640 Précy-Sur-Oise, France

Name of manufacturer	Chaux de Provence

Address of manufacturer	Ancien Chemin de Martigues, 13 160 Châteauneuf Les Martigues, France
Location of manufacturing sites	Ancien Chemin de Martigues, 13 160 Châteauneuf Les Martigues, France

Name of manufacturer	Chaux et Dolomies du Boulonnais
Address of manufacturer	Rue Jules Guesde, 62 720 Réty, France
Location of manufacturing sites	Rue Jules Guesde, 62 720 Réty, France

Name of manufacturer	Chaux de la Tour
Address of manufacturer	1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France
Location of manufacturing sites	1 chemin des Chaux de la Tour 13 820 Ensues La Redonne, France

Name of manufacturer	Clogrennane Lime LTD
Address of manufacturer	Clogrennane Lime LTD, Clogrennane, Carlow, R93 EV26, Ireland
Location of manufacturing sites	Clogrennane, Carlow, R93 EV26, Ireland

Name of manufacturer	Dumont-Wautier
Address of manufacturer	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium
Location of manufacturing sites	Rue la Mallieue, 95, B-4470 Saint-Georges-sur-Meuse, Belgium

Name of manufacturer	Etablissement Leon Lhoist
Address of manufacturer	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium
Location of manufacturing sites	Usine de On-Jemelle, 6900 Marche-en-Famenne, Belgium

Name of manufacturer	Européenne des Chaux et Liants
Address of manufacturer	2745 route du Bugey, CS22015, 38307 Bourgoin-Jallieu, France
Location of manufacturing sites	Usine de Duin, 38460 TREPT, France

Name of manufacturer	Lhoist Bukowa Sp. z o.o.
Address of manufacturer	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland
Location of manufacturing sites	Bukowa, ul. Osiedlowa 10, 29-105 Krasocin, Poland.

Name of manufacturer	Lhoist France Ouest
Address of manufacturer	15 rue Henri Dagallier, 38 100 Grenoble, France

Location of manufacturing sites	15 rue Henri Dagallier 38 100 Grenoble, France

Name of manufacturer	Lhoist UK Ltd
Address of manufacturer	Hindlow, Buxton, Derbyshire, SK17 OEL, UK
Location of manufacturing sites	Hindlow, Buxton, Derbyshire, SK17 OEL, UK

Name of manufacturer	Lusical
Address of manufacturer	Valverde, 2025-201 Alcanede, Portugal
Location of manufacturing sites	Valverde, 2025-201 Alcanede, Portugal

Name of manufacturer	Nordkalk AB
Address of manufacturer	Box 901 SE-731 29 Köping Sweden
Location of manufacturing sites	Nordkalk AB, Köping, Kungsängsvägen 22, SE-731 36 Köping, Sweden Nordkalk AB, KPAB Storugns Lärbro, Lärbro Storugns 2741, SE-624 53, Lärbro, Sweden

Name of manufacturer	Nordkalk AS
Address of manufacturer	Faehlmanni tee 11A, Rakke 46 301, Lääne-Virumaa, Estonia
Location of manufacturing sites	Faehlmanni tee 11A, Rakke 46 301, Lääne-Virumaa, Estonia

Name of manufacturer	Nordkalk Oy Ab
Address of manufacturer	Skräbbölevägen 18, 21600 Pargas, Finland
Location of manufacturing sites	Nordkalk Oy Ab, Louhi, Louhi, Fi-57100, Savonlinna, Finland Nordkalk Oy Ab, Tytyri, Tytyrinkatu 7, Fi-08100, Lohja, Finland. Nordkalk Oy Ab, Pargas, Kalkhamnsvägen 5, Fi-21600, Pargas, Finland

Name of manufacturer	Pigeon Chaux SAS
Address of manufacturer	29 Rue des Ruettes, 53410 Saint-Pierre-la-Cour, France
Location of manufacturing sites	La Hunaudiere - 53480 Vaiges, France

Name of manufacturer	See Bruyeres & Fils
Address of manufacturer	Le Bourg - 47500 Saint Front sur Lémance, France
Location of manufacturing sites	Le Bourg - 47500 Saint Front sur Lémance, France

Name of manufacturer	Singleton Birch

Address of manufacturer	Melton Ross Quarries, Barnetby, N Lincolnshire, DN38 6AE, UK
Location of manufacturing sites	Melton Ross Quarries, Barnetby, N.Lincolnshire, DN38 6AE, UK

Name of manufacturer	SMA Mineral AB
Address of manufacturer	Box 329, SE-682 27 Filipstad, Sweden
Location of manufacturing sites	Luleå lime plant, C/O SSAB Europe SE-971 88 Luleå, Sweden. Boda lime plant, Kärvsåsen Kalkveerksvägen 15 SE-795 96 Boda kyrkby, Sweden. Rättivik lime plant, Kalkvägen 7 SE-795 32 RÄTTVIK, Sweden. SSAB Industriområde, Kalkverket, SE-613 80 Oxelösund, Sweden.

Name of manufacturer	SMA Mineral Burgas Var LTD
Address of manufacturer	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. N°52
Location of manufacturing sites	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. N°52

Name of manufacturer	SMA Mineral Oy
Address of manufacturer	Selleenkatu 281, 95450 Torino, Finland
Location of manufacturing sites	SMA Mineral Oy, Röyttä Lime Plant, Selleenkatu 281, 95450 Torino, Finland

Name of manufacturer	Société des fours à chaux de Sorcy
Address of manufacturer	Route de Sorcy B.P.16, 55 190 Void, France
Location of manufacturing sites	Route de Sorcy B.P.16, 55 190 Void, France

Name of manufacturer	Spenner GmbH & Co. KG
Address of manufacturer	Bahnhofstraße 20, D-59597 Erwitte, Germany
Location of manufacturing sites	Hüchtchenweg 2, D-59597 Erwitte, Germany

Name of manufacturer	Trzuskawica S.A.
Address of manufacturer	Trzuskawica S.A., Sitkówka 24, 26-052 Nowiny, Poland
Location of manufacturing sites	Trzuskawica S.A., Sitkówka 24, 26-052 Nowiny, Poland

Name of manufacturer	Unicalce S.p.A
Address of manufacturer	Via Tonio da Belledo, 30 l-23900 Lecco (LC), Italy
Location of manufacturing sites	Via Ponti, 18 1-24012 Val Brembilla (BG), Italy. Via Lisso, 12 l-24010 Sedrina (BG) Italy.

	Strada Amerina Località S.Pellegrino l-05035 Narni (TR) Italy. Via Di S.Vincenzo 21 I-57021 Campiglia Marittima (LI) Italy. S.S.Appia km 134 l-04020 Itri (LT) Italy. Contrada Lupini – C.P.33 l-74019 Palagiano (TA) Italy.

Name of manufacturer	Vápenka Vitošov s.r.o
Address of manufacturer	č.p. 54, 78901 Hrabová, Czech Republic
Location of manufacturing sites	č.p. 54, 78901 Hrabová, Czech Republic

Name of manufacturer	Wietersdorfer & Peggauer Zementwerke GmbH
Address of manufacturer	Wietersdorf 1, 9373 Klein St. Paul, Austria
Location of manufacturing sites	Alois-Kern-Straße 1, 8120 Peggau, Austria

Name of manufacturer	Zakłady Wapiennicze Lhoist S.A.
Address of manufacturer	ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland
Location of manufacturing sites	ul. Fabryczna 22, 47-316 Górażdże, Poland ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland ul. Bolesława Chrobrego 77B, 59-550 Wojcieszów, Poland

Name of manufacturer	Zement- und Kalkwerke Otterbein GmbH & Co. KG
Address of manufacturer	Hauptstrasse 50, 36137 Grossenlueder-Mues, Germany
Location of manufacturing sites	Georg-Otterbein-Strasse 123, 36137 Grossenlueder-Mues, Germany

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

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

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Burnt lime	Calcium oxide	Active substance (technical)	1305-78-8	215-138-9	100 (min. purity of CaO: 800g/kg)

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

The biocidal product contains 100% of the active substance calcium oxide.
According to the ED conclusions in the BPC opinions (ref. BPC OPI PT2, BPC OPI PT3, 2016) from the active substance approval, burnt lime is not considered to have endocrine disrupting properties.
The biocidal product does not have ED properties.

2.1.2.6 Information on the substance(s) of concern

The biocidal product does not contain any substance of concern.

2.1.2.7 Type of formulation

DP: Dustable powder

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin irritation, category 2 Eye damage, category 1 STOT SE, category 3
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Labelling	
Signal words	GHS05, GHS07
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Precautionary statements	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves/protective clothing/eye protection/face protection. P405: Store locked up P302+P352: IF ON SKIN: Wash with plenty of water/... P321: Specific treatment (see … on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTRE or doctor/physician. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTRE/doctor/…if you feel unwell. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P501: Dispose of contents/container in accordance with local regulation.
Note	EUH014 - reacts violently with water

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – **Disinfection of sewage sludge**

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

Target organism (including development stage)	Bacteria Endoparasites: helminth eggs
Field of use	Indoor. The product is dosed into the sewage sludge and mixed by means of a blender.
Application method(s)	Automatic direct application
Application rate(s) and frequency	Ready to use product The dry product is mixed with the sewage sludge in an open mixer. The product should be loaded by fully automated processes. The dose must be high enough to achieve a pH of > 12 and a temperature >50°C during the contact time. Contact time: 24h
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg

2.1.4.1.1 Use-specific instructions for use

- The dose must be high enough to achieve a pH of > 12 and a temperature >50°C during 24 hours.
- Application rate: 0.15 – 1.5 kg product / kg dry weight of substrate; typical dry solids content - 12-25% in sewage sludge.
- The ratios may vary between applications and treatment plant designs. The user must ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case

2.1.4.1.2 Use-specific risk mitigation measures

- The loading of burnt lime powder into the treatment unit and the application must be done fully automatically.
- Considering the use of big bags (a half to 1.2 tone), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags, wear :
    - a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
    - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
    - protective coverall (coverall material to be specified by the authorisation holder within the product information).
- During the treatment of sewage sludge, the wear of air fed or canister RPE specific for ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m^3 for this gas.
- Wear protective gloves and protection coverall during the manual handling of treated sewage sludge.
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.

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

-

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

-

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

-

2.1.4.2 Use description

Table 2. Use # 2 – **Disinfection of manure**

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Virus, Endoparasites: helminth eggs
Field of use	Indoor The product is dosed into the manure and mixed by means of a blender.
Application method(s)	Automatic direct application
Application rate(s) and frequency	Ready to use of product The product is mixed with the manure. The product should be loaded by fully automated processes. The application rate must be sufficient to maintain a pH of > 12 and a temperature > 60°C during the contact time. Contact time: 24 hours
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg

2.1.4.2.1 Use-specific instructions for use

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

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

2.1.4.2.2 Use-specific risk mitigation measures

- The loading of burnt lime powder into the treatment unit and the application must be done fully automatically.
- Considering the use of big bags (a half to 1.2 tone), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).
- During the loading of the product and the disposal of empty bags, wear :
  - a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - protective coverall (coverall material to be specified by the authorisation holder within the product information).
- During the treatment of manure, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EU OEL of 14 mg/m^3 for this gas.
- Wear protective gloves and protection coverall during the manual handling of treated manure.
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water.

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

-

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

-

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

-

2.1.4.3 Use description

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

Product Type	PT3

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, fungi, viruses
Field of use	Indoor The product is spread directly onto the floors of animal accommodations using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
Application method(s)	Direct application
Application rate(s) and frequency	Ready to use 800 g CaO / m² Frequency in animal housing: Before each production cycle Frequency in animal transportation: After each animal transport Contact time 48h
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg Paper sacks (with PP or PE inner layer): 25 kg

2.1.4.3.1 Use-specific instructions for use

- The product is spread onto the floors of animal accommodations and transportation using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
- A long-handled shovel has to be used for the manual spreading application

A. On concrete floors:

1. Wash the installation with running water,
2. Sprinkle approx. 800 g of CaO per m^2 to cover the damp ground and add 0.9 L/m² of water,
3. Leave to act for at least 48 h.

B. On beaten-earth floor:

1. Brush and wet the floor,
2. Sprinkle approx. 800 g of CaO per m^2 on the damp ground and add 0.9 L/m² of water,
3. Leave to act for at least 48 h.

2.1.4.3.2 Use-specific risk mitigation measures

- During the loading, the application of the product on the floor and the disposal of empty bags, wear :
  - a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);

○ a protective coverall (coverall material to be specified by the authorisation holder within the product information). - Considering the use of big bags (a half to 1.2 tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin). - During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimise the remaining powder. - Fold carefully the small bag in order to avoid any spills. - During the disposal of the product after the application, wear: ○ a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter); ○ chemical resistant gloves (glove material to be specified by the authorisation holder within the product information); ○ protective coverall (coverall material to be specified by the authorisation holder within the product information). - Animals must not be present during all the treatment duration. - Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals. - Feed and drinking water must be carefully covered or removed during the application of the product. - Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water.

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

-

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

- After treatment, remove the lime by brushing. Collect the resulting dry waste and recycle them as agricultural liming material or dispose the dry waste according to local requirements. For animal transportation use only: after brushing, rinse and clean the vehicle

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

-

2.1.4.4 Use description

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

Product Type	PT3

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, fungi and virus
Field of use	Outdoor. The product is spread directly onto the surfaces (floors) of animal enclosures using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
Application method(s)	Direct application
Application rate(s) and frequency	Ready to use 600 - 800 g CaO/m² Contact time 48 hours Frequency: maximum two applications per year
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1200 kg Paper sacks (with PP or PE inner layer): 25 kg

2.1.4.4.1 Use-specific instructions for use

- Brush and wet the floor before the application of the product.
- At the beginning of a production cycle, spread 600 - 800 g CaO/m^2 of the product onto the ground then apply water.
- Leave to act for at least 48 hours before bringing in the animals.
- Do not apply in case of wind or rain

2.1.4.4.2 Use-specific risk mitigation measures

- During the loading, the application of the product on floor and the disposal of the empty bags, wear :
  - a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - protective coverall (coverall material to be specified by the authorisation holder within the product information);

- Considering the use of big bags (a half to 1.2 tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).

- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimise the remaining powder.
- Fold carefully the small bag in order to avoid any spills.

- During the disposal of the product after the application, wear :
  - a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);

○ chemical resistant gloves (glove material to be specified by the authorisation holder within the product information); ○ protective coverall (coverall material to be specified by the authorisation holder within the product information); - Do not exceed two applications per year. - Animals must not be present during all the treatment duration. - Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals. - Feed and drinking water must be carefully covered or removed during the application of the product

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

-

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

- After treatment, remove the lime by brushing. Collect the resulting dry waste and recycle them as agricultural liming material or dispose the dry waste according to local requirements.

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

-

2.1.5 General directions for use

2.1.5.1 Instructions for use

- Comply with the instructions for use.
- Respect the indicated contact time and pH for the required antimicrobial activity.
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- For outdoor uses, do not apply in case of rain of wind

2.1.5.2 Risk mitigation measures

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

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

- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTER or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging (….) and all other waste, in accordance with local regulations.

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

- Do not store at a temperature above 30°C.
- Protect from humidity.
- Shelf-life: 15 months.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Big bag/sack	500 – 1200 kg	Body cover: Polypropylene white Anti-UV treatment according to ISO 21898 : 2004; or paper Lining: Type: Polyethylene	No specific closure material	Professional	Yes
Sack	25 kg	Body cover: Polypropylene or paper Lining (if included): Type: Polyethylene	No specific closure material	Professional	Yes

** powder tanker up to 30T are not including in this table even it was claimed by applicant as it is not considered as a storage packaging but only use for transport. Moreover, the silos that could be used by the customer for storage do not appear here as it is not provided by the applicant.*
The big-bag/sacks should be adapted to be opened and transferred with an automatized system.

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

European Lime Association is the applicant supporting the active substance. A letter of access to the active substance dossier is not required.

2.2 Assessment of the biocidal product

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

Table 2. 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 an open mixer. The product can be loaded manually or using semi- or fully automated processes. 0.15 – 1.5 kg product / kg dry weight of substrate; Typical dry solids content - 12-25% in sewage sludge and 1-6% in liquid manures. The dose must be high enough to achieve a pH of > 12 for a minimum of 3 hours. Note; the rate may vary between application
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper sacks: 25 kg

Table 3. 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 10 kg lime/m^3 of litter or manure. 2. For treatment: Add approx. 100 kg lime/m^3 of litter or manure 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water. 4. Stockpile the lime treated manure.

	5. After at least 24h, dispose of the lime treated manure according to local legislation. Application of lime to litter or manure inside animal houses 1. For Prevention: Spread approx. 10 kg/m3 (2 kg of lime /m2 for 20 cm litter) on the litter or manure inside the poultry house 2. For treatment: Spread approx. 100 kg/m3 (20 kg of lime /m2 of 20 cm litter) on the litter or manure inside the animal house 3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water 4. Remove the lime/manure or lime/litter mixture from the animal house 5. Homogenise the lime/manure or litter mixture 6. Stockpile the lime treated manure 7. After at least 24 h, dispose the lime treated manure according to the local legislation
Category(ies) of users	Professional
Pack sizes and packaging material	Bulk: Powder Tanker up to 30 tonnes Bulk Big bags or sacks: 500 - 1200 kg Paper sacks: 25 kg

Table 4. Use # 3 – Disinfection of indoor floor surfaces of animal accommodations and transportation

Product Type	3
Where relevant, an exact description of the authorised use	The product is spread directly onto the floors of animal 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. 800 g of lime/m²) 3. Spray sufficient water to quench the steaming reaction with the product (e.g. 1 litre of water per m² of quicklime) 4. Leave to act for at least 2 h 5. Brush and remove the hydrated lime 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. 800 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 quicklime 4. Leave to act for at least 24 h 5. Brush and remove the burnt lime 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 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
Target organism (including development stage)	Bacteria, yeast, fungi and virus
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 600 - 800 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 the animals 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 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 product is used undiluted (ready to use)
The content of hydrocarbons or H304 co-formulants in the product is ≤10% and therefore cannot be classified for aspiration hazard.
Packaging: paper bags with PP or PE inner layer.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Physical state at 20 °C and 101.3 kPa	Not indicated	Not indicated	Solid	AS dossier: A3.1.3/01.	Accepted in the CAR of active substance
Colour at 20 °C and 101.3 kPa	Not indicated	Not indicated	Off-white		
Odour at 20 °C and 101.3 kPa	Not indicated	Not indicated	Not specified		
Acidity / alkalinity	CIPAC MT 31	Ca. 98% w/w (CaO forms $Ca(OH)_2$ on addition of water.)	0.24 – 0.26 % m/m as NaOH	B3.5/01	Accepted in the CAR of active substance
Relative density / bulk density	CIPAC MT 186 OECD 106 EC Method A3	≥ 97.0%	Relative density: 3.09 Bulk density: 0.8 g/mL Tap density: 1.04 g/mL	AS dossier: A3.1.3/02 A3.1.3/03	Accepted in the CAR of active substance
Storage stability test –	Waiver		Lime products are not degradable. If stored in damp conditions the products may react, but		No accelerated storage study was

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
accelerated storage			there is no loss of the active substance. A storage stability study is therefore not appropriate for this type of material.		provided. In consequence, the mitigation measure is added: **Product do not store above 30°C.**
Storage stability test – **long term storage at ambient temperature**	not indicated	As described in Section B2	See AS dossier (product PRECAL 30S): Bagged material must be stored under dry conditions because Burnt lime is hygroscopic. The uptake of CO2 and water by Precal 30S stored in paper bags was measured for a period of 24 weeks (extrapolated to 26 weeks which correspond to 6 months). The water content of the product raised from 0.5 to 1.6% (w/w) in this period, which indicates that part of the Burnt lime was transformed into Hydrated lime. The CO2 content remained unchanged. The reactivity of Precal 30S, measured as t60°C (time needed to reach 60 °C in the standard reactivity test according to EN 459-2:2001) dropped slightly from t60°C = 0.3 min. to t60°C = 0.6 min. This difference is insignificant and has no influence on the use of the product as a biocide. It is due to reaction of a small part of the CaO to Ca(OH)2. During storage, no hard lumps are formed.	AS Dossier 3.7	Based on AS dossier, a shelf life of 6 months is acceptable. A new long term storage study will be provide by the applicant in the 10 days following the APCP Working group at the latest.
	CIPAC MT184	100% CaO	A new study was provide to follow some technical properties during 12months storage The material packaging is not known	[redacted] 2021 Study Mo6493*	The tested product is not an Eula product but the results can be taken into

<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>Comments</th></tr>
<tr><td></td><td>CIPAC MT53.3

CIPAC MT 171.1

CIPAC MT 178</td><td></td><td>
<table>
<tr><td>Test</td><td>Initial</td><td>3months</td><td>9months</td><td>12months</td></tr>
<tr><td>Suspensibility (20%w/v)</td><td>19%</td><td>11%</td><td>-</td><td>8%</td></tr>
<tr><td>Wettability</td><td>1sec</td><td>1sec</td><td>-</td><td>1sec</td></tr>
<tr><td>Dustiness</td><td>19.5 Essentially non-dusty</td><td>15.8 Essentially non-dusty</td><td>-</td><td>9.5 Nearly dust-free</td></tr>
<tr><td>Attrition (%)</td><td>99.81</td><td>99.96</td><td>99.81</td><td>99.92</td></tr>
</table>
</td><td></td><td>account as it is 100% of CaO (same composition than Eula product).

Suspsensibility is low as the active substance (CaO) is not miscible in water.
Nevertheless, as the product is undiluted in water (DP formulation) this test is not required according to FAO.</td></tr>
<tr><td></td><td>Norm EN 459-2

CIPAC MT31</td><td>Oxilime 90, DP</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 15months in big-bags</td></tr>
<tr><td>Content (%w/w)</td><td></td><td></td></tr>
<tr><td>CaO</td><td>78.5</td><td>80.7</td></tr>
<tr><td>CO2</td><td>10.2</td><td>8.4</td></tr>
<tr><td>SO3</td><td>1.15</td><td>1.2</td></tr>
<tr><td>MgO</td><td>5.6</td><td>4.7</td></tr>
<tr><td>SiO2</td><td>2.1</td><td>2.1</td></tr>
<tr><td>Fe2O3</td><td>0.5</td><td>0.5</td></tr>
<tr><td>Al2O3</td><td>0.4</td><td>0.4</td></tr>
<tr><td>K2O</td><td>0.13</td><td>0.14</td></tr>
<tr><td>Na2O</td><td>0.05</td><td>0.02</td></tr>
<tr><td>MnO2</td><td>0.06</td><td>0.06</td></tr>
<tr><td>pH</td><td>12.5</td><td>12.5</td></tr>
</table>
</td><td>[redacted]
WA-Nr.: 161-1/20*</td><td>Acceptable
The tested product is not an Eula product but the results can be taken into account as it is 100% of CaO (same composition than Eula product).

The particle size shows that no aggregation is</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results			Reference	Comments
			Alkalinity	0.27% NaOH	0.29% NaOH		observed during storage. The content of CaO is slightly under the minimum purity of 80%, nevertheless, taking into account the standard deviation of the analytical method and the tolerance limits product (±25g/kg for nominal content above 500g/kg according to ECHA Guidance on BPR, Volume I Information requirements, Parts A+B+C. version 2.1 March 2022) it is considered acceptable till a content of 77.5% of CaO. The content of active substance as other oxide forms is stable.
			Particle size	D10: 1.4µm D50: 23µm D90: 118µm D100: 350µm	D10: 1.5µm D50: 27µm D90: 162µm D100: 350µm		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
					Concerning the packaging, according to the guidance on the biocidal products regulation vol I p 70 table 7, for solid product no interaction is expected between the product and the packaging, the extrapolation to all types of packaging is acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver		Not applicable		Active substance is not light sensible (see CAR of active substance). Moreover, the active substance is a solid powder extract from natural quarries exposed to direct sunlight.
Effects on content of the active substance and technical characteristics	Waiver		Lime products are not degradable. If stored in damp conditions the products may react, but there is no loss of the active substance. Active substance is stable at very high temperature (no decomposition up to melting point at 2500°C according to the CAR).		In view of the nature of the biocidal product/active substance, effects of temperature and humidity on content

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
of the biocidal product – **temperature and humidity**					of the active substance and technical characteristics of the biocidal product should be follow as the humidity as an impact on the active substanceA mitigation sentence **'protect from humidity'** is added on the label.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	No Guideline followed	CaO	The corrosion study indicates that aluminium and stainless steel packaging is suitable for transport and storage of the product. Experience indicates that paper bags lined with plastic (to prevent contact with moisture), plastic bags, steel, stainless steel and Aluminium do not react significantly with dry lime and so can be used as container material for this product. Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime based products (e.g. milk of lime) For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk transportation of wet lime products.	AS Dossier: Doc. No.: 245-001; CB3.7/01	Product is stored in paper bags (with PP or PE inner layer). Therefore, packaging is suitable but as the substance is hygroscopic and very reactive to water, the product should be **protect from humidity**. According to the guidance on the biocidal products regulation vol I p 70 table 7, for solid product no

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
					interaction is expected between the product and the packaging, the extrapolation to all types of packaging is acceptable. Therefore as the product is a solid product no reactivity towards the contained material is expected.
Wettability	Waiver		Not applicable		
Suspensibility, spontaneity and dispersion stability	Waiver		Not applicable		
Wet sieve analysis and dry sieve test	EN 459-1 Particle size ≥ 2 mm shall be determined by dry sieving in accordance with EN 459–2:2010, 6.1 and particle	CaO ≥ 80% (active substance Reference Specification)	The product conforms to the requirement of EN 459 -1 in that >= 95% of the product must be less than 0.2 mm in size and >= 85% must be less than 0.09 mm in size. The products are defined as being very dusty powders. ASTM C110 - 15 are the standard test methods for physical testing of quicklime, hydrated lime and limestone. The standard sieve sizes are > 1 mm, 0.1 - 0.99 mm and < 0.099 mm. The majority(> 95%) of the substance falls within	EN 459-1 [redacted] PSD/laser diffraction data (2017)	Accepted in AS dossier

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
	size < 2 mm by air-jet sieving in accordance with EN 459–2:2010, 6.2.		the 0.1 - 0.99 mm size range. The substance is therefore considered to be the inhalable/respirable range.		
Emulsifiability, re-emulsifiability and emulsion stability	Waiver		Not applicable		
Disintegration time	Waiver		Not applicable		
Particle size distribution, content of dust/fines, attrition, friability	EN 459-1 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	CaO ≥ 80% (active substance Reference Specification)	The product conforms to the requirement of EN 459 -1 in that >= 95% of the product must be less than 0.2 mm in size and >= 85% must be less than 0.09 mm in size. The products are defined as being very dusty powders. ASTM C110 - 15 are the standard test methods for physical testing of quicklime, hydrated lime and limestone. The standard sieve sizes are > 1 mm, 0.1 - 0.99 mm and < 0.099 mm. The majority(> 95%) of the substance falls within the 0.1 - 0.99 mm size range. The substance is therefore considered to be the inhalable/respirable range.	EN 459-1 [redacted] PSD/laser diffraction data (2017)	Accepted in AS dossier.

<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>Comments</th></tr>
<tr><td></td><td>with EN 459–2:2010, 6.2.</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Sartorius Model MA40, electronic moisture analyser</td><td>Calcium oxide Oxi Lime 23 Batch number BE1121.5.6</td><td><table><tr><td></td><td>Particle size distribution (µm)</td></tr><tr><td>D10</td><td>4.8</td></tr><tr><td>D50</td><td>229.6</td></tr><tr><td>D90</td><td>1082.4</td></tr><tr><td>Moisture</td><td>0.2%</td></tr></table></td><td>[redacted] 2022 Report N° S3016011300 R1/2022</td><td>Acceptable.</td></tr>
<tr><td>Flowability/Pourability/Dustability</td><td>EN 459-1 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>CaO ≥ 80% (active substance Reference Specification)</td><td>See above</td><td>EN 459-1 [redacted] PSD/laser diffraction data (2017)</td><td>Accepted in AS dossier.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Burning rate — smoke generators			Not relevant for DP products		
Burning completeness — smoke generators			Not relevant for DP products		
Composition of smoke — smoke generators			Not relevant for DP products		
Spraying pattern — aerosols			Not relevant for DP products		
Physical compatibility	Waiver		According to long-time experience, burnt lime (and consequently the burnt lime products) can be stored without any problems in paper and plastic materials/ bags and in silos.		See storage study Moreover, the product is not expected to be mixing with another product.
Chemical compatibility			Calcium oxide will react with water to generate the hydroxide form in a highly exothermic reaction.		A mitigation measure should be provided for labelling: EUH014 react violently with water.
Degree of dissolution and dilution stability	Waiver		Not applicable		
Surface tension			Not applicable to solids		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Viscosity			Not applicable to solids		

** A position paper sets out to show that the products tested in three study reports:*
- Determination of physico-chemical properties for several products. [redacted] Biogenius Report no Mo6493. 2021-05-27
- Test report WA no.: 161-1/20. [redacted] IKM Institut für Kalk- und Mörtelforschung e.V. Annastr. 67-71 29-11-2020
- Test report WA no.: 161-2-k2/20. [redacted] IKM Institut für Kalk- und Mörtelforschung e.V. Annastr. 67-71 29-11-2020
are equivalent to EuLA Hydra-lime and Oxi-Lime and therefore may be used as read-across in support of UA authorisations (100% of active substance).

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

The product is the same as the active substance. The substances are naturally occurring inorganic salts.
The product is a white dusty solid of naturally occurring origin. The dusts are within the inhalable/respirable range. The solid has an alkalinity of 0.24-0.26% w/w as NaOH.
A 6 months shelf-life was accepted in the AS dossier and can be accepted for the product. However, based on storage stability study provided, the product is considered stable during 15 months in commercial packaging (big-bag). Therefore, a 15 months shelf-life can be granted as the tested products contain the same content of active substance (100% technical CaO).

Implication for labelling: Protect from humidity.
Do not store above 30°C.
Shelf-life: 15 months
EUH014: reacts violently with water.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	eCA Comments
Explosives	Waiver		Not explosive	AS dossier	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	eCA Comments
			According to the CLP regulation, "*A substance or mixture is not classified as explosive when there are no chemical groups associated with explosive properties present in the molecule*". As Ca-O does not contain chemical group having explosive properties, the product is not considered classified.	IIIA 3.15	AS has no explosive properties according to CLP regulation
	Waiver based on composition	CaO Batch BE1110.144.1	There are no chemical groups within the structure that would imply explosive properties according to the manual of recommendation on the Transport of dangerous goods.	[redacted] 2010 Project number 2937/0004	
Flammable solids	Waiver		According to CLP regulation, "*For inorganic material, testing may be waived in cases where the substance is commonly known to be not flammable (i.e. stable salts or metal oxides) or where a flammability hazard can be excluded by any other scientific reasoning."* As Ca-O is a metal oxide, the product is not considered having flammable properties.	AS dossier IIIA 3.11	AS has no flammable properties according to CLP regulation
	EEC A10 (Test N.1)	CaO Batch BE1110.144.1	The substance does not ignite within the 2min screening test.	[redacted] 2010 Project number 2937/0004	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	eCA Comments
Self-reactive substances and mixtures	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that CaO is instable at high temperatures. CaO is produced from limestone (CaCO3) at 900 – 1300 °C. It can be concluded that CaO is stable at least at this temperature range and that SADT test would not show an exothermic peak. Therefore, the substance is not considered having self-reactive nor self-heating properties.	AS dossier	Not self-reactive according to CLP regulation
Pyrophoric liquids	Waiver		Not relevant		
Pyrophoric solids	Waiver		In CaO, Calcium and Oxygen are in their respective preferred oxidation state. The active substance and hence the products are not pyrophoric. Moreover, the substance is not known having pyrophoric properties as CaO is produced from limestone (CaCO3) at 900 – 1300 °C. It can be concluded that CaO is stable at least at this temperature range.	AS dossier	The product is not pyrophoric solid
Self-heating substances and mixtures	Waiver		The CaO is produced from limestone (CaCO3) at 900-1300°C. Therefore we can considered that the product does not react with air at temperature up to 400°C and is not classified self-heating.	AS dossier	Not self-heating according to CLP regulation

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	eCA Comments
	UN Test N.4	Calcium oxide Oxi Lime 23 Batch number BE1121.5.6	After 24h in an "Fan Assisted" oven at an isothermical temperature of 140°C, the sample does not self-heat more than 140°C. Basket Size (mm cube): 100 Test Temperature (°C): 140 Test System: 9 Test Item Weight (g): 1154.1 Ignition Yes / No: No	[redacted] 2022 Report N° S3016011300R1/2022	The product (active substance) has no self-heating properties.
Substances and mixtures which in contact with water emit flammable gases	Waiver		In contact with water, the active substance and hence the products will not emit flammable gases. However, according to CLP regulation, "*EUH014 – 'Reacts violently with water' For substances and mixtures which react violently with water, such as acetyl chloride, alkali metals, titanium tetrachloride. There are no criteria or test methods provided for these EUH statements.*"	AS dossier	The product is classified EUH 014 : reacts violently with water
Oxidising solids	Waiver		Base on chemical structure, the calcium oxide does not contain a surplus of oxygen or any structural groups known to correlated with tendency to react exothermally with combustible material. The calcium and oxygen are in their preferred oxidation state.	AS dossier IIIA 3.16	According to CLP regulation, it can be reasonably considered that the substance/product is not classified as oxidising substance.
	Waiver based on composition	CaO Batch BE1110.144.1	The substance is inorganic and does not contain halogens.	[redacted] 2010 Project number 2937/0004	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	eCA Comments
Organic peroxides	Waiver		Not applicable		
Corrosive to metals	waiver		Not required for solid		The test is not required for solid product. Not corrosive to metal
Auto-ignition temperatures of products (liquids and gases)	Waiver		not applicable		
Relative self-ignition temperature for solids	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that CaO is instable at high temperatures. Therefore, the substance is not considered having self-ignition properties. Moreover, the substance/product is not flammable.	AS dossier	Acceptable
	EEC A16	CaO Batch BE1110.144.1	No self-ignition point below 400°C	[redacted] 2010 Project number 2937/0004	
Dust explosion hazard	Waiver		Calcium oxide will react with water to generate the hydroxide form in a highly exothermic reaction. A stream explosion rather than a dust explosion may potentially occur.	AS dossier	Acceptable

Conclusion on the physical hazards and respective characteristics of the product
Calcium oxide will react exothermically upon contact with water to form calcium dihydroxide. Mitigation measure needed: EUH014 - reacts violently with water.

The product is not classified for other physical hazard properties.

2.2.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance (CaO, MgO)	Gravimetric, Volumetric, EDTA, Pyrophosphate, Insoluble matter	N/A	N/A	N/A	See Table below			N/A	ASTM C25-99 (1999)

Active substance (Na, Mg)	X-ray spectrometric analysis Ca as % CaO Ca as % $CaCO_3$ Mg as % MgO	5			53.347 53.683 54.304 55.599 55.837 80 - 99 0.176 0.216 0.637 0.919 1.406		0.28 % 0.30 % 0.23 % 0.20 % 0.26 % 8.52 % 2.78 % 1.10 % 1.09 % 3.49 %		ASTM C1271-99 (1999)
Active substance (calcium, magnesium, oxide and hydroxide)	ICP AA	Duplicate							ASTM CC 1301 – 95 (1995) (Reapproved 2001)
Active substance	Titration		N/A	Reproducibility: 12.64%			*2.30*		EN12945
Active substance	AA (Mg)			Reproducibility: 0.25%			*0.21*		DIN EN 12946 DIN EN 12947 DIN EN 12048 DIN EN 14397-2

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

Analytical methods for soil
Relevant residues of Lime variants may be calcium, magnesium and hydroxide-ions. The determination of calcium and magnesium may be done e.g. with a complexometric method with EDTA or an Atomic Absorption method as described for the analysis of the active. Hydroxide-ions can be determined by acid-base titration or the measurement of pH-values. The main influences of Lime variants on soil are the change of the pH-value and the change of Ca^{2+} and Mg^{2+} contents. The applicant has provided details of the following standards to measure these changes; NF ISO 10390: "French standard: Soil quality – determination of pH". Doc. No. 492-020. NF X 31-108: "Soil quality – Determination of ammonium acetate extractable Ca++, Mg++, K+ and Na+ cations – Agitation method"". However, given that these ions will occur naturally in soil and hydrated lime is commonly used for agricultural liming it would not be possible to determine the source of these ions as being from biocidal use. In addition, the biocidal use of quicklime (CaO) allows for application of the treated sewage or manure to agricultural land (as a replacement for agricultural liming). Given this, the normal requirement for more detailed analysis of the active/residues in soil would seem unnecessary.

Analytical methods for air

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

				between the hydroxides and salts detectable by this method.					

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

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

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

Conclusion on the methods for detection and identification of the product
The analytical methods for the active substance are applicable to the product.

The ISO method for detection of the substance in air is applicable to monitor workplace exposures.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants

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

The biocidal product EULA OXI-LIME 23 is a dustable powder, intended for use in the disinfection of liquid and dry sludge prior to spreading on the land or prior incineration (PT2), and applied on hard surfaces, manures, equipment and vehicles for veterinary applications such as livestock housing and the transportation of animals (PT3).

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

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

Disinfectant is intended to control bacteria, yeast, fungi, viruses and endoparasites: helminth eggs

The product is used for the purpose of the protection of human and animal health.

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

Several effects of Burnt lime are known:

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

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

for a synergistic effect with high pH be reached.

3) Increased temperature - Burnt lime (CaO) react with water to form Calcium hydroxide in an exothermic reaction. A typical initial temperature following addition of Burnt lime to wet sewage sludge would be in the range of 45-75 °C. Pathogens are inactivated during exposure to heat, which must be above their optimum growth temperature in order to be effective. The exposure time required depends both on the temperature and on the species. In a study contracted for the European Commission Directorate-General Environment (Carrington, 2001), the following graph is included, in which results from numerous studies have been collated to indicate a "safety zone". When the operating parameters in this zone are above the minimum requirements, the heat-treated sewage sludge is virtually pathogen-free. The increase in temperature has a synergistic effect on the denaturation of protein structures in the alkaline environment.

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

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

2.2.5.5 Efficacy data

Efficacy tests have been performed with calcium oxide and/or calcium hydroxide based-products.

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

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

Calcium oxide produces calcium hydroxide in contact with water.

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

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

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

First, sewage substrate was combined, with a range of inocula (Salmonella, Streptococci, *E.coli*, *Clostridium perfringens*, Bovine parvovirus, ECBO and *Ascaris suum*) and the biocidal product (study 6.7-01).
Temperature and pH were measured over time, the amount of lime required was calculated as a percentage of the dry content of the sewage sludge.
=>A range of application rates from 0.7 kg/kg sludge to 1.2 kg of CaO/kg dry sludge, with a range of contact times (1hr-24hrs) were shown to be effective at controlling all target organisms. Greater than 5 log reduction in bacteria, greater than 4 log reduction in viruses and a 3 log reduction for Ascaris eggs were observed, depending on the temperature and pH.
=>pH above 12 is needed and contact time needed to obtain a sufficient efficacy decreased with a rise in temperature.
It has to be noted that no negative control has been performed in the test.

In a second study (6.7.02), inactivation kinetics of Ascaris eggs were established in different situations (contaminated sludge with milk of lime and heat, naturally contaminated sludge treated with slaked lime and heat, naturally contaminated sludge treated with quick lime, and sludge treated at full scale with quick lime). Indeed, Ascaris eggs are the most resistant to liming, and hence, may serve as indicators of hygienic quality of biosolids.
=> Depending on the experimental situation, the inactivation threshold period was found to fluctuate between 5 and 75 min at 55°C, and between 1 and 8 min at 60°C, pH should be maintained at 12 or more.
It has to be noted that in the conditions tested, efficacy is related to the effects of pH and heat.

In the third study (6.7.03), the disinfectant effect of hydrated lime added to raw sewage sludge was investigated with special consideration of the influence on the following digestion process. In preliminary investigations in laboratory scale, the necessary pH-value and contact time of the sludge/lime mixture for a safe inactivation of salmonellas as test microorganisms were determined. In a further laboratory experiment, the effect of the high alkalinity of the limed raw sludge on the following digestion process was investigated for a mean hydraulic retention time of 20 days. No adverse effects could be recorded.
The level of contamination in the digester where no treatment was applied was the same than the raw sludge used to feed it during the 20 days.

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

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

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

Regarding virus for the disinfection of sewage sludge, the EFF WG (WG I 2022 meeting) concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study.

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

According to the intended use, based-lime products are dosed directly into the manure or litter and mixed by means of a blender. The type of manures to be disinfected is defined by the content of water (qualified as liquid or solid manure). The quantity of lime depends on the quantity of dry matter.

To demonstrate the efficacy, a first simulated-use study (6.7-06) has been performed to assess the effect of calcium oxide in solid manure and calcium hydroxide in liquid manure, against bacteria (Salmonella and Enterococci), virus (parvovirus bovine) and eggs of *Ascaris suum*.

Solid manure (pig and poultry) was treated with calcium oxide (pH= 12.01) and liquid manure (pig and cattle) was treated with calcium hydroxide (pH=12.59). For calcium oxide, temperature measured is 60° and 70°C, and for calcium hydroxide, the liquid manure is heated at 60°C for the *Ascaris suum* testing.

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

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

From the efficacy study, the quantity of lime to be applied should be enough to reach a pH>12 and a temperature > 60°C in all the cases. Contact time should be at least 24H. Two recommendations are presented by the applicant, one for routine application (10 kg lime/m3 of manure) and one in case of outbreak (100 kg lime/m3 of manure). Since application rate should be adapted to the type of manure in order to achieve a pH>12 and a temperature >60 °C, the SPC should only specify that 100 kg lime/m3 of manure should not be exceeded whatever the circumstances of manure treatment.

<table>
<tr><th colspan="7">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Disinfectant for sewage sludge</td>
<td>PT2 – Use 1</td>
<td>Burnt Lime specified according to the "Building Lime Standard" EN 459-1 as "CL 90".
Calcium Oxide content was 93.7%. The reactivity was defined as T60 =2.5 minutes and Tmax =73C. Mean density was 0.95kg/L.</td>
<td><u>Bacteria</u> (2,3.10^3 – 23.10^6 CFU/g)

Salmonella senftenberg (H$_2$S positive DSM 10062 SIT 100, H2S negative DSM 10062 SIT 112), Streptococci, Clostridium perfringens DSM 765, E.coli DSM 498

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

<u>Nematodes</u>
Ascaris suum eggs

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

Direct mixing of sewage sludge with the biocidal product
The test was applied on two different scales: one to simulate small scale use (mixers of 130 L and 145 L) and the second to simulate industrial scale treatment (cavity mixer-unknown volume).
For the small scale tests, burnt lime was homogeneously mixed into the substrates. The mixture was sampled at intervals to determine the numbers of viable bacteria, viruses or Ascaris eggs.

For the industrial scale test, the mix was pumped and piled for storage. Samples were taken from the stored material at intervals, to determine the numbers of viable</td>
<td>0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solids

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

temperatures and pH values were recorded over the time</td>
<td>0.9 – 1.1 kg burnt lime / kg dried sludge

Small scale test :
pH>12.9

<table>
<tr><th>Substrate</th><th colspan="2">Virus</th><th colspan="2">Bacteria</th><th colspan="2">Worm eggs</th></tr>
<tr><td>Sewage sludge (22% dry matter)</td><td colspan="2">not tested</td><td>pH > 12.9
T_{max}: 26°C</td><td>24 hours</td><td>pH > 12.9
T_{max}: 17°C</td><td>4-8 weeks</td></tr>
<tr><td></td><td>AR: 0.9
T_{max}: 57°C</td><td>> 10 hours</td><td>pH > 12.9
T_{max}: 57°C</td><td>0.5 hours</td><td>pH > 12.9
T_{max}: 57°C</td><td>5-10 hours</td></tr>
<tr><td></td><td>AR: 1.1
T_{max}: 71°C</td><td>2 hours</td><td>pH > 12.9
T_{max}: 71°C</td><td>0.5 hours</td><td>pH > 12.9
T_{max}: 71°C</td><td>2-5 hours</td></tr>
<tr><td colspan="7"></td></tr>
<tr><td>Paunch contents (16% or 28% dry matter)</td><td>AR: 1.25
T_{max}: 35°C</td><td>>24 hours</td><td>AR: 0.2
T_{max}: 22°C</td><td>24 hours</td><td>AR: 1.25
T_{max}: 35°C</td><td>< 4 weeks</td></tr>
<tr><td></td><td>AR: 1.56
T_{max}: 55°C</td><td>> 24 hours</td><td>AR: 0.3
T_{max}: 22°C</td><td>1 hour</td><td>AR: 1.56
T_{max}: 55°C</td><td>5-10 hours</td></tr>
<tr><td></td><td>AR: 0.7
T_{max}: 64°C</td><td>> 10 hours</td><td>AR: 0.6
T_{max}: 22°C</td><td>1 hour</td><td>AR: 0.7
T_{max}: 64°C</td><td>3-5 hours</td></tr>
<tr><td></td><td>AR: 0.9
T_{max}: 74°C</td><td>5 hours</td><td>AR 1.25
T_{max}: 35°C</td><td>< 1 hour</td><td>AR: 0.9
T_{max}: 74°C</td><td>0.5-2 hours</td></tr>
</table>

Industrial scale test:

<table>
<tr><th>Application rate (kg Lime / kg dry matter in substrate)</th><th>Temperature (°C)</th><th>Ascaris eggs</th><th>BPV</th><th>Salmonella senftenberg</th><th>Streptococci</th></tr>
<tr><td>0.9</td><td>50-55</td><td>0.5 hours</td><td>24 hours</td><td>0.25 hours</td><td>0.5 hours</td></tr>
<tr><td>1.0-1.1</td><td>65-75</td><td>0.25 hours</td><td>0.5-2 hours</td><td>0.25 hours</td><td>0.25 hours</td></tr>
</table>

Efficacy criteria achieved:
5 log reduction bacteria
4 log reduction viruses
3 log reduction nematode eggs</td>
<td>6.7-01

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

				bacteria, viruses or Ascaris eggs.			
Disinfectant for sewage sludge	PT2 – Use 1	Milk of lime $(Ca(OH)_2$ suspension in water Dry hydrated lime $(Ca(OH)_2$ Burnt lime (CaO)	<u>Nematodes</u> *Ascaris suum* eggs (Sludge from pig slaughter houses) Sludge A: 924 ± 295 eggs per 10 g solid Total solids: 33% Sludge B 132 ± 108 eggs per 10 g solid Total solids: 15%	Simulated-use tests: 1), Artificially contaminated milk of lime was heated to 50°C, 55°C and 60°C. 2) Naturally contaminated sewage sludges were treated with slaked lime (40% weight slaked lime per weight of sludge dry solids) and afterwards heated to either 50°C or 60°C. 3) Naturally contaminated sewage sludge was treated with quick lime at a predetermined dose in order to reach 50°C, 55°C and 60°C. 4) Sewage sludge was treated at full scale with a predetermined dose of quick lime in order to reach temperatures ranging from 50°C to 60°C and stockpiled. When the stockpile target	Contact time : 5-160 minutes pH ≥12	Inactivation threshold: duration required to reach a level of inactivation at which no viable egg was detected per g of solid sludge (TS) Inactivation threshold is: - in milk of lime and heat, is equal to 70, 5 and 2 min, respectively at 50°C, 55°C and 60°C - with quick lime, is equal to 120 min at 50°C, to 45 min at 55°C, and 5 min at around 60°C - with slaked lime and heat, is higher than 128 min at 50°C, and ranges between 4 and 8 min at 60°C - is equal to 75 min at 55°C and 5 min at 60°C in the industrial situation (quicklime) => This study has demonstrated that in the four investigated situations, either 75 min at 55°C or 8 min at 60°C will lead to a negligible level of viable Ascaris eggs	6.7-02 RI=2

				temperature was reached, bags containing Ascaris eggs were inserted in it.			
Disinfectant for sewage sludge	PT2 – use 1	Calcium hydroxide (10% Ca(OH)2 in water: milk of lime)	<u>Bacteria</u> *Salmonella senftenberg* (10^8 CFU/mL) Coliforms (10^6 CFU/mL)	Simulated tests Direct mixing of sewage sludge with the biocidal product	Two laboratory scale pilot-plant tests were used for the trial proper (Digester 1 and Digester 2), that were fed with dry sludge (the sludge had a mean hydraulic retention time of 20 days). Step 1: The sludge was fed through the digesters for 20 days. Step 2: Days 21-39 Digester 1 was fed with 10% milk of lime to pH=12.8 and given 3 hours agitation. Step 3: From day 30 to day 50, raw sludge was inoculated with Salmonella and only Digester 1 was treated with lime. Raw sludge from both digesters inoculated with Salmonella. Digester 1 is treated with decreasing amounts of Lime (pH is reduced from 12.9 from 11.6), Digester 2 is also treated with Lime.	Step 1: The total bacterial and coliform counts of raw sludge and digested sludge are in the same order. No impact of the digestion on the level of contamination. Step 2: in Digester 1, after 3 hours contact time, 3 to 4 log reduction is obtained for bacteria (no coliforms isolated). Step 3: Salmonellas and coliforms were never isolated and total germ count were reduced by 6 logs Step 4: in Digester 1, Salmonella and coliforms are detected, while in Digested 2 (treated for the first time), total germs decreased of 3 log.	6.7-03 RI=2

Disinfectant for manure and litter	PT3 – Use 2	Calcium hydroxide (liquid manure) Calcium oxide (solid manure) (EuLA specifications)	<u>Bacteria</u> (lab collection) *Salmonella senftenberg 775W (H2S negative)* *Enteroococcus faecium* For each bacteria: 5.10^8 CFU/ml, <u>Virus</u> *Bovine Parvovirus* The virus host cells were MDCK cells <u>Nematodes</u> *Ascaris suum* eggs (recovered from adult female worms) 2 ml egg suspension in gaze-bags (200000 eggs)	Simulated test Direct mixing of manure with the biocidal product Suspension of bacteria was added to liquid manure (100 ml) and filled into the steel pipe, or added to 500 g lime-treated solid manure Virus: Sandwich-germ-carrier technique was used (viral suspension was given on an electropositive charged membrane, and exposed to liquid or solid waste) Nematodes: Stockpiled lime treated manure and contaminated with gaze-bags of eggs At the end of the trial the treated aliquots were compared to untreated (unlimed) controls and log reduction calculated	Liquid manure: Bacteria and viruses: 72H and 96 hours contact time (except for A. suum eggs – 60 min with heated manure at 60°C) Solid manure 60 and 120 min contact time Temperature : 60 and 70°C pH >12	Liquid pig and cattle manure (Ca(OH)2) at 72H and 96H contact time: Virus: > 5 log reduction Bacteria: > 7 log reduction *Ascaris suum* eggs: 100% development inhibition at 60 min exposure time (manure heated à 60°C) Solid pig manure and poultry manure (CaO), at 60° C (CT of 60 and 120 min) and at 70°C (CT of 30 and 60 min) : Virus: > 5 log reduction Bacteria: > 7 log reduction *Ascaris suum* eggs: 100% development inhibition	6.7-06 RI=2

Uses #3 and 4 surface disinfection (PT 3)

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

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

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

- ✓ Laboratory surface tests (phase 2, step 2 tests) according to EN 14349 and EN 16437 have been provided with some deviations from the standard methodology (test coupons are larger, test procedure adapted). Efficacy criteria and experimental conditions (temperature, contact time, interfering substances and test organisms) met the requirements of the norms.
  - ⇨ Bactericidal activity is demonstrated on non-porous surfaces, according to EN 14349, at 10°C, with a contact time of 30 min, in clean (3 g/L BSA) and dirty conditions (10 g/L BSA and 10 g/L yeast extract), with Calcium oxide-based product, at the application rate of 800 g CaO/m².
  - ⇨ Bactericidal activity is not demonstrated on porous surfaces, according to EN 16437, at 10 °C, with a contact time of 60 min, in clean conditions (3 g/L BSA), neither with Calcium oxide-based product at the application rate of 800 g CaO/m².

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

- ✓ Simulated-use tests on a larger scale have been carried out with calcium oxide, following a methodology inspired from the French norm NF T 72 281 (for the test procedure and validation parameters) to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice (mosaic tile as stone carriers is then used). Efficacy criteria and experimental conditions (temperature, contact time, interfering substances and test organisms) met the requirements of the surface norms for vet areas.
  - ⇨ Bactericidal activity (4 Log reduction according to EN 14349) and yeasticidal activity (3 Log reduction according to EN 16438) are demonstrated, at 15-22°C, with a contact time of 24 hours, in dirty conditions (10 g/L BSA and 10 g/L yeast extract), at the application rate of 600 g CaO / m².
    In these conditions, fungicidal activity is not proven (< 3 log reduction).
  - ⇨ Fungicidal activity (3 log reduction according to EN 16438) is demonstrated, at 15-22°C, with a contact time of 24 hours, in clean conditions (3 g/L BSA), at respectively the application rate of 600 g CaO / m².

- ⇨ Virucidal activity (3 log reduction according to prEN 17122) is demonstrated, at 15-22°C, with a contact time of 2 hours, in dirty conditions (10 g/L BSA + 10 g/L yeast extract), at respectively the application rate of 600 g CaO / m².

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

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

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

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

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

=> In 2019 study, the initial microbial load was lower than in 2018. The results obtained with quicklime treatment at 600 g/m² show significantly higher reductions than those measured on the control. Indeed, no reduction exceeding 2 Log is observed for the control while for the majority of pathogens followed in the quicklime modality, the measured contents are below the detection limit of the laboratory. The levels of inoculum after treatment for aerobic microorganisms, yeasts and moulds are similar to those of 2018.

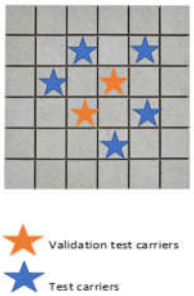
A third trial has been carried out in order to study the efficacy of lime products in pig farm (France) in real conditions of crawlspace. The treatment was carried out in the feeder building, specifically in the pig room at the end of the fattening. The quicklime used in these tests was provided in the form (100% CaO) at the dose of 600 g and 800 g CaO / m² of floor. The floor is moistened with a water pressure washer before treatment. For the sake of similarity between "control" and "treated" housing, the "witness" housing were also sprayed with a water pressure washer.

Microorganisms monitored during these studies are: aerobic microorganisms at 30°C, Escherichia coli B glucuronidase positive at 44 °C, spores of Clostridium perfringens, intestinal enterococci, enterobacteria presumed at 30 ° C, Pseudomonas sp., yeasts and moulds, and Aspergillus sp.
=>As a result, a slight mortality of microorganisms in untreated area due to the cleaning the water pressure washer was noticed. Reduction of the order or more than 2/3 logs is obtained for aerobic microorganisms, Pseudomonas sp., yeast and moulds. Abatement is less for other microorganisms since populations in untreated areas are present in small quantities (E. coli, *Clostridium perfringens*, intestinal enterococci). The applied dose of 600 g/m² gives similar results to 800 g/m².

These field studies have been conducted on concrete floors. Treatment of beaten-earth floors have been also claimed and the applicant points out that both types of surface are in effect largely semi-porous structures and arguable very similar. This one is shown in a thesis of the Sheffield Hallam University[3] which identified rammed earth as having the same porosity and a moisture ingress typical equal or lower than concrete.
Then lime efficacy demonstrated on concrete floors can be extrapolated to beaten-earth floors.

3 http://shura.shu.ac.uk/id/eprint/19744

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant	PT3 – Uses 3/4	Calcium oxide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349 modified Test coupons: 3.14 cm² with 251 mg of powder applied to obtain an application rate: equivalent to 800 g/m² product mixed with 2000 ml/m² water water controls were treated with the equivalent volume of synthetic hard water only	Clean conditions (3 g/L BSA) T°C : 10°C TC : 30 min 800 g/m²	PASS >4 log reduction	6.7-07 RI = 2
Disinfectant	PT3 – Uses 3/4	Calcium oxide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349 modified Test coupons: 3.14 cm² with 251 mg of powder applied to obtain an application rate: equivalent to 800 g/m² product mixed with 2000 ml/m² water	Dirty conditions (10 g/L BSA + 10 g/L yeast extract) T°C : 10°C TC : 30 min 800 g/m²	PASS >4 log reduction	6.7-08 RI = 2
Disinfectant	PT3 – Uses 3/4	Calcium oxide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 16437 modified Test coupons: 2 cm² with 160 mg of powder applied to obtain an application rate: equivalent to 800 g/m² product mixed with 2000 ml/m² water	3 g/L BSA) T°C : 10°C TC : 60 min 800 g/m²	FAIL P.aeruginosa and P.vulgaris=>4log S.aureus and E. hirae <4log reduction	6.7-11 RI = 3
Disinfectant	PT3	CaO (> 80 %)	*Enterococcus hirae* CIP 58.55 *Pseudomonas aeruginosa* DSM 939	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of	Contact time: 2h *Pseudomonas aeruginosa* *Candida albicans* Contact time: 24 h	Calcium Oxide PASS Bactericidal (> 4 log reduction):	6.7-14 RE-1102/0219

			Stapylococcus aureus DSM 799 *Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404 Strains have been chosen in accordance with those used in the standard EN16437, EN16438 Test suspensions prepared in accordance with NF T 72-281, and mix with soiling 5 test carriers 2 validation test carriers 3 control carriers	the material, as typically used in practice, to come into contact with the test organisms: ✓ The mix (organisms+soiling) are placed on carriers (mosaic tiles) and air-dried. ✓ The tiles are placed in the test room and 0.45 L/m2 water added (no pressure); ✓ The test material was applied and another aliquot of water as above to give total water of 0.9 L/m2 ✓ Let in contact during contact time ✓ Take off excess of powder on carriers Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers Efficacy criteria: Bacteria 3 log reduction Yeasts/fungi: 3 log reduction	Remaining organisms Test suspensions prepared in accordance with NF T 72-281 Interfering substance: 10 g/L yeast extract and 10g/L bovine albumin Test temp: 15 – 22 °C Test material: CaO: 600 g/m^2  	*Pseudomonas aeruginosa* 2 hours contact time PASS Bactericidal (> 4 log reduction)l: *Enterococcus hirae* *Staphylococcus aureus* 24 hours contact time PASS Yeasticidal (> 3 log reduction): *Candida albicans* 2 hours contact time FAIL: Not Fungicidal (2.3 log reduction) *Aspergillus brasiliensis*	
Disinfectant	PT3	CaO	*Aspergillus brasiliensis* DSM 1988 Strain has been chosen in accordance	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come	Clean conditions (3 g/L BSA) T°C : 15-22°C Contact time: 24h *Aspergillus brasiliensis*	PASS (>3 log reduction): *Aspergillus brasiliensis* 24H contact time	6.7-14A RE-1302/0919/A RI = 2

			with those used in the standard EN test: EN16438,	into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried. The tiles are placed in the test room and 0.25 L/m^2 water added (no pressure); The test material was applied and another aliquot of water as above to give total water of 0.5L/m^2 Survivors counted in accordance with NF T-72-281 Log reduction calculated by comparison between test carriers and control carriers Veterinary Low Level Soil conditions (3.0 g/L bovine albumin) Efficacy criteria: Fungi: 3 log reduction	Test suspensions prepared in accordance with NF T 72-281 Test material: $Ca(OH)_2$: 600 g/m^2		
Disinfectant	PT3	CaO	Porcine parvovirus Strain has been chosen in accordance with those used in the standard EN test: prEN17122.	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms. The organisms are placed on carriers (mosaic tiles) and air-dried.	Dirty conditions (10 g/L BSA+ 10 g/L yeast extract) T°C : 15-22°C Contact time: 2h Porcine parvovirus Test suspensions prepared in accordance with NF T 72-281 Test material:	PASS: Virucidal (>3 log reduction) Porcine parvovirus	6.7-14B RE-1297/0819 RI = 2

<table>
<tr><td></td><td></td><td></td><td></td><td>The tiles are placed in the test room and 0.25L/m^2 water added (no pressure);

The test material was applied and another aliquot of water as above to give total water of 0.5L/m^2

Survivors counted in accordance with NF T-72-281

Log reduction calculated by comparison between test carriers and control carriers

Veterinary High Level Soil conditions
Efficacy criteria:
Virus; 3 log reduction</td><td>Ca(OH)$_2$: 600 g/m^2</td><td></td><td></td></tr>
<tr><td>Disinfectant</td><td>PT3</td><td>100% CaO</td><td>Organisms monitored:

Aerobic microorganisms at 30°C

Escherichia coli
B glucuronidase positive at 44 °C

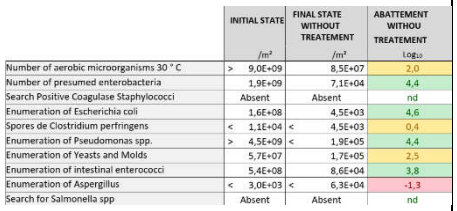
Clostridium Perfringens intestinal enterococci
enterobacteria at 30°C
Pseudomonas spp
Aspergillus
Salmonella
Staphylococci Coagulase</td><td>Field Trial (poultry farm in France)

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

Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.

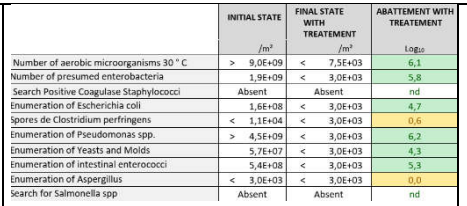
Samples are taken on delimited areas of 1x1 m. Each modality is represented by 6 repetitions, ie 6 zones of 1x1 m</td><td>Phase 1 control
Standard treatment

Phase 2:
800 g of CaO / m² of soil
Contact time: 48 h
Temp: ambient (max 31.4 deg C)

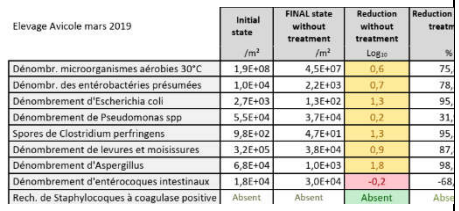
 
<table>
<tr><th></th><th>INITIAL STATE /m³</th><th>FINAL STATE WITHOUT TREATEMENT /m³</th><th>ABATTEMENT WITHOU TREATEMENT Log10</th></tr>
<tr><td>Number of aerobic microorganisms 30 °C</td><td>> 9,0E+09</td><td>8,5E+07</td><td>2,0</td></tr>
<tr><td>Number of presumed enterobacteria</td><td>1,9E+09</td><td>7,1E+04</td><td>4,4</td></tr>
<tr><td>Search Positive Coagulase Staphylococci</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
<tr><td>Enumeration of Escherichia coli</td><td>1,6E+08</td><td>4,5E+03</td><td>4,6</td></tr>
<tr><td>Spores de Clostridium perfringens</td><td>< 1,1E+04</td><td>< 4,5E+03</td><td>0,4</td></tr>
<tr><td>Enumeration of Pseudomonas spp.</td><td>> 4,5E+09</td><td>< 1,9E+05</td><td>4,4</td></tr>
<tr><td>Enumeration of Yeasts and Molds</td><td>5,7E+07</td><td>1,7E+05</td><td>2,5</td></tr>
<tr><td>Enumeration of intestinal enterococci</td><td>5,4E+08</td><td>8,6E+04</td><td>3,8</td></tr>
<tr><td>Enumeration of Aspergillus</td><td>< 3,0E+03</td><td>< 6,3E+04</td><td>-1,3</td></tr>
<tr><td>Search for Salmonella spp</td><td>Absent</td><td>Absent</td><td>nd</td></tr>
</table></td><td>100% CaO at 800 g/m^2 (48h contact time):

> Log 4 reduction in all organisms analysed

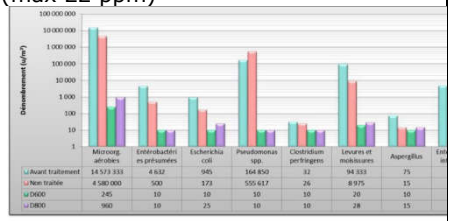
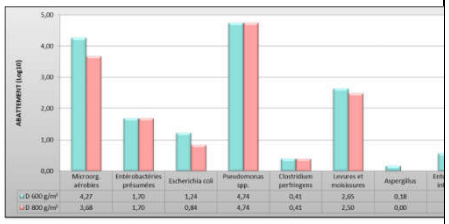
Reduction greater than 4 Log for microorganisms monitored with high initial concentrations (greater than 4 Log10).</td><td>6.7-16
RITTMO 18-445R
RI = 2</td></tr>
</table>

			Yeasts Moulds Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods	For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried. 2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored			

	INITIAL STATE /m²	FINAL STATE WITH TREATEMENT /m³	ABATTEMENT WITH TREATEMENT Log10
Number of aerobic microorganisms 30 ° C	> 9,0E+09	< 7,5E+03	6,1
Number of presumed enterobacteria	1,9E+09	< 3,0E+03	5,8
Search Positive Coagulase Staphylococci	Absent	Absent	nd
Enumeration of Escherichia coli	1,6E+08	< 3,0E+03	4,7
Spores de Clostridium perfringens	< 1,1E+04	< 3,0E+03	0,6
Enumeration of Pseudomonas spp.	> 4,5E+09	< 3,0E+03	6,2
Enumeration of Yeasts and Molds	5,7E+07	< 3,0E+03	4,3
Enumeration of intestinal enterococci	5,4E+08	< 3,0E+03	5,3
Enumeration of Aspergillus	< 3,0E+03	< 3,0E+03	0,0
Search for Salmonella spp	Absent	Absent	nd

Disinfectant	PT3	100% CaO	Organisms monitored: Escherichia coli B glucuronidase at 44 °C Clostridium Perfringens intestinal enterococci enterobacteria at 30°C Pseudomonas spp Aspergillus Salmonella Staphylococci Coagulase Yeasts Moulds Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods	Field Trial (Poultry farm in France) The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in poultry farming (indoor floor disinfection) Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product. Samples are taken on delimited areas of 1x1 m. Each modality is represented by 6 repetitions, i.e. 6 zones of 1x1 m For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.	600 g of CaO / m² of soil Contact time: 48 h Temp: ambient (Feb 2019: max 7.6 deg C). The increase of the soil temperature is + 3.1 ° between the start of the test and the end of the quicklime intake pH = 11 after 48H exposure and after hydration. The soil temperature is increased by 3.1 °C between the start of the test and the end of the quicklime intake. traces of ammonium (NH3) were measured in the breeding room (between 2 and 6ppm) during product treatment 	100% CaO at 600 g/m² (48h contact time): Pathogen concentration has declined sharply to reach values close to the detection limit for these pathogens (< 10 cfu/m²). Populations of aerobic microorganisms, intestinal enterococci and Pseudomonas have a reduction of more than 3 Logs. Staphylococci are not detected Initial level s of organisms low with some less than Log3.	6.7-17 RITTMO 19415R RI = 2

Elevage Avicole mars 2019	Initial state /m²	FINAL state without treatment /m²	Reduction without treatment Log10	Reduction treatm %
Dénombr. microorganismes aérobies 30°C	1,9E+08	4,5E+07	0,6	75,
Dénombr. des entérobactéries présumées	1,0E+04	2,2E+03	0,7	78,
Dénombrement d'Escherichia coli	2,7E+03	1,3E+02	1,3	95,
Dénombrement de Pseudomonas spp	5,5E+04	3,7E+04	0,2	31,
Spores de Clostridium perfringens	9,8E+02	4,7E+01	1,3	95,
Dénombrement de levures et moisissures	3,2E+05	3,8E+04	0,9	87,
Dénombrement d'Aspergillus	6,8E+04	1,0E+03	1,8	98,
Dénombrement d'entérocoques intestinaux	1,8E+04	3,0E+04	-0,2	-68,
Rech. de Staphylocoques à coagulase positive	Absent	Absent	Absent	Abse

				2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored	Elevage Avicole mars 2019 / INITIAL state /m² / FINAL state D600 /m² / reduction D600 Log10 / reduction D6 % Dénombr. microorganismes aérobies 30°C: 1,9E+08 / 6,8E+04 / 3,4 / 99, Dénombr. des entérobactéries présumées: 1,0E+04 / < 10 / 3,0 / 99, Dénombrement d'Escherichia coli: 2,7E+03 / < 10 / 2,4 / 99, Dénombrement de Pseudomonas spp: 5,5E+04 / < 10 / 3,7 / 99, Spores de Clostridium perfringens: 9,8E+02 / < 10 / 2,0 / 98, Dénombrement de levures et moisissures: 3,2E+05 / 6,5E+03 / 1,7 / 97, Dénombrement d'Aspergillus: 6,8E+04 / < 100 / 2,8 / 99, Dénombrement d'entérocoques intestinaux: 1,8E+04 / < 10 / 3,2 / 99, Rech. de Staphylocoques à coagulase positive: Absent / Absent / Absent / Abs		
Disinfectant	PT3	100% CaO	Organisms monitored: Escherichia coli B glucuronidase Clostridium Perfringens intestinal enterococci enterobacteria Pseudomonas spp Aspergillus Salmonella Staphylococci Coagulase Yeasts Moulds Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods	Field Trial (pig farm in France) The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in pig farms (indoor floor disinfection) Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product. Three treatments were studied: an untreated housing unit, a housing unit treated with 600 g / m² of product, and a last housing unit treated with 800 g / m² of product. Concrete floor and/or gratings 12 housing of equivalent sizes (4, 5x2 m) – 3 per treatment Samples are taken on delimited areas of 1x1 m. For an area of 1x1 m zone, the microorganisms are removed using sampling cloths 4 per zone (1/4 surface/wipe). The lime	600 or 800 g of CaO / m² of soil Contact time: 40 h Temp: ambient (ave 8.5 deg C), the temperature rise associated with the hydration of quicklime is limited (max 1.1 °C) pH = 11 after 40H exposure and after hydration Follow up of the emissions of ammoniac (NH3): increase emissions of NH3 in the box treated, even they remain very low (max 22 ppm)  Figure 5 : Population count of different microorganismes before traitement and after treatemen treated and non-treated areas.  Figure 6 : Reduction (log_{10}) of microbe populations between treated and non-treated zones 40h treatment	100% CaO at 600 g/m² (40h contact time): >2/3 Log for aerobic microorganisms, Pseudomonas spp, yeast and moulds Less reduction for the other microorganisms (small level of initial population) No significant difference between 600 and 800 g/m² application in terms of reduction.	6.7-18 RITTMO 19-431R RI = 2

				crust is removed from the soil using a shovel rinsed in ethanol and air-dried. 2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored			

Conclusion on the efficacy of the product
The product EULA OXI-LIME 23 has shown a sufficient efficacy, for the following uses claimed: ✓ For the disinfection of sewage sludge (PT 2) against bacteria and endoparasites (helminth eggs). The effective final use concentration and contact time are variable. pH should be > 12 and temperature > 50°C during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature. It should be calculated by the user with regard to the dry weight of the substrate. No data has been provided for yeast and fungi for the disinfection of sewage sludge. Regarding virus, for the disinfection of sewage sludge, the EFF WG (WG-I-2022 meeting) concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study. ✓ For the disinfection of manure (PT3), against bacteria, virus and endoparasites (helminth eggs). The effective final use concentration and contact time are variable. pH should be > 12 and temperature > 60°C during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH and temperature. It should be calculated by the user with regard to the dry weight of the substrate. No data has been provided for yeast and fungi for the disinfection of manure. ✓ For the disinfection of indoor floor surfaces of animal accommodations and transportation, and floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus at the application rate of 600 g CaO / m². The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA). To ensure a satisfactory level of efficacy and avoid the development of resistance, the provisions proposed in the SPC have to be implemented.

2.2.5.6 Occurrence of resistance and resistance management

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

Also the other effects described:

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

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

2.2.5.7 Known limitations

There are no known limitations for the biocidal products.

2.2.5.8 Evaluation of the label claims

Please refer to the SPC

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

Not applicable

2.2.6 Risk assessment for human health

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

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritation to the skin
Justification for the value/conclusion	No new data on skin corrosion and irritation was provided. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%), a classification Skin Irrit.2 H315 is needed.
Classification of the product according to CLP	Classification Skin irritation, category 2 - H315: Causes skin irritation is required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to the eye
Justification for the value/conclusion	No new data on eye irritation was provided. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%), a classification Eye Dam.1 H318 is needed.
Classification of the product according to CLP	Classification Serious eye damage cat. 1, H318: Causes serious eye damage is required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No new data on irritation in the respiratory tract was provided. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%), a classification STOT SE 3 H335 is needed.
Classification of the product according to CLP	Classification STOT SE 3 H335: May cause respiratory irritation is required.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin
Justification for the value/conclusion	No new data on skin sensitisation was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%) that is not classified for skin sensitization, No classification is required for the product.
Classification of the product according to CLP	No classification for skin sensitisation is required.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	No new data on respiratory sensitisation was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%) that is not classified for respiratory sensitization, no classification is required for the product.
Classification of the product according to CLP	No classification for respiratory sensitisation is required.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic by the oral route.
Justification for the selected value	No new data on acute oral toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%) that is not classified for acute oral toxicity, no classification is required for the product.
Classification of the product according to CLP	No classification for acute oral toxicity is required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via inhalation.
Justification for the selected value	No new data on acute inhalation toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%) that is not classified for acute inhalation toxicity, no classification is required for the product.
Classification of the product according to CLP	No classification for acute inhalation toxicity is required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by the dermal route.
Justification for the selected value	No new data on acute dermal toxicity was provided. Therefore, the classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the product (100%) that is not classified for acute dermal toxicity, no classification is required for the product.
Classification of the product according to CLP	No classification for acute dermal toxicity is required.

Information on dermal absorption

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

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

According to the definition of a substance of concern described in the guidance of the BPR Volume III Human health- Part B and C Risk assessment, there are no substance of concern identified, the product containing 100% of active substance.

Available toxicological data relating to a mixture

Not applicable.

Other

None.

2.2.6.2 Exposure assessment

EULA OXI-LIME 23 is used for disinfection of sewage sludge (PT2), of manures and of floor surfaces of animal accommodations indoor and outdoor (PT3) by professionals.

Burnt lime powder is packed in small sack of 25 kg, in big bags of 500 to 1200 kg and in powder tanker containing up to 30 T.
For the disinfection of sewage sludge and manure, the lime powder is poured into the hopper of the dosing equipment for the disinfection treatment. After that, it is mixed with the dewatered sludge/sewage or the manure with a blender in a fully automated process.

For the disinfection of floor surfaces of animal accommodations (indoor and outdoor), the lime powder is loaded into a wheelbarrow or a low impact spreader for the manual and semi-automated application tasks.
Considering the different mode of application and the available packaging sizes, exposure is expected to occur during the following tasks:

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

Inhalation and dermal exposure are considered for these different operations.

Adverse effects

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

Calcium and magnesium contents

The main contents of the lime variants are calcium, magnesium and their oxides and hydroxides.
According to the CAR on active substance, an assessment of **calcium and magnesium** is proposed. The following contents in the product EULA OXI-LIME 23 are considered for exposure assessment:

Calcium and magnesium contents in EULA OXI-LIME 23	
CaO (nominal)	100 %
MgO	5 %
Ca (equivalent) (max.)*	71.5 %
Mg (equivalent) (max.)	3 %

*Content in Ca considering CaO

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

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
Disinfection of sewage sludge and manures (Uses # 1 & 2)			
1.	Loading (manual)	**Primary exposure** –Manual loading of the product to sewage sludge and manures. This scenario takes into account also the opening of the bags.	Professionals
2.	Loading (semi-automated)	**Primary exposure** – Semi-automated loading of the product to sewage sludge and manures	Professionals
3.	Loading (automated)	**Primary exposure** – Automated loading to sewage sludge and manures	Professionals
4.	Cleaning	**Primary exposure**- Cleaning of the treatment unit	Professionals
5.	Disposal	**Primary exposure** - Disposal of empty bags	Professionals
6.	Disposal	**Primary exposure**- Disposal of treated waste	Professionals
Disinfection of floor surfaces of animal accommodations (indoor) and animal transportation (Use # 3)			
7.	Loading (manual)	**Primary exposure** - Manual loading of the product to a wheelbarrow or a low-impact spreader This scenario takes into account the opening of bags.	Professionals
8.	Application (manual)	**Primary exposure** - Manual spreading of dry product onto floor of animal accommodation using a shovel- indoor	Professionals
9.	Loading (Semi-automated)	**Primary exposure** - Semi-automated loading of the product to the tank of tractor. This scenario takes into account the opening of bags.	Professionals
10.	Application (Semi-automated)	**Primary exposure** - Semi- automatic application of dry product onto floor of animals accommodations using a spreader- indoor	Professionals
11.	Disposal	**Primary exposure** - Disposal of empty bags	Professionals
12.	Disposal	**Primary exposure**- Disposal of lime product after application	Professionals
Disinfection of floors of outdoor animal enclosures (Use # 4)			
13.	Application (manual)	**Primary exposure** - Manual spreading of dry product onto animal enclosure using a shovel - outdoor	Professionals

14.	Loading (Semi-automated)	**Primary exposure** - Semi-automated loading of the product to the tank of tractor in outdoor conditions. This scenario takes into account the opening of bags.	Professionals
15.	Application (Semi-automated)	**Primary exposure** - Semi- automatic application of dry product onto animal enclosure - outdoor	Professionals
16.	Disposal	**Primary exposure** - Disposal of empty bags	Professionals
17.	Disposal	**Primary exposure**- Disposal of lime product after application	Professionals

Industrial exposure

No industrial use for this product.

Professional exposure

Disinfection of sewage sludge and manures (Uses # 1 & 2)

Scenario [1]: Loading - Manual loading to sewage sludge and manures

Description of Scenario [1]
EULA OXI-LIME 23 is available in sack of 25 kg for manual loading to sewage sludge and manures. The bags are manually opened and emptied in the storage container (hopper) of the unit of treatment. Workers are not protected by any cab. The lime is then transferred to the sludge mixer through a screw conveyor (closed system). The actual mixing can occur before or after dewatering. The same assumption is made for the treatment of manures where bags of 25 kg calcium oxide are opened and emptied manually in an open area. Dermal exposure is assessed using RISKOFDERM Dermal Exposure Model and by taking into account an application rate of 25 kg/min and a task duration of 10 min (for details, please refer to output tables in Annexe 3.2). A dermal exposure of **56.9 mg bp/min** (75th percentile) is calculated. It has to be noted that exposure value for body is not available with this model (only hand exposure value). Gloves are taken into consideration in Tier 2. A field study for the measurement of potential inhalation exposure has been submitted by EULA in the CAR on the active substance[4]. The objective of the study was to measure inhalation exposure of two operators opening and emptying lime sacks into sludge treatment units at three different sites in France. The results of this study are as follows. When normalised over 8 hours, a daily exposure to inhalable dust was 0.27 to 2.58 mg of bp/m^3, with an average of 1.07 mg/m^3. The value retained from the study for the assessment is therefore equal to **2.58** mg pb/m^3. For Tier 2, a respiratory mask (APF 40) is taken into account.

	Parameters[1]	Value	References
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data

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

	Duration (min)	10	General time duration for a M&L scenario in accordance with the CAR on active substance PT 2
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3) – full shift	2.58	Field study from the CAR PT 2
	Inhalation exposure (mg/m^3) – task only	23.2	Field study from the CAR PT2
	Dermal absorption value	100 %	Active substance data (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14 , 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14 , 2017
Tier 2a	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory Protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [1]

Systemic effect - Calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	Tier 1/no PPE	3.07E-01	6.78E+00	7.09E+00
Scenario [1]	Tier 2a/gloves	3.07E-01	3.39E-01	6.46E-01

Systemic effect - Magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	Tier 1/no PPE	1.29E-02	2.85E-01	2.97E-01

Local effect – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [1]	Tier 1/no PPE	2.32E+01
Scenario [1]	Tier 2b/ respiratory mask (RPE40)	5.80E-01

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

Description of Scenario [2]
EULA OXI-LIME 23 is available in big sacks from 500 to 1200 kg for semi-automated loading of the burnt lime to sewage sludge and manures. The big-bag is lifted onto the hopper/discharger using a **telehandler (closed cabin) or a forklift (no cabin)** where it is automatically cut at the bottom to discharge the product. The worker can stay in the vehicle during the discharge. Alternatively, the bag can be placed at the top of the hopper and is not removed until it is empty (cf. CAR on active substance PT 2). The same assumption is made for the treatment of manures. Exposure is limited to the loading of lime before contact with sludge or manure. For dermal exposure, the indicative value of **56.9 mg/min** for manual loading is taken into account with an application rate of 25 kg/min (worst-case assumption as the product is lifted and not handled by the worker) and a task duration of 10 min. For Tier 2, gloves are taken into consideration. Potential inhalation exposure of the product is estimated using ART (Advanced Reach Tool) taking into account 100% active substance and a transfer of 100 to 1000 kg of active substance/min. A task duration of 120 min is taken into account. The predicted 75th percentile is equal to (see Annex 3.2 for reports): For full shift: - **0.27 mg/m^3 and 1.8 mg/m^3 for telehandler** for outdoor and indoor activities, respectively. - **0.62 mg/m^3 and 4.3 mg/m^3 for forklift** for outdoor and indoor activities, respectively. For task only: - **1.1 mg/m^3 and 7.3 mg/m^3 for telehandler** for outdoor and indoor activities, respectively. - **2.5 mg/m^3 and 17 mg/m^3 for forklift** for outdoor and indoor activities, respectively The values estimated during the task only are chosen for inhalation exposure as a worst-case.

	Parameters	**Value**	**References**
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure – Telehandler (with a closed cabin) indoors (mg/m^3) task only	1.1	ART model
	Inhalation exposure – Forklift indoors (mg/m^3) task only	17	ART model
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)

	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [2]

Systemic effect - Calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2]	Tier 1/no PPE	5.12E-01	6.78E+00	7.29E+00
Scenario [2]	Tier 2a/gloves	5.12E-01	3.39E-01	8.51E-01

Systemic effect - Magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2]	Tier 1/no PPE	2.15E-02	2.85E-01	3.06E-01

Local effect– oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [2] FORKLIFT indoor	Tier 1/no PPE	1.70E+01
	Tier 2b/ respiratory mask (APF40)	4.25E-01
Scenario [2] TELEHANDLER indoor	Tier 1/no PPE	1.10E+00
	Tier 2b/ respiratory mask (APF40)	0.03E+00

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

Description of Scenario [3]

EULA OXI-LIME 23 is available in powder tanker up to 30 T for automated loading to sewage sludge and manures.

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

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

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

Potential inhalation exposure is estimated using ART taking into account 100% of the active substance and a transferring 100 – 1000 kg of active substance/min. A task duration of 120 min is considered.

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

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

	Parameters	**Value**	**References**
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Dermal exposure – Hand only (mg/min)	7.97	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.97	ART model
	Inhalation exposure (mg/m^3)- task only	3.9	ART model
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAD hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [3]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	Tier 1/no PPE	1.16E-01	9.50E-01	1.07E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	Tier 1/no PPE	4.85E-03	3.99E-02	4.47E-02

Local effect – oxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [3]	Tier 1/no PPE	3.90E+00
Scenario [3]	Tier 2b/ RPE (APF 40)	9.75E-02

Scenario [4]: Cleaning of the treatment unit

Description of Scenario [4]			
According to the information presented in the CAR (PT2) on calcium oxide, cleaning of equipment is required for PT3. The cleaning of equipment (dry process) is reported to be done very carefully to reduce dust in suspension with vacuum cleaners or exhaust ventilation used during the cleaning process. For PT3, cleaning activities such as keeping surfaces clean in order and protected against corrosion (by lubricating components and equipment) are considered covered by exposure of PT2. There is no specific model to estimate exposure during this task. The closest model found in the BEAT database (2008) is the 'Cleaning of spray equipment' model, which includes rinsing and rubbing (with paper, rag or brush) tasks. The indicative exposure values for dermal exposure are as follows: - 35.8 µL/min for hands; - 19.2 µL/min for body. It is assumed that the air concentration during the cleaning task would be no higher than predicted for manual loading in the field study presented in the CAR (see above scenario [1]). Therefore, during the task, an inhalation exposure value of **23.2 mg/m³** is taken into account. A task duration of 30 min is considered.			
	Parameters	**Value**	**References**
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	30	Default value for this task
	Product density (tap density)	1.04 g/mL	Applicant's data
	Inhalation exposure (mg/m³)	23.2	Field study from CAR PT2
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m³/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 90%	HEEG Opinion 9, 2010
	coated coverall	PF = 90%	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [4]

Systemic effect - calcium

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	Tier 1/no PPE	1.73E-01	1.97E+01	-	1.99E+01
Scenario [4]	Tier 2a/gloves	1.73E-01	8.17E+00	-	8.35E+00
Scenario [4]	Tier 2b /gloves + coated coverall	1.73E-01	2.66E+00		2.83E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	Tier 1/no PPE	7.25E-03	8.27E-01	8.35E-01
Scenario [4]	Tier 2a/gloves	7.25E-03	3.43E-01	3.50E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [4]	Tier 1/no PPE	2.32E+01
Scenario [4]	Tier 2b/ RPE (APF 40)	5.80E-01

Scenario [5]: Cleaning – Disposal of empty bags

Description of Scenario [5]
After loading the lime powder from the big bags into the treatment unit using a telehandler (with a closed cabin), the bags are disposed of still using a telehandler. No dermal exposure is expected during this task that is performed using a vehicle. Potential inhalation exposure is estimated using ART taking into account 100% of the active substance and a task duration of 10 min. As a worst-case situation the "Handling of substantially and visibly contaminated objects (layer of more than 0.5 kg)" has been chosen. The model has been run for outdoor and indoor simulations. The predicted 75th percentile is equal to (see Annex 3.2 for reports): For full shift: - **0.015** mg/m^3 (outdoor); - **0.051** mg/m^3 (indoor). For task only: - **0.39** mg/m^3 (outdoor); - **2.5** mg/m^3 (indoor). As a worst-case approach, only indoor value is retained for the risk assessment.

	Parameters	**Value**	**References**
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	0.015 (out) 0.051 (in)	ART model
	Inhalation exposure (mg/m^3)- task only	0.39 (out) 2.5 (in)	ART model
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAD hoc Recommendation no. 14, 2017
Tier 2	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [5]

Systemic effect - calcium

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

Summary table: systemic exposure from professional uses				
Scenario [5]	Tier 1/no PPE	6.21E-03	-	6.21E-03

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5]	Tier 1/no PPE	2.6E-04	-	2.6E-04

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [5]	Tier 1/no PPE	2.5
Scenario [5]	Tier 2b/ RPE (APF 40)	0.063

Combined effect (scenario 1-2 + 4 + 5)

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

As described in the scenario 3, the automatically unloading of the burnt lime powder in the treatment unit is usually performed by the truck driver and not the professional that's why no combined exposure has been performed with this scenario.

Systemic exposure – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1+4+5	Tier 1/no PPE	1.79E-01	2.65E+01	2.67E+01
	Tier 2/ gloves for loading and gloves + coverall for cleaning	1.79E-01	3.00E+00	3.48E+00
Scenario 2+4+5	Tier 1/no PPE	1.79E-01	2.65E+01	2.67E+01
	Tier 2/gloves for loading and gloves + coverall for cleaning	1.79E-01	3.00E+00	3.19E+00

Systemic exposure – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1+4+5	Tier 1/no PPE	7.5E-03	1.11E+00	1.12E+00
	Tier 2/ gloves	7.5E-03	3.30E-01	3.50E-01
Scenario 2+4+5	Tier 1/no PPE	7.5E-03	1.11E+00	1.12E+00
	Tier 2/ gloves	7.5E-03	3.30E-01	3.50E-01

Scenario [6]: Disposal of treated sludge and manure

Description of Scenario [6]
According to the information reported in the CAR (PT3), the oxide component would be transformed to hydroxide and a significant degree of further chemical reaction would take place with components of the treated substrate producing a non-dusty product. Workers have to wear personal protective equipment during the disposal phase and any residual contamination effectively minimised.

Disinfection of floor surfaces of animal accommodations (indoor) and animal transportation (Uses # 3)

Scenario [7]: Loading – Manual loading into a wheelbarrow or a low impact spreader for disinfection of floor surfaces

Description of Scenario [7]

The product is available in paper sack of 25kg, which can be manually opened thanks to a knife and then emptied in a wheelbarrow or a low-impact spreader for application of the product onto animal accommodation floor surfaces.

During this task, professionals are not enclosed into a cabin, therefore dermal and inhalation exposure can occur.
RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model). An application rate of 25 kg/min and a task duration of 10 min are taken into consideration. The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2).
For Tier 2, gloves are taken into account.

Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s and a transfer of 10 – 100 kg of active substance/min. A task duration of 10 min is considered.

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

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

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

	Parameters	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	2	ART Model
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [7]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7]	Tier 1/no PPE	2.62E-01	6.78E+00	7.04E+00
Scenario [7]	Tier 2a/gloves	2.62E-01	3.39E-01	6.01E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [7]	Tier 1/no PPE	1.10E-02	2.85E-01	2.96E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [7]	Tier 1/no PPE	1.10E+02
Scenario [7]	Tier 2b/ RPE (APF 40)	2.75E+00

Scenario [8]: Application– Manual spreading of dry product onto floor surfaces of animal accommodation using a shovel- indoor

After the transfer of the burnt lime powder from bags to a wheelbarrow or a spreader (scenario 7), the lime is manually spread using a spade or shovel over the area to be treated.
During this task, professionals are not enclosed into a cabin therefore dermal and inhalation exposure can occurred.
Indoor application are taken into account for the disinfection of poultry, cattle and sheep floor surfaces (as intended by the applicant) with only good natural ventilation.

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

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

Based on the following equation: T = d/v

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

It can be possible to calculate a task time duration.

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

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

Round trips = 58 m / 0.5 m = 116.

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

d = √surface area x round trips
d = √3330 m^2 x 116

d = 6 693.9 m (rounded to **6.7 km**).

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

Since the estimation of potential exposure, especially inhalation exposure, is dependent to the treated surface area, the scenario [8] has been split into 4 sub-scenario taking into account the minimum and the maximum default surface values defined for poultry and cattle. The different scenarios developed below are as follows:

- Scenario [8a]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**;
- Scenario [8b]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**;
- Scenario [8c]: Application– Manual spreading of dry product onto floor surfaces of **cattle _ Minimum surface area**;
- Scenario [8d]: Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**.

Description of Scenario [8a] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**
According to the ESD PT3, a poultry covers different subcategories of housing (batteries, free range, etc.) with different floor surfaces ranging from 390 to 3330 m^2. Taking into account the surface/time ratio calculated above, a task time duration of 18.74 min (rounded to 19 min) is calculated for the lowest default surface value of 390 m^2 for poultry. (see Annex 3.2 for the detailed calculations). RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above. A dermal exposure (75th percentile) of **122** mg of bp/min is obtained. For Tier 2, gloves are taken into account. The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of bp/min is retained as it corresponds to the dose range of the model proposed for a manual task. A minimal room volume of 1000 m^3 has been taken account in the model. This volume corresponds approximately to the surface of 390 m^2 multiplied by a height of 2.7 m calculated from the ESD PT 3 data[5]. The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

[5] Based on the data on floor surface area presented in the ESD PT 3 it is possible to calculate a default value for height.
A wall and roof area of 600 $m^2$is presented in the ESD associated to a floor area of 390 m2. Making the worst-case assumption that the floor surface area is equal to the ceiling surface area, this leads to a total wall surface area of 210 m^2 meaning that a single wall is of 52.5 m^2 surface area. Making the assumption that the floor is a squared surface with a 24 m length side, a maximal wall height of 2.7 m is obtained.

Description of Scenario [8a] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**
- For full shift (normalised over 8 hours): **4.3** mg bp/$m^{3,}$ - For task only (19 min): **110** mg/ m^3. For Tiers 2, a respiratory protection (APF 40) is taken into account.

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	19	See calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	4.3	ART Model
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [8a]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8a]	Tier 1/no PPE	5.12E-01	2.76E+01	2.81E+01
Scenario [8a]	Tier 2a/gloves	5.12E-01	1.38E+00	1.89E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8a]	Tier 1/no PPE	2.15E-02	1.16E+00	1.18E+00
Scenario [8a]	Tier 2a/gloves	2.15E-02	5.80E-02	7.95E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [8a]	Tier 1/no PPE	1.10E+02
Scenario [8a]	Tier 2/ (APF 40)	2.75E+00

Description of Scenario [8b] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **122** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of active substance/min is retained as it corresponds to the dose range of the model proposed for a manual task.
A maximal room volume of 3000 m^3 has been taken account in the model.
It has to be noted that this volume corresponds to the maximal volume which can be selected in ART. This value is conservative since a maximal volume of 19 314 m^3 is calculated taking into account a maximal floor surface area of 3330 m^2 and a height of 5.8 m calculated from the ESD PT 3 data[6].

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	160	See calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	32	ART Model
	Inhalation exposure (mg/m^3)- task only	97	ART Model

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

Description of Scenario [8b] : Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**			
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [8b]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8b]	Tier 1/no PPE	3.81E+00	2.33E+02	2.36E+02
Scenario [8b]	Tier 2a/gloves	3.81E+00	1.16E+01	1.54E+01
Scenario [8b]	Tier 2b /gloves RPE (APF 40)	9.53E-02	1.16E+01	1.17E+01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8b]	Tier 1/no PPE	1.60E-01	9.76E+00	9.92E+00
Scenario [8b]	Tier 2a/gloves	1.60E-01	4.88E-01	6.48E-01
Scenario [8b]	Tier 2b /gloves + RPE (APF 40)	4.00E-03	4.88E-01	4.92E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [8b]	Tier 1/no PPE	9.70E+01
Scenario [8b]	Tier 2a/ RPE (APF 40)	2.43E+00

Description of Scenario [8c] : Application– Manual spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**

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

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **122** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of active substance/min is retained as it corresponds to the dose range of the model proposed for a manual task.
A minimal room volume of 300 m^3 has been taken account in the modelling. This volume corresponds approximately to the mean surface of 160 m^2 multiplied by a height of 3.3 m calculated from the ESD PT 3 data[7].

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	8	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	2.4	ART Model
	Inhalation exposure (mg/m^3)- task only	140	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)

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

Description of Scenario [8c] : Application– Manual spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**			
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [8c]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8c]	Tier 1/no PPE	2.86E-01	1.16E+01	1.19E+01
Scenario [8c]	Tier 2a/gloves	2.86E-01	5.82E-01	8.68E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8c]	Tier 1/no PPE	1.20E-02	4.88E-01	5.00E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [8c]	Tier 1/no PPE	1.40E+02
Scenario [8c]	Tier 2b/ RPE (APF 40)	3.50E+00

Combined effect (scenario 7 + 8c)

Systemic effect – calcium

Description of Scenario [8d] : Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above.
A dermal exposure (75th percentile) of **122** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of active substance/min is retained since an application rate of 16.65 kg/min has been calculated above.
A maximal room volume of 3000 m^3 has been selected in the ART model. This volume corresponds approximately to the maximum surface of 1170 m^2 multiplied by a height of 3.7 m calculated from the ESD PT 3 data[8].

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	56	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	11	ART Model
	Inhalation exposure (mg/m^3)- task only	97	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017

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

Description of Scenario [8d] : Application– Manual spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**			
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [8d]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8d]	Tier 1/no PPE	1.31E+00	8.14E+01	8.27E+01
Scenario [8d]	Tier 2a/gloves	1.31E+00	4.07E+00	5.38E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [8d]	Tier 1/no PPE	5.50E-02	3.42E+00	3.47E+00
Scenario [8d]	Tier 2a/gloves	5.50E-02	1.71E-01	2.26E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [7d]	Tier 1/no PPE	9.70E+01
Scenario [7d]	Tier 2b/ RPE (APF 40)	2.43E+00

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

A field study with measured exposure data has been provided by the applicant in order to refine inhalation exposure assessment that is overestimated when using exposure models.

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

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

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

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

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

For Tiers 3b, a respiratory protection (APF 40) is taken into account.

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	9.58
	Tier 3b/ RPE (APF 40)	2.40E-01

Scenario [9]: Loading – Semi automated loading into the tank of a tractor for disinfection of floor surfaces

Description of Scenario [9]
The product is available in big bags from 500 to 1000 kg, which can be : - fully automatically raised and discharged into a reception hopper for direct application on floor surfaces; - semi-automatically raised and emptied into the tank of a tractor for application of the product onto animal accommodation floor surfaces. Assuming that not all the farmers have *Big Bag emptying stations,* the second assumption has been retained in the risk assessment in worst case. During this task, it's considered that the worker stays in the vehicle of the forklift (partial enclosure) during the full discharge of the bag. RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model). An application rate of 25 kg/min and a task duration of 10 min are taken into consideration by making the worst case hypothesis that worker holds the bag during the unloading. The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2). For Tier 2, gloves are taken into account. Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s and a transfer of 100 – 1000 kg of active substance/min. The predicted 75th percentile obtained is equal to (see Annex 3.2 for ART reports): - For full shift (normalised over 8 hours), **0.94** mg bp/m^3, - For task only (10min), **45** mg/ m^3. For Tier 2, a respiratory protection (mask with APF 40) is taken into account.

	Parameters	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.94	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [9]

Systemic effect – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9]	Tier 1/no PPE	1.12E-01	6.78E+00	6.89E+00
Scenario [9]	Tier 2a/gloves	1.12E-01	3.39E-01	4.51E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [9]	Tier 1/no PPE	4.70E-03	2.85E-01	2.89E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [9]	Tier 1/no PPE	4.50E+01
Scenario [9]	Tier 2b/ RPE (APF 40)	1.13E+00

Scenario [10]: Application– Semi-automated spreading of dry product onto floor surfaces of animal accommodation using a low-impact spreader - indoor

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

Based on the following equation: T = d/v

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

It can be possible to calculate a task time duration.

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

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

Round trips = 58 m / 1 m = 58.

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

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

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

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

- Scenario [10a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**;
- Scenario [10b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**;
- Scenario [10c]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Minimum surface area**;
- Scenario [10d]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**.

Description of Scenario [10a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**

The burnt lime powder contained in bulk big sacks (500-1200 kg) could be loaded into the tank of a tractor/ low impact spreader for a semi-automated application of burnt lime powder onto floor surfaces.
Taking into account the surface/time ratio of 83.25 kg/min calculated above, a task time duration of 4.68 min (rounded to 5 min) is calculated for the lowest default surface value of 390 m^2 for poultry (see Annex 3.2 for the detailed calculations).

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 100 – 1000 kg of active substance/min is retained as it corresponds to the dose range of the model proposed for an automatic task.
In this scenario, the emission source is considered to be far from the worker's breast.
A minimal room volume of 1000 m^3 has been taken account in the model. This volume corresponds approximately to the real surface of 390 m^2 multiplied by a height of 2.7 m calculated from the ESD PT 3 data.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.1	ART Model

Description of Scenario [10a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area**			
	Inhalation exposure (mg/m^3)- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [10a]

Systemic exposure - calcium

Summary table: systemic exposure from -professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10a]	Tier 1/no PPE	1.31E-01	1.18E+00	1.31E+00

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10a]	Tier 1/no PPE	5.50E-03	4.95E-02	5.50E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [10a]	Tier 1/no PPE	1.10E+02
Scenario [10a]	Tier 2b/ RPE (APF 40)	2.75E+00

Description of Scenario [10b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area**

Taking into account the surface/time ratio calculated above, a task time duration of 40 min is calculated for the highest default surface value of 3330 m^2 for poultry (see Annex 3.2 for the detailed calculations).
During this task, professionals are enclosed in a partial cab without mechanic ventilation so dermal and inhalation exposure can potentially occurred during the application of the product.
RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 100 – 1000 kg of bp/min is retained.
In this scenario, the emission source is considered to be far from the worker's breast.

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	3.8	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [10b]

Systemic exposure - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10b]	Tier 1/no PPE	4.53E-01	9.44E+00	9.89E+00
Scenario [10b]	Tier 2a/gloves	4.53E-01	4.72E-01	9.25E-01

Systemic exposure - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10b]	Tier 1/no PPE	1.90E-02	3.96E-01	4.15E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m^3)**
Scenario [10b]	Tier 1/no PPE	4.50E+01
Scenario [10b]	Tier 2b/RPE (APF 40)	1.13E+00

Description of Scenario [10c]: Application– Semi-automatic spreading of dry product onto floor surfaces of **Cattle _ Minimum surface area**

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

Taking into account the surface/time ratio of 66.6 m^2/min calculated above, a task time duration of 1.92 min (rounded to 2 min) is calculated for the lowest default surface value of 160 m^2 for cattle (see Annex 3.2 for the detailed calculations).

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 100 – 1000 kg of bp/min is retained.
In this scenario, the emission source is considered to be far from the worker's breast.
A minimal room volume of 300 m^3 has been selected in the ART modelling. This volume corresponds approximately to the minimal surface of 160 m^2 multiplied by a height of 3.3 m calculated from the ESD PT 3 data.

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	2	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.5	ART Model
	Inhalation exposure (mg/m^3)- task only	360	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [10c]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10c]	Tier 1/no PPE	1.79E-01	4.72E-01	6.51E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10c]	Tier 1/no PPE	7.50E-03	1.98E-02	2.73E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [10c]	Tier 1/no PPE	3.60E+02
Scenario [10c]	Tier 2a/ RPE (APF 40)	9.00E+00

Description of Scenario [10d]: Application– Semi-automatic spreading of dry product onto floor surfaces of **cattle _ Maximum surface area**

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

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

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

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

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

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	14	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.3	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [10d]

Systemic effect- calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10d]	Tier 1/no PPE	1.55E-01	3.30E+00	3.46E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [10d]	Tier 1/no PPE	6.50E-03	1.39E-01	1.45E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [10d]	Tier 1/no PPE	4.50E+01
Scenario [10d]	Tier 2a/ RPE (APF 40)	1.13E+00

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

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

It is assumed that inhalation exposure of professional will be greater using a low impact spreader rather than a tractor for the application.
Indeed, with a tractor, professionals are enclosed in a partial cab and so more protected from particles emissions than during manual application with a low impact spreader.
Thus, measured data obtained for manual application with a low impact spreader can be used as refinement of the scenario 10 corresponding to semi-automated application of lime products with a tractor.

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

For Tiers 3b, a respiratory protection (APF 20) is taken into account.

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	5.59E+00
	Tier 3b/ RPE (APF 20)	2.80E-01

Scenario [11]: Cleaning – Disposal of empty bags

Description of Scenario [11]
After loading the lime powder from the big bags into the emptying device using a telehandler (with a closed cabin), the bags are disposed of still using a telehandler. No dermal exposure is expected during this task that is performed using a vehicle. Potential inhalation exposure is estimated using ART taking into account 100% of the active substance and a task duration of 10 min. As a worst-case situation the "Handling of substantially and visibly contaminated objects (layer of more than 0.5 kg)" has been chosen. The model has been run for outdoor and indoor simulations. The predicted 75th percentile is equal to (see Annex 3.2 for reports): For full shift: - **0.015** mg/m^3 (outdoor); - **0.051** mg/m^3 (indoor). For task only: - **0.39** mg/m^3 (outdoor); - **2.5** mg/m^3 (indoor). As a worst-case approach, only indoor value is retained for the risk assessment. For the disposal of small bags (25 kg), the potential exposure during this task is considered covered by the assessment performed for the manual application on the floor (using a shovel). Indeed, the potential exposure during this task is deemed to be of a lower extend compared to the application.

	Parameters	**Value**	**References**
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Inhalation exposure (mg/m^3)- full shift	0.015 (out) 0.051 (in)	ART model
	Inhalation exposure (mg/m^3)- task only	0.39 (out) 2.5 (in)	ART model
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAD hoc Recommendation no. 14, 2017
Tier 2	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [11]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [11]	Tier 1/no PPE	6.21E-03	-	6.21E-03

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [11]	Tier 1/no PPE	2.6E-04	-	2.6E-04

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [11]	Tier 1/no PPE	2.5
Scenario [11]	Tier 2b/ RPE (APF 40)	0.063

Combined exposure (M&L + application + disposal of empty bags)

Manual process (M&L and application)

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 7+8a+11	Tier 1/no PPE	7.8E-01	3.44E+01	3.52E+01
	Tier 2/gloves for loading and gloves + mask APF 40 for application	7.8E-01	1.72E+00	2.49E+00
Scenario 7+8b+11	Tier 1/no PPE	4.08E+00	2.39E+02	2.43E+02
	Tier 2/gloves for loading and gloves + mask APF 40 for application	3.6E-01	1.20E+01	1.23E+01
Scenario 7+8c+11	Tier 1/no PPE	2.30E-02	5.5E-01	1.84E+01
	Tier 2/gloves for loading and gloves + mask APF 40 for application	2.30E-02	5.5E-01	9.21E-01
Scenario 7+8d+11	Tier 1/no PPE	1.57E+00	8.82E+01	8.98E+01
	Tier 2/gloves for loading and gloves + RPE APF 40 for application	3.0E-01	4.41E+00	4.70E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 7+8a+11	Tier 1/no PPE	3.3E-02	1.44E+00	1.48E+00
	Tier 2/gloves for loading and gloves + mask APF 40 for application	3.3E-02	7.22E-02	1.05E-01
Scenario 7+8b+11	Tier 1/no PPE	1.71E-01	1.00E+01	1.02E+01
	Tier 2/gloves for loading and gloves + mask APF 40 for application	1.60E-02	5.02E-01	5.17E-01
Scenario 7+8c+11	Tier 1/no PPE	2.40E-02	7.73E-01	7.96E-01
	Tier 2/gloves	2.40E-02	3.86E-02	6.26E-02
Scenario 7+8d+11	Tier 1/no PPE	6.66E-02	3.70E+00	3.77E+00
	Tier 2/gloves	6.66E-02	1.85E-01	2.51E-01

Semi-automated process (loading and application)

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 9+10a+11	Tier 1/no PPE	2.46E-01	7.96E+00	8.20E+00
	Tier 2/gloves	2.46E-01	3.98E-01	6.4E-01
Scenario 9+10b+11	Tier 1/no PPE	5.7E-01	1.62E+01	1.68E+01
	Tier 2/gloves	5.7E-01	8.11E-01	1.38E+00
Scenario 9+10c+11	Tier 1/no PPE	2.97E-01	7.25E+00	7.54E+00
	Tier 2/gloves	2.97E-01	3.63E-01	6.6E-01
Scenario 9+10d+11	Tier 1/no PPE	2.7E-01	1.01E+01	1.04E+01
	Tier 2/gloves	2.7E-01	5.04E-01	7.77E-01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 9+10a+11	Tier 1/no PPE	1.05E-02	3.34E-01	3.44E-01
Scenario 9+10b+11	Tier 1/no PPE	2.39E-02	6.81E-01	7.04E-01
	Tier 2/gloves	2.39E-02	3.40E-02	5.8E-02
Scenario 9+10c+11	Tier 1/no PPE	1.24E-02	3.04E-01	3.17E-01
Scenario 9+10d+11	Tier 1/no PPE	1.12E-02	4.23E-01	4.34E-01

Scenario [12]: – Disposal of lime product after application

Description of Scenario [12] : Post application - Disposal of lime product
According to the information reported in the provided field study, after the maturation task, the burnt lime powder is swept off the treated floor and thrown into a suitable bag. During this cleaning task, dermal and inhalation exposure of the professional can occur. For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 8a has been used. For inhalation exposure, measurements from the field data have been used. The results for inhalation exposures (95th percentile) from the study are as follow: - For full shift (normalised over 8 hours): 0.23 mg /m^3; - For task only: 2.79 mg/ m^3. For Tiers 3, a respiratory protection (APF 10) is taken into account.

Calculations for Scenario [12]

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Field study	Tier 3/no PPE	2.74E-02	2.76E+01	2.77E+01
	Tier 3a/ gloves	2.74E-02	1.38E+00	1.41E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Field study	Tier 3/no PPE	1.15E-03	1.16E+00	1.16E+00
	Tier 3a/ gloves	1.15E-03	5.80E-02	5.91E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	2.79E+00
	Tier 3b/ RPE (APF 10)	2.79E-01

Disinfection of floors of outdoor animal enclosures (Use # 4)

Scenario [13]: Application– Manual spreading of dry product onto ground of animal enclosure using a shovel - outdoor

As disclaimed in the SPC, the product could be used outdoor for the disinfection surfaces of animal enclosures.

Compared to the scenario [8], the variability of the model depends on only one parameter: the work area. Indeed, in this context, both the source and the worker are located outdoors and not in a room with a specific size enclosed by walls on each side and a roof on top limiting the concentration of the product in the air. As indoor scenarios have also been developed in the assessment and are worst case scenarios, it was considered more relevant to assess the outdoor exposure in very different conditions. Therefore, for outdoor scenarios, it was considered that the source of exposure was not located close to the building.

Otherwise, the same parameters than those chosen and calculated for scenario [8] applied.

The scenario [13] has been split into 2 sub-scenario taking into account minimum and maximum surfaces to be treated for poultry. Indeed, considering the type of application it is assumed that poultry areas represent the surfaces that generates the highest exposure of the operator during the spreading of lime products.

- Scenario [13a]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Minimum surface area (outdoor);**
- Scenario [13b]: Application– Manual spreading of dry product onto floor surfaces of **poultry _ Maximum surface area (outdoor).**

Description of Scenario [13a]: Application– Manual spreading of dry product onto floor surfaces of **animal enclosure _ Minimum surface area (outdoor)**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during this task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above. A dermal exposure (75th percentile) is **122** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of active substance/min is retained.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	19	see calculation above

Description of Scenario [13a]: Application– Manual spreading of dry product onto floor surfaces of **animal enclosure _ Minimum surface area (outdoor)**			
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	1.8	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [13a]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13a]	Tier 1/no PPE	2.15E-01	2.76E+01	2.78E+01
Scenario [13a]	Tier 2a/gloves	2.15E-01	1.38E+00	1.60E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13a]	Tier 1/no PPE	9.00E-03	1.16E+00	1.17E+00
Scenario [13a]	Tier 2a/gloves	9.00E-03	5.80E-02	6.70E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [13a]	Tier 1/no PPE	4.50E+01
Scenario [13a]	Tier 2b/ RPE (APF 40)	1.13E+00

Description of Scenario [13b] : Application– Manual spreading of dry product onto floor surfaces of **animal enclosure _ Maximum surface area (outdoor)**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during this task. An application rate of 16.65 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 20.8 m^2/min calculated above. A dermal exposure (75th percentile) is **122** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 10 – 100 kg of active substance/min is retained.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

- For full shift (normalised over 8 hours), **15** mg bp/m^3,
- For task only (160 min), **45** mg/ m^3.

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	160	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	15	ART Model
	Inhalation exposure (mg/m^3)- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [13b]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13b]	Tier 1/no PPE	1.79E+00	2.33E+02	2.34E+02

Summary table: systemic exposure from professional uses				
Scenario [13b]	Tier 2a/gloves	1.79E+00	1.16E+01	1.34E+01
Scenario [13b]	Tier 2b /gloves + RPE (APF 40)	4.47E-02	1.16E+01	1.17E+01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13b]	Tier 1/no PPE	7.50E-02	9.76E+00	9.84E+00
Scenario [13b]	Tier 2a/gloves	7.50E-02	4.88E-01	5.63E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [13b]	Tier 1/no PPE	4.50E+01
Scenario [13b]	Tier 2b/ RPE (APF 40)	1.13E+00

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

In the field study, no inhalation exposure measurements have been performed for outdoor application of lime products for surface disinfection. All the measurements have been performed for indoor activities (for more details please refer to the paragraph "*Monitoring data"* of the PAR).
It is assumed that inhalation exposure of professionals during outdoor manual application of powder product is of a low order compared to indoor application.
Thus, it is considered that outdoor inhalation exposure is covered by the indoor exposure applying the same PPE.
Please refer to scenario [8].

Scenario [14]: Loading – Semi automated loading into the tank of a tractor for disinfection of outdoor floors

Description of Scenario [14]
The product is available in big bags from 500 to 1200 kg, which are mechanically raised and emptied into the tank of a tractor for application of the product onto floors of animal enclosures. During this task, it's considered that the worker stays in the cabin of the forklift (partial enclosure) during the full discharge of the bag. RISKOFDERM Dermal Exposure Model is used to estimate the potential dermal exposure during this task (only hand exposure is estimated with this model). An application rate of 25 kg/min and a task duration of 10 min are taken into consideration by making the worst case hypothesis that worker holds the bag during the unloading. The resulting dermal exposure (75th percentile) is **56.9** mg of bp/min (see reports in Annexe 3.2). For Tier 2, gloves are taken into account. Potential inhalation exposure is estimated using Advanced Reach Tool (ART) by taking into account 100% a.s and a transfer of 100 – 1000 kg of active substance/min. The predicted 75th percentile obtained is equal to (see Annex 3.2 for ART reports): - For full shift (normalised over 8 hours), **0.18** mg bp/m^3, - For task only (10min), **8.8** mg/ m^3. For Tier 2, a respiratory protection (mask with APF 40) is taken into account.

	Parameters	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.18	ART Model
	Inhalation exposure (mg/m^3)- task only	8.8	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [14]

Systemic effect – calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14]	Tier 1/no PPE	2.15E-02	6.78E+00	6.80E+00
Scenario [14]	Tier 2a/gloves	2.15E-02	3.39E-01	3.60E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [14]	Tier 1/no PPE	9.00E-04	2.85E-01	2.85E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [14]	Tier 1/no RPE	8.80E+00
Scenario [14]	Tier 2b/ RPE (APF 40)	2.20E-01

Scenario [15]: Application–Semi automated application of dry product onto ground of animal enclosure - outdoor

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

In this context, both the source and the operator are located outdoor where the concentration of the product in the air is not retained by walls and roof top as in indoor conditions. This difference of exposure is taken account in the modelling.
The scenario [15] has been split into 2 sub-scenario taking into account minimum and maximum surfaces to be treated for poultry:

- Scenario [15a]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Minimum surface area (outdoor);**
- Scenario [15b]: Application– Semi-automatic spreading of dry product onto floor surfaces of **poultry _ Maximum surface area (outdoor).**

Description of Scenario [15a] : Application– Semi-automatic spreading of dry product onto floor surfaces of **animal enclosure _ Minimum surface area outdoor**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task. An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 100 – 1000 kg of active substance/min is retained.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.12	ART Model
	Inhalation exposure (mg/m^3)- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)

Description of Scenario [15a] : Application– Semi-automatic spreading of dry product onto floor surfaces of **animal enclosure _ Minimum surface area outdoor**			
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [15a]

Systemic effect - calcium

Summary table: systemic exposure from non-professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [15a]	Tier 1/no PPE	1.43E-02	1.18E+00	1.19E+00

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [15a]	Tier 1/no PPE	6.00E-04	4.95E-02	5.01E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [15a]	Tier 1/no RPE	1.10E+01
Scenario [15a]	Tier 2a/ respiratory mask (RPE40)	2.75E-01

Description of Scenario [15b] : Application– Semi-automatic spreading of dry product onto floor surfaces of **animal enclosure _ Maximum surface area outdoor**

RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure during the task.
An application rate of 66.6 kg/min is calculated based on the dose of 0.8 kg bp/m^2 proposed by the applicant in the SPC and the application rate of 83.25 m^2/min calculated above.
A dermal exposure (75th percentile) of **19.8** mg of bp/min is obtained.
For Tier 2, gloves are taken into account.

The potential inhalation exposure is estimated using the Advanced Reach Tool (ART) and taking into account 100% a.s. A transfer of 100 – 1000 kg of active substance/min is retained.
The results for potential inhalation exposure are as follows (see Annex 3.2 for ART reports):

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

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

	Parameters[1]	**Value**	**References**
Tier 1	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	71.5%	Applicant's data
	Assumed magnesium fraction	3%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m^3)- full shift	0.96	ART Model
	Inhalation exposure (mg/m^3)- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m^3/hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2a	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
Tier 2b	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

Calculations for Scenario [15b]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [15b]	Tier 1/no PPE	1.14E-01	9.44E+00	9.55E+00
Scenario [15b]	Tier 2a/gloves	1.14E-01	4.72E-01	5.86E-01

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [13b]	Tier 1/no PPE	4.80E-03	3.96E-01	4.01E-01

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [15b]	Tier 1/no RPE	1.10E+01
Scenario [15b]	Tier 2a/ RPE (APF 40)	2.75E-01

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

In the field study, no inhalation exposure measurements have been performed for outdoor application of lime products for surface disinfection. All the measurements have been performed for indoor activities (for more details please refer to the paragraph *"Monitoring data"* of the PAR).
It is assumed that inhalation exposure of professionals during outdoor semi-automated application of powder product is of a low order compared to indoor application.
Thus, it is considered that outdoor inhalation exposure is covered by the indoor exposure applying the same PPE.
Please refer to scenario [10].

Scenario [16]: Cleaning – Disposal of empty bags

Description of Scenario [16]
After loading the lime powder from the big bags into the tank of a tractor using a telehandler (with a closed cabin), the bags are disposed of still using a telehandler. For the disposal of small bags (25 kg), the potential exposure during this task is considered covered by the assessment performed for the manual application on the floor (using a shovel). Indeed, the potential exposure during this task is deemed to be of a lower extend compared to the application. The same parameters than those presented in scenario [11] have been used. Please refer to scenario [11]

Calculations for Scenario [16]

Systemic effect - calcium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [16]	Tier 1/no PPE	6.21E-03	-	6.21E-03

Systemic effect - magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [16]	Tier 1/no PPE	2.6E-04	-	2.6E-04

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Scenario [16]	Tier 1/no PPE	2.5
Scenario [16]	Tier 2b/ RPE (APF 40)	0.063

Combined exposure (M&L + application + disposal of empty bags)

<u>Manual process (M&L and application)</u>

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 7+13a+16	Tier 1/no PPE	4.8E-01	3.44E+01	3.49E+01
	Tier 2/gloves	4.8E-01	1.72E+00	2.20E+00
Scenario 7+13b+16	Tier 1/no PPE	2.05E+00	2.39E+02	2.41E+02
	Tier 2/gloves for loading and gloves + mask APF 40 for application	3.1E-01	1.20E+01	1.23E+01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 7+13a+16	Tier 1/no PPE	2.00E-02	1.44E+00	1.46E+00
	Tier 2/gloves	2.00E-02	7.22E-02	9.22E-02
Scenario 7+13b+16	Tier 1/no PPE	8.60E-02	1.00E+01	1.01E+01
	Tier 2/gloves for loading and gloves + mask APF 40 for application	1.3E-02	5.02E-01	5.15E-01

Semi-automated process (loading and application)

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 14+15a+16	Tier 1/no PPE	4.2E-02	7.96E+00	8.00E+00
	Tier 2/gloves	4.2E-02	3.98E-01	4.4E-01
Scenario 14+15b+16	Tier 1/no PPE	1.42E-01	1.62E+01	1.64E+01
	Tier 2/gloves	1.42E-01	8.11E-01	9.5E-01

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 14+15a+16	Tier 1/no PPE	1.80E-03	3.34E-01	3.36E-01
Scenario 14+15b+16	Tier 1/no PPE	5.90E-03	6.81E-01	6.87E-01
	Tier 2/gloves	5.90E-03	3.40E-02	3.99E-02

Scenario [17]: – Disposal of lime product after application

Description of Scenario [17] – Post application – Disposal of lime product after application
According to the information reported in the provided field study, after the maturation step, the burnt lime powder is swept off the treated floor and thrown into a suitable bag. During this cleaning task, dermal and inhalation exposure of the professional can occur. For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 8a has been used. For inhalation exposure, the exposure measurements obtained for indoor activities described in the study have been used as a worst case approach. The results for inhalation exposures (95th percentile) from the study are as follow: - For full shift (normalised over 8 hours): 0.23 mg /m^3; - For task only: 2.79 mg/ m^3. For Tiers 3, a respiratory protection (APF 10) is taken into account.

Systemic effect – calcium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Field study	Tier 3/no PPE	2.74E-02	2.76E+01	2.77E+01
	Tier 3a/ gloves	2.74E-02	1.38E+00	1.41E+00

Systemic effect – magnesium

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Field study	Tier 3/no PPE	1.15E-03	1.16E+00	1.16E+00
	Tier 3a/ gloves	1.15E-03	5.80E-02	5.91E-02

Local effect – calcium oxide

Summary table: local exposure from professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/m3)**
Field study	Tier 3/no RPE	2.79E+00
	Tier 3b/ RPE (APF 10)	2.79E-01

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

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

Monitoring data

Context of the study

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

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

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

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

Worker selection

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

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

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

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

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

Sampling strategy

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

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

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

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

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

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

The sampling of the particles and their subsequent analysis have been performed in accordance with the NFX43-259 standard[9].

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

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

Data processing

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

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

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

Table1: Measured exposure concentrations (mg/m^3) on the task duration per HEG

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

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

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

Exposure was calculated by weighting the measured concentration to the reference time of a working day (8h). A summary of the results obtained is described in the table below.

Table 2 : Measured Exposure concentrations (mg/m^3) per HEG normalized- 8h

	HEG N°1 (manual application using a shovel)	HEG N°2 (application with a spreader)	HEG N°3 (surface cleaning)
	0.346	0.197	0.0319

	0.0466	0.0774	0.118
	0.0746	0.124	0.101
	0.0951	0.166	0.2
	0.387	0.0708	0.21
	0.088	0.298	0.159
	0.207	0.0893	0.243
	0.0911	0.142	0.108
	0.134	0.0843	0.117
Mean	**0.16**	**0.14**	**0.14**
95th percentile	**0.37**	**0.26**	**0.23**

Assessment of the field study values

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

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

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

Dietary exposure

Regarding intended uses on sewage sludge (TP2 use#1) and manure (TP3 use#2), no dietary exposure is expected.
Regarding intended uses on floors indoor in livestock accommodations or transportations (TP3 use#3) and uses on floors of outdoor animal enclosures (TP3 use#4), no dietary exposure is expected considering the risk mitigation measures ("*Animals should not be present during all the treatment duration" and "feed and drinking water must be carefully covered or removed during the application of the product"*)

Information of non-biocidal use of the active substance

Calcium oxide is not approved under Reg. (EC) No 1107/2009 and thus default MRL of 0.01* mg/kg apply according to Art 18(1)(b) Reg 396 / 2005.
Calcium oxide is listed in table 1 of Regulation No. 37/2010 annex, as allowed pharmacologically active substance for which an MRL in foodstuffs of animal origins is not required.
Calcium oxide is also listed in annex II of regulation 1333/2008, as approved food additives at "quantum satis" and in annex II of regulation 1925/2006 as approved food supplements.

Residue definitions

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

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

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

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

Estimating Livestock Exposure to Active Substances used in Biocidal Products

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

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

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

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

Only professional uses are intended in this dossier.

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

Not applicable

Aggregated exposure

Not applicable

Summary of exposure assessment

Systemic effect – calcium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures (Uses #1 & 2)			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	7.09E+00
		Tier 2a/gloves	6.46E-01
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	7.28E+00
		Tier 2a/gloves	8.40E-01
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	1.07E+00
Scenario [4] – cleaning of the treatment unit	Professionals	Tier 1/no PPE	1.99E+01
		Tier 2a/gloves	8.35E+00
		Tier 2b/ gloves + coated coverall	2.83E+00
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	6.21E-03
Disinfection of floor surfaces of animal accommodations and transportation (Use # 3)			
Scenario [7] – manual loading into the wheelbarrow	Professionals	Tier 1/no PPE	7.04E+00
		Tier 2a/gloves	6.01E-01
Scenario [8a] – manual application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	2.81E+01
		Tier 2a/gloves	1.89E+00
Scenario [8b] – manual application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	2.36E+02
		Tier 2a/gloves	1.54E+01
		Tier 2b/gloves + RPE (APF 40)	1.17E+01
Scenario [8c] – manual application – indoor – **Minimal** floor surfaces - C**attle**	Professionals	Tier 1/no PPE	1.19E+01
		Tier 2a/gloves	8.68E-01
Scenario [8d] – manual application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	8.27E+01
		Tier 2a/gloves	5.38E+00
Scenario [9] – semi automated loading into the tank of tractor	Professionals	Tier 1/no PPE	6.89E+00
		Tier 2a/gloves	4.51E-01
Scenario [10a] – semi-automated application – indoor – **Minimal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	1.31E+00
Scenario [10b] – semi-automated application – indoor – **Maximal** floor surfaces - **Poultry**	Professionals	Tier 1/no PPE	9.89E+00
		Tier 2a/gloves	9.25E-01

Scenario [10c] – semi-automated application– indoor – **Minimal** floor surfaces - C**attle**	Professionals	Tier 1/no PPE	6.51E-01
Scenario [10d] – semi-automated application – indoor – **Maximal** floor surfaces - **Cattle**	Professionals	Tier 1/no PPE	3.46E+00
Scenario [11] – Disposal of empty bags	Professionals	Tier 1/no PPE	6.21E-03
Scenario [12] – Disposal of product after floor application	Professionals	Tier 1/no PPE	2.77E+01
		Tier 3a/gloves	1.41E+00
Disinfection of floors of outdoor animal enclosures (Use # 4)			
Scenario [13a] – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	2.78E+01
		Tier 2a/gloves	1.60E+00
Scenario [13b] – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	2.34E+02
		Tier 2a/gloves	1.34E+01
		Tier 2b/gloves + RPE (APF 40)	1.17E+01
Scenario [14] – semi-automated loading into the tank of a tractor	Professionals	Tier 1/no PPE	6.80E+00
		Tier 2a/gloves	3.60E-01
Scenario [15a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	1.19E+00
Scenario [15b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	9.55E+00
		Tier 2a/gloves	5.86E-01
Scenario [16] – Disposal of empty bags	Professionals	Tier 1/no PPE	6.21E-03
Scenario [17] – Disposal of product after disinfection- outdoor	Professionals	Tier 1/no PPE	2.77E+01
		Tier 3a/gloves	1.41E+00

Local effect – calcium oxide

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures (Uses # 1 & 2)			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	2.32E+01
		Tier 2/ RPE (APF 40)	4.25E-01
Scenario [2] – semi-automated loading (using a FORKLIFT)	Professionals	Tier 1/no PPE	1.70E+01
		Tier 2/ RPE (APF 40)	4.25E-01
Scenario [2] – semi-automated loading (using a TELEHANDLER with a closed cabin)	Professionals	Tier 1/no PPE	1.10E+00
		Tier 2/RPE (APF 40)	0.03E+00
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	3.90E+00
		Tier 2/ RPE (APF 40)	9.75E-02
Scenario [4] – cleaning of the unit	Professionals	Tier 1/no PPE	2.32E+01
		Tier 2/ RPE (APF 40)	5.80E-01
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.5
		Tier 2/ RPE (APF 40)	0.063
Disinfection of floor surfaces of animal accommodations and transportation (Use #3)			
Scenario [7] – manual loading for floor application	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2/ RPE (APF 40)	2.75E+00
Scenario [7a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2a/ RPE (APF 40)	2.75E+00
Scenario [8b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	9.70E+01
		Tier 2b/ RPE (APF 40)	2.43E+00
Scenario [8c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Professionals	Tier 1/no PPE	1.40E+02
		Tier 2b/ RPE (APF 40)	3.50E+00
Scenario [8d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Professionals	Tier 1/no PPE	9.70E+01
		Tier 2b/ RPE (APF 40)	2.43E+00
Scenario [8] – manual loading + application onto floor surfaces- indoor – **Field study**	Professionals	Tier 3/no PPE	9.58
		Tier 3b/ RPE (APF 40)	2.40E-01
Scenario [9] – semi automated loading for floor application - indoor	Professionals	Tier 1/no PPE	4.50E+01
		Tier 2/ RPE (APF 40)	1.13E+00
Scenario [10a] – Semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2b/ RPE (APF 40)	2.75E+00
Scenario [10b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	4.50E+01
		Tier 2b/ RPE (APF 40)	1.13E+00
	Professionals	Tier 1/no PPE	3.60E+02

Scenario [10c] – Semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**		Tier 2b/ RPE (APF 40)	9.00E+00
Scenario [10d] – Semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Professionals	Tier 1/no PPE	4.50E+01
		Tier 2b/ RPE (APF 40)	1.13E+00
Scenario [10] – Semi automated loading + application onto floor surfaces- indoor – **Field study**	Professionals	Tier 3/no PPE	5.59E+00
		Tier 3b/RPE (APF 20)	2.80E-01
Scenario [11] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.5E+00
		Tier 2/RPE (APF 40)	6.3E-02
Scenario [12] – Cleaning- Post application- indoor – **Field study**	Professionals	Tier 3/no PPE	2.79E+00
		Tier 3b/RPE (APF 10)	2.79E-01
Disinfection of outdoor animal enclosures (Use #4)			
Scenario [13a] – manual application onto **minimal** floor surfaces-outdoor - **Poultry**	Professionals	Tier 1/no RPE	4.50E+01
		Tier 2/ RPE (APF40)	1.13E+00
Scenario [13b] – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no RPE	4.50E+01
		Tier 2/ RPE (APF40)	1.13E+00
Scenario [13] – manual loading + application onto floor surfaces- outdoor – **Field study**	Professionals	Tier 3/no PPE	9.58
		Tier 3b/ RPE (APF 40)	2.40E-01
Scenario [14] – semi automated loading - outdoor	Professionals	Tier 1/no PPE	8.80E+00
		Tier 2/ RPE (APF 40)	2.20E-01
Scenario [15a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no RPE	1.10E+01
		Tier 2/ RPE (APF40)	2.75E-01
Scenario [15b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no RPE	1.10E+01
		Tier 2/ RPE (APF40)	2.75E-01
Scenario [15] – Semi automated loading + application onto floor surfaces- outdoor– **Field study**	Professionals	Tier 3/no PPE	5.59E+00
		Tier 3b/RPE (APF 20)	2.80E-01
Scenario [16] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.5E+00
		Tier 2/RPE (APF 40)	6.3E-02
Scenario [17] – Cleaning- Post application- outdoor– **Field study**	Professionals	Tier 3/no PPE	2.79E+00
		Tier 3b/RPE (APF 10)	2.79E-01

Systemic effect – magnesium

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Disinfection of sewage sludge and manures (Uses #1 & 2)			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	2.97E-01
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	3.06E-01
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	4.47E-02
Scenario [4] – cleaning	Professionals	Tier 1/no PPE	8.35E-01
		Tier 2a/gloves	3.23E-01
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.6E-04
Disinfection of floor surfaces of animal accommodations and transportation (Use #3)			
Scenario [7] – manual loading - indoor	Professionals	Tier 1/no PPE	2.96E-01
Scenario [8a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	1.18E+00
		Tier 2a/gloves	7.95E-02
Scenario [8b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	9.92E+00
		Tier 2a/gloves	6.48E-01
		Tier 2b/gloves + RPE (APF 40)	4.92E-01
Scenario [8c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Professionals	Tier 1/no PPE	5.00E-01
Scenario [8d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Professionals	Tier 1/no PPE	3.47E+00
		Tier 2a/gloves	2.26E-01
Scenario [9] –semi automated loading-indoor	Professionals	Tier 1/no PPE	2.89E-01
Scenario [10a] – Semi-automated application onto **minimal** floor surfaces-indoor - **Poultry**	Professionals	Tier 1/no PPE	5.50E-02
Scenario [10b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Professionals	Tier 1/no PPE	4.15E-01
Scenario [10c] – Semi-automated application onto **minimal** floor surfaces-indoor - **Cattle**	Professionals	Tier 1/no PPE	2.73E-02
Scenario [10d] – Semi-automated application onto maximal floor surfaces-indoor - Cattle	Professionals	Tier 1/no PPE	1.45E-01
Scenario [11] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.6E-04
Scenario [12] – Disposal of product after floor application	Professionals	Tier 1/no PPE	1.16E+00
		Tier 3a/ gloves	5.91E-02
Disinfection of outdoor animal enclosures (Use #4)			
Scenario [13a] – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	1.17E+00
		Tier 2a/gloves	6.70E-02
Scenario [13b] – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Professionals	Tier 1/no PPE	9.84E+00
		Tier 2a/gloves	5.63E-01
Scenario [14] – semi automated loading - outdoor	Professionals	Tier 1/no PPE	2.85E-01

Scenario [15a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	5.01E-02
Scenario [15b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Professionals	Tier 1/no PPE	4.01E-01
Scenario [16] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.6E-04
Scenario [17] – Disposal of product after floor application	Professionals	Tier 1/no PPE	1.16E+00
		Tier 3a/ gloves	5.91E-02

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

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

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

[1] default for dynamic intraspecies differences

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

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEL short, medium & long-term (UL calcium)	-	-	-	-	42 mg/kg bw/day
ARfD	Not applicable				
ADI	Not applicable				

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

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

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

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

Consequently, an exceedance of 13% of the UL is expected for uses where more exposure to lime product occurs.
Furthermore, professional exposure during the disinfection of sludge and manure has been estimated using a field study available in the CAR.
In the PAR, a worst-case assessment has been performed by eCA to estimate systemic exposure during disinfection of floor and bedding materials. This assessment is based on many assumptions and the use of ART (Advanced Reach Tool) and Riskofderm Models leading to an overestimation of the systemic exposure.
Based on these elements, the eCA is of the opinion that the cut-off value of 13% of the ULs (for Ca^{2+} and Mg^{2+}) has not to be taken into account as a TRV for the RA performed in the frame of the UA but only the UL values of **2 500 mg/d (= 42 mg/kg bw/d) for Ca^{2+}** and **250 mg/d (= 4.2 mg/kg bw/d) for Mg^{2+}**.During the meeting WG I 2022, it has been demonstrated that even considering a recommended daily intake of 950 mg Ca^{2+}/d (corresponding to 15.8 mg/kg bw/d) from the diet, the total calcium intake was still below the UL value for all the envisaged scenarios. This approach has been approved by the WG members (please refer to the supporting document presented during the meeting in Annexe 3.3).

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

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

Risk for industrial users
Not applicable.

Risk for professional users

Disinfection of sewage sludge and manures (Uses # 1 & 2)

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [1] – manual loading	Tier 1/no PPE	42	7.09E+00	16.88%	YES
	Tier 2a/gloves	42	6.46E-01	1.54%	YES
Scenario [2] – semi-automated loading	Tier 1/no PPE	42	7.28E+00	17.34%	YES
	Tier 2a/gloves	42	8.40E-01	2.00%	YES
Scenario [3] – automated loading	Tier 1/no PPE	42	1.07E+00	2.54%	YES
	Tier 2a/gloves	42	1.63E-01	0.39%	YES
Scenario [4]-cleaning	Tier 1/no PPE	42	1.99E+01	47.35%	YES
	Tier 2a/gloves	42	8.35E+00	19.88%	YES
	Tier 2b/ gloves + coated coverall	42	2.83E+00	6.75%	YES
Scenario [5]-Disposal of empty bags	Tier 1/no PPE	42	6.21E-03	0.01%	YES

Combined exposure – [Loading phase + cleaning phase + disposal of empty bags]

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario 1-4+5	Tier 1/no PPE	42	2.67E+01	63.50%	YES
	Tier 2/ gloves + coated coverall		3.48E+00	8.29%	YES
Scenario 2-4+5	Tier 1/no PPE	42	2.67E+01	63.50%	YES
	Tier 2/ gloves + coated coverall		3.19E+00	7.58%	YES

Systemic effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [1] – manual loading	Tier 1/no PPE	4.2	2.97E-01	7.08%	YES
Scenario [2] – semi-automated loading FORKLIFT- INDOOR	Tier 1/no PPE	4.2	3.06E-01	7.27%	YES
Scenario [3] – automated loading	Tier 1/no PPE	4.2	4.47E-02	1.06%	YES
Scenario [4]-cleaning	Tier 1/no PPE	4.2	8.35E-01	19.87%	YES
	Tier 2a/gloves	4.2	3.23E-01	7.70%	YES
Scenario [5]-cleaning	Tier 1/no PPE	4.2	2.6E-04	0.01%	YES

Combined Exposure – [Loading phase+ cleaning phase + Disposal of empty bags] (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario 1-4+5	Tier 1/no PPE	4.2	1.12E+00	26.64%	YES
	Tier 1/gloves		3.50E-01	8.34%	YES
Scenario 2-4+5	Tier 1/no PPE	4.2	1.12E+00	26.64%	YES
	Tier 1/gloves		3.50E-01	8.34%	YES

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

Task/ Scenario	Tier	AEC (mg/m^3)	Estimated concentration (mg/m^3)	Estimated concentration / AEC (%)
Scenario [1] – manual loading	Tier 1/no RPE	0.3	2.32E+01	**7733.3%**
	Tier 2/ RPE (APF40)	0.3	4.25E-01	**141.7%**
Scenario [2] – semi-automated loading FORKLIFT - indoor	Tier 1/no RPE	0.3	1.70E+01	**5666.7%**
	Tier 2/ RPE (APF40)	0.3	4.25E-01	**141.7%**
Scenario [2] - semi-automated loading TELEHANDLER - indoor	Tier 1/no PPE	0.3	1.10E+00	**367**
	Tier 2b/ RPE (APF40)	0.3	0.03E+00	10
Scenario [3] – automated loading	Tier 1/no RPE	0.3	3.90E+00	**1300.0%**
	Tier 2/ RPE (APF40)	0.3	9.75E-02	32.5%
Scenario [4] - cleaning	Tier 1/no RPE	0.3	2.32E+01	**7733%**
	Tier 2/ RPE (APF40)	0.3	5.80E-01	**193.3%**
Scenario [5] – Disposal of empty bags	Tier 1/no RPE	0.3	2.5	**833**
	Tier 2/ RPE (APF40)	0.3	0.063	21

- **Qualitative local risk assessment**

The product EULA OXI-LIME 23 is classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and is intended to be applied by professionals. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects for a product classified H315- H318 – H335 - Disinfection of sewage sludge and manures (Uses # 1 & 2)

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

								- Substance/ task appropriate gloves - Protection coverall - Face shield - Substance/ task appropriate respirator	
Low	STOT SE 3, H335		2&3	Professionals	Opening and handling bags Cleaning	Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Disinfection of sewage sludge and manures (Use #1 & 2) - Conclusion

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

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

Moreover, it is also likely that the addition of calcium oxide to sewage or manure leads to the production of ammonia gas, which may be of concern. During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas.

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

- The pouring of the burnt lime into the treatment unit must be done fully automatically.
- Considering the use of big bags (a half to one tone), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge and manures, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EU OEL of 14 mg/m^3 for this gas.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

Disinfection of indoor floor surfaces of animal accommodations and animal transportation (Use # 3)

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [7] – manual loading for floor application	Tier 1/no PPE	42	7.04E+00	16.77%	YES
	Tier 2a/gloves	42	6.01E-01	1.43%	YES
Scenario [8a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	2.81E+01	66.99%	YES
	Tier 2b/gloves + RPE (APF 40)	42	1.39E+00	3.32%	YES
Scenario [8b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	2.36E+02	562.92%	**NO**
	Tier 2b/gloves + RPE (APF 40)	42	1.17E+01	27.92%	YES
Scenario [8c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	1.19E+01	28.37%	YES
	Tier 2b/gloves + RPE (APF 40)	42	5.89E-01	1.40%	YES
Scenario [8d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	8.27E+01	196.97%	**NO**
	Tier 2b/gloves + RPE (APF 40)	42	4.10E+00	9.77%	YES
Scenario [9] – semi-automated loading- indoor	Tier 1/no PPE	42	6.89E+00	16.41	YES
	Tier 2a/gloves	42	4.51E-01	1.07	YES
Scenario [10a] – Semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	1.31E+00	3.12%	YES
	Tier 2a/gloves	42	1.90E-01	0.45%	YES
Scenario [10b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	9.89E+00	23.55%	YES
	Tier 2a/gloves	42	9.25E-01	2.20%	YES
Scenario [10c] – Semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	6.51E-01	1.55%	YES
	Tier 2a/gloves	42	2.02E-01	0.48%	YES

Scenario [10d] – Semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	3.46E+00	8.23%	YES
	Tier 2a/gloves	42	3.20E-01	0.76%	YES
Scenario [11] – Disposal of empty bags	Tier 1/no PPE	42	6.21E-03	0.01%	YES
Scenario [12] – Disposal of the product after application	Tier 1/no PPE	42	2,77E+01	65.83%	YES
	Tier 2a/gloves		1.41E+00	3.35%	YES

Combined exposure – [Loading phase + application phase + disposal of empty bags]

Combined effects (Ca^{2+})

Task/ Scenario	**Tier**	**UL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ UL (%)**	**Acceptable (yes/no)**
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	3.52E+01	83.76%	YES
	Tier 2a/gloves		2.49E+00	5.94%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	2.43E+02	579.69%	**NO**
	Tier 2b/gloves + RPE (APF 40)		1.23E+01	29.35%	YES
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	1.90E+01	45.14%	YES
	Tier 2a/gloves		1.47E+00	3.5%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	8.98E+01	213.73%	**NO**
	Tier 2b/gloves + RPE (APF 40)		4.70E+00	11.20%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	8.20E+00	19.53%	YES
	Tier 2a/gloves		6.41E-01	1.53%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	1.68E+01	39.96%	YES
	Tier 2a/gloves		1.38E+00	3,28%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	7.54E+00	17.96%	YES
	Tier 2a/gloves		6.6E-01	1.57%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	42	1.04E+01	24.64%	YES
	Tier 2a/gloves		7.77E-01	1.85%	YES

Systemic effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (YES/NO)
Scenario [7] – manual loading for floor application	Tier 1/no PPE	4.2	2.96E-01	7.04%	YES
Scenario [8a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.18E+00	28.11%	YES
	Tier 2a/gloves		7.95E-02	1.89%	YES
Scenario [8b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	9.92E+00	236.19%	NO
	Tier 2b/gloves + RPE (APF 40)		4.92E-01	11.71%	YES
Scenario [8c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	5.00E-01	11.90%	YES
Scenario [8d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	3.47E+00	8.64%	YES
Scenario [9] – semi-automated loading-indoor	Tier 1/no PPE	4.2	2.89E-01	6.89%	YES
Scenario [10a] – Semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	5.50E-02	1.31%	YES
Scenario [10b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	4.15E-01	9.88%	YES
Scenario [10c] – Semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	2.73E-02	0.65%	YES
Scenario [10d] – Semi-automated application onto **maximal** floor	Tier 1/no PPE	4.2	1.45E-01	3.45%	YES

surfaces- indoor - **Cattle**					
Scenario [11]- Disposal of empty bags	Tier 1/no PPE	4.2	2.6E-04	0.01%	YES
Manual disposal of lime after application	Tier 1/no PPE	4.2	1.16E+00	27.62%	YES
	Tier 3a/gloves		5.91E-02	1.41%	YES

Combined exposure – [Loading phase + application phase]

Combined effects (Mg^{2+})

Task/ Scenario	**Tier**	**UL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ UL (%)**	**Acceptable (yes/no)**
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tiers 1/no PPE	4.2	1.48E+00	35.14%	YES
	Tier 2a/gloves		1.05E-01	2.49%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.02E+01	243.23%	NO
	Tier 2b/gloves + RPE (APF 40)		5.17E-01	12.31%	YES
Manual loading – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	7.96E-01	18.94%	YES
	Tier 2a/gloves		6.26E-02	1.49%	YES
Manual loading – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	3.77E+00	89.68%	YES
	Tier 2a/gloves		2.51E-01	5.98%	YES
Semi-automated loading – semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	3.44E-01	8.20%	YES
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	7.04E-01	16.77%	YES
	Tier 2a/gloves		5.8E-02	1.38%	YES
Semi-automated loading – semi-automated application	Tier 1/no PPE	4.2	3.17E-01	7.54%	YES

onto **minimal** floor surfaces- indoor - **Cattle**					
Semi-automated loading – semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	4.2	4.34E-01	10.34%	YES

- **Semi-quantitative local risk assessment**

Task/ Scenario	Tier	AEC (mg/m3)	Estimated concentration (mg/m3)	Estimated concentration / AEC (%)
Scenario [7] – manual loading for floor application	Tier 1/no PPE	0.3	1.10E+02	**36666.7%**
	Tier 2/ RPE (APF40)		2.75E+00	**916.7%**
Scenario [8a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	0.3	1.10E+02	**36666.7%**
	Tier 2a/ RPE (APF 40)		2.75E+00	**916.7%**
Scenario [8b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	0.3	9.70E+01	**32333.3%**
	Tier 2b/ RPE (APF 40)		2.43E+00	**808.3%**
Scenario [8c] – manual application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	0.3	1.40E+02	**46666.7%**
	Tier 2b/ RPE (APF 40)		3.50E+00	**1166.7%**
Scenario [8d] – manual application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	0.3	9.70E+01	**32333.3%**
	Tier 2b/ RPE (APF 40)		2.43E+00	**808.3%**
Scenario [8] – manual application onto floor surfaces - indoor – **Field study**	Tier 3/no PPE	0.3	1.18E+01	**3940.0%**
	Tier 3b/ RPE (APF 40)		2.96E-01	98.5%
Scenario [9] – semi-automated loading- indoor	Tier 1/no PPE	0.3	4.50E+01	**15000.0%**
	Tier 2b/ RPE (APF 40)		1.13E+00	**375.0%**
Scenario [10a] – Semi-automated application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	0.3	1.10E+02	**36666.7%**
	Tier 2b/ RPE (APF 40)		2.75E+00	**916.7%**
Scenario [10b] – Semi-automated application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	0.3	4.50E+01	**375.0%**
	Tier 2b/ RPE (APF 40)		1.13E+00	**375.0%**

Scenario [10c] – Semi-automated application onto **minimal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	0.3	3.60E+02	**120000.0%**
	Tier 2b/ RPE (APF 40)		9.00E+00	**3000.0%**
Scenario [10d] – Semi-automated application onto **maximal** floor surfaces- indoor - **Cattle**	Tier 1/no PPE	0.3	4.50E+01	**15000.0%**
	Tier 2b/ RPE (APF 40)		1.13E+00	**375.0%**
Scenario [10] – Semi-automated application onto floor surfaces of - indoor – **Field study**	Tier 3/no PPE	0.3	5.59E+00	**1863.3%**
	Tier 3b/ RPE (APF 20)		2.80E-01	93.2%
Scenario [11] – Disposal of empty bags	Tier 1/no PPE	0.3	2.5E+00	**833**
	Tier 2/RPE (APF 40)	0.3	6.3E-02	21
Scenario [12] – Disposal of lime- indoor – **Field study**	Tier 3/no PPE	0.3	2.79E+00	**930.0%**
	Tier 3b/ RPE (APF 10)		2.79E+00	93.00%

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

The product EULA OXI-LIME 23 is classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and is intended to be applied by professional. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects – Qualitative assessment for disinfection of indoor floor surfaces of animal accommodation and animal transportation

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

						- cleaning		respirator	
Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Disinfection of indoor floor surfaces of animal accommodation and animal transportation (Use #3) - Conclusion

Using ART model for floor surfaces disinfection lead to an overestimation of the inhalation exposure and then to unacceptable risks for professionals.
In this context, a field study has been requested to the applicant in order to obtain specific exposure data for this use (see "Monitoring data").
The provided monitoring data have been deemed reliable by the eCA.
However, it has to be noted that the inhalation exposure measurements from the study refers to the **respirable** fraction (particles with a diameter ≤ 1µm) whereas the AEC value set for CaO refers to the **inhalable** fraction. A direct comparison of the exposure values from the study with the AEC is therefore considered not reliable to conclude on the acceptability of the risk.

In this context and without any additional data, eCA proposed a weight of evidence approach to conclude on the acceptability of the risk for professionals using lime product during disinfection of floor surfaces of animal accommodations and transportation.
The WoE approach is divided into two points:

- The local risk assessment;
- The setting of AEC.

The products EULA OXY LIME 23 is formulated with 100% active substance.
Based on the toxicological properties of the a.s, the following classification has been proposed for the product:

- STOT SE 3 (H335, May cause respiratory irritation);
- Eye Dam 1 (H318, Causes serious eye damage);
- Skin irrit 2 (H315, causes skin irritation).

According to the "Guidance on the BPR, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017", a classification STOT SE 3 – H335 triggers a qualitative risk assessment based on the irritant properties of the respiratory tract. Considering this, an appropriate respiratory protection is required and recommended during the activities of work, to counteract the local irritant effects of lime.

In order to select the most appropriate RPE based on the irritant properties of lime, different factors have to be taken into account including the type of chemical contaminants and the filtering efficiency.
Considering the type of chemical contaminant (particles suspended in the air), a filtering facial piece using P filters is considered the most appropriate equipment for exposure of professionals to dust exposure.
According to the European standard *NF EN 149*[10] *and NF EN 143*[11], there are three classes of particle filters based on their filtering efficiency; P1, P2 and P3 in ascending order to filtering efficiency.
In order to ensure the highest protection to the workers against the irritant properties of the product, a **P3 filter** (corresponding to an assigned protection factor (APF) of 40) is proposed by the eCA.
Considering the type of mask to be used, lime products being classified for eye and skin irritant properties, a **full-face respiratory protective equipment** (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149) is required.

10 NF EN 159: Respiratory protective devices – Recommendations for selection, use, care and maintenance – Guidance document.
11 NF EN 143: Respiratory protective devices – Particles filters – Requirements, testing, marking.

Moreover as stated in the NF EN 149, it is recommended to apply other means to decrease professional exposure before using RPE.
In the context of lime products, the following RMMs are proposed:

- Use only in a well-ventilated area;
- Moisten the soil before application (in order to prevent the aerosols generation).

Finally, it is assumed that during the application of the product, the professional won't stay in the generated "cloud of aerosols" (this information is available in the field study where the behaviour of the applicator has been observed) which will tend to reduce inhalation exposure.

Regarding the toxicological reference value set in the CAR on the active substance, it has to be noted that the AEC value of 0.3 mg/m^3 (short, medium and long-term) is based on an epidemiological study in humans (*Cain et al., 2004* [12]).
In this study, 12 volunteers were exposed during 20 min to 0, 1, 2 and 5 mg/m^3 CaO dust. The parameters studied included nasal resistance, nasal secretion, mucociliary transport time and chemestetic magnitude (irritation, pungency, piquancy, cooling and burning).
According to the authors, there were no significant effects in quantified parameters (nasal secretion, etc…) at any tested doses; however chemestetic effects (pungency) have been reported at all concentrations (in the nose, eyes and throat). As stated in the CAR (Doc IIA), a NOAEC value of 1 mg/m^3 CaO for 20-min exposure has been identified for this study based on subjective descriptions of sensory irritation of the nose and throat at the next higher concentrations of 2 and 5 mg/m^3.
This means that the NOAEC has been based on the psychophysical judgments of few volunteers. Using this NOAEC value and a factor of 3.2 (default for dynamic intra-species differences) leads to a very low AEC value of 0.3 mg/m^3.
This value is deemed **very conservative** by the eCA since it only takes into account the beginnings of a feeling of irritation as a relevant effect to set a TRV. This effect is considered very subjective and therefore very dependent on the number of volunteers in the study (only 12). In this context, using this TRV in a risk assessment is very conservative since it is designed to protect against a feeling of irritation and not effects that can be quantified with parameters such as nasal secretion, nasal resistance and so on.
Finally, it is important to note that the proposal for classification STOT SE 3 – H335 is based on the effects observed in the study using to derive the AEC value (*Cain et al., 2004*).

Based on the elements presented above, the eCA considered that the recommended respiratory protective equipment (**a full-face mask with P3 filters (APF 40)**), combined with relevant RMMs are sufficient to prevent inhalation exposure and protect the professionals against the irritation properties of the lime on the respiratory tract.
This point has been extensively discussed during the WG I 2022; the majority of the Member states agreed with this approach.

[12] Cain *et al*., 2004 : Sensory and associated reactions to mineral dusts : sodium borate, calcium oxide and calcium sulphate. Journal of Occupational and Environmental Hygiene, 1 : 222-236 (2004).

Disinfection of floors of outdoor animal enclosures (Use # 4)

Systemic effects (Ca^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [13a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	2.78E+01	66.28%	YES
	Tier 2a/gloves		1.60E+00	3.8%	YES
Scenario [13b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	42	1.34E+01	31.95%	YES
	Tier 2b/gloves + RPE (APF 40)		1.17E+01	27.8	YES
Scenario [14] – semi-automated loading- outdoor- **Poultry**	Tier 1/no PPE	42	6.80E+00	16.2	YES
	Tier 2a/gloves		3.60E-01	0.86	YES
Scenario [15a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	42	1.19E+00	2.84%	YES
Scenario [15b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	42	9.55E+00	22.74%	YES
	Tier 2a/gloves		5.86E-01	1.40%	YES
Scenario [16] – Disposal of empty bags	Tier 1/no PPE	42	6.21E-03	0.01%	YES
Scenario [17] – Disposal of the product after the application	Tier 1/no PPE	42	2.77E+01	65.83%	YES
	Tier 2a/gloves		1.41E+00	3.35%	YES

Combined exposure – [Loading phase + application phase + Dispoal of empty bags]

Combined effects (Ca^{2+})

Task/ Scenario	**Tier**	**UL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/UL (%)**	**Acceptable (yes/no)**
Manual loading – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Tiers 1/no PPE	42	3.49E+01	83.05%	YES
	Tier 2a/gloves		2.20E+00	5.23%	YES
Manual loading – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Tier 1/no PPE	42	2.41E+02	574.87%	**NO**
	Tier 2b/gloves + RPE (APF 40)		1.23E+01	29.23%	YES
Semi-automated loading-semi-automated application onto **minimal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	42	8.00E+00	19.04%	YES
	Tier 2a/gloves		4.4E-01	1.05%	YES
Semi-automated loading-semi-automated application onto **maximal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	42	1.64E+01	38.94%	YES
	Tier 2a/gloves		9.5E-01	2.26%	YES

Systemic effects (Mg^{2+})

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [13a] – manual application onto **minimal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.21E+00	28.86%	YES
	Tier 2a/gloves		9.29E-02	2.21%	YES
Scenario [13b] – manual application onto **maximal** floor surfaces- indoor - **Poultry**	Tier 1/no PPE	4.2	1.02E+01	242.98%	**NO**
	Tier 2b/gloves + RPE (APF 40)		7.81E-01	18.60%	YES
Scenario [14] – semi-automated loading- outdoor- **Poultry**	Tier 1/no PPE	4.2	2.85E-01	6.8%	YES
Scenario [15a] – semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE		5.01E-02	1.19%	YES
Scenario [15b] – semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no PPE	4.2	4.01E-01	9.54%	YES
Scenario [16]- cleaning	Tier 1/no PPE	4.2	2.6E-04	0.01%	YES
Scenario [17] – Disposal of the product after application	Tier 1/no PPE	4.2	1.16E+00	27.62%	YES
	Tier 2a/gloves		5.91E-02	1.41%	YES

Combined exposure – [Loading phase + application phase + Disposal of empty bags]

Combined effects (Mg^{2+})

Task/ Scenario	**Tier**	**UL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ UL (%)**	**Acceptable (yes/no)**
Manual loading – manual application onto **minimal** floor surfaces- outdoor - **Poultry**	Tiers 1/no PPE	4.2	1.46E+00	34.85%	YES
	Tier 2a/gloves		9.22E-02	2.19%	YES
Manual loading – manual application onto **maximal** floor surfaces- outdoor - **Poultry**	Tier 1/no PPE	4.2	1.01E+01	241.20%	**NO**
	Tier 2b/gloves + RPE (APF 40)		5.15E-01	12.26%	YES
Semi-automated loading- semi-automated application onto **minimal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	4.2	3.36E-01	7.99%	YES
Semi-automated loading- semi-automated application onto **maximal** floor surfaces-outdoor- **Poultry**	Tiers 1/no PPE	4.2	6.87E-01	16.36%	YES
	Tier 2a/gloves		3.99E-02	0.95%	YES

- **Semi-quantitative local risk assessment**

Task/ Scenario	Tier	AEC (mg/m3)	Estimated concentration (mg/m3)	Estimated concentration / AEC (%)
Scenario [13a] - manual application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.70E+02	**56666.7%**
	Tier 2/ RPE (APF40)		4.25E+00	**1416.7%**
Scenario [13b] – manual application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.70E+02	**56666.7%**
	Tier 2/ RPE (APF40)		4.25E+00	**1416.7%**
Scenario [13] - Manual application onto floor surfaces outdoor– **Field study**	Tier 3/no PPE	0.3	1.18E+01	**3940.0%**
	Tier 3b/ RPE (APF 40)		2.96E-01	98.5%
Scenario [14] - semi-automated loading- outdoor- poultry	Tier 1/no RPE	0.3	8.80E+00	**2933.3%**
	Tier 2/ RPE (APF40)		2.20E-01	73.3%
Scenario [15a] - semi-automated application onto **minimal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.10E+01	**3666.7%**
	Tier 2/ RPE (APF40)		2.75E-01	91.7%
Scenario [15b] - semi-automated application onto **maximal** floor surfaces- outdoor- **Poultry**	Tier 1/no RPE	0.3	1.10E+01	**3666.7%**
	Tier 2/ RPE (APF40)		2.75E-01	91.7%
Scenario [15] - Semi-automated application onto floor surfaces of **Field study**	Tier 3/no PPE	0.3	5.59E+00	**1863.3%**
	Tier 3b/ RPE (APF 20)		2.80E-01	93.2%
Scenario [16] – Disposal of empty bags	Tier 1/no PPE	0.3	2.5E+00	**833**
	Tier 2/RPE (APF 40)		6.3E-02	21
Scenario [17] - Disposal of lime- outdoor – **Field study**	Tier 3/no PPE	0.3	2.79E+00	**930.0%**
	Tier 3b/ RPE (APF 10)		2.79E+00	93.00%

- **Qualitative local risk assessment**

The product EULA OXI-LIME 23 is classified severe eye damage (H318), skin irritant (H315) and irritant for the respiratory tract (H335) and is intended to be applied by professional. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

Local effects – Qualitative assessment for disinfection on floors of outdoor animal enclosures

Hazard			**Exposure**				**Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)**	**Risk**	
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
Very High	Eye Dam.1, H318	-	3	Professionals	-Loading from the bags to the wheelbarrow/tractor -Application on the floor surfaces- outdoor -Disposal of the lime product after application	Dermal Sources for contamination being from: - opening and handling bags - cleaning - hand to eye transfer	few minutes per day or less	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM: - Wear: - Substance/ task appropriate gloves - Protective coverall - Face shield - Substance/ task appropriate respirator	Acceptable following the relevant RMM and PPE
Low	Skin Irrit.2, H315	-				Dermal Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Disinfection of floor of outdoor animal enclosures (Use #4) - Conclusion:

Using ART model for outdoor floor surfaces disinfection and considering that the source is located or not to buildings lead to an overestimation of the real inhalation exposure.

It is assumed that inhalation of the professional applying lime product outdoor is of a low order compared to the disinfection of indoor animal accommodations (Use #3).
In this context and based on the weight of evidence approach presented for Use #3 above, the eCA considered that the recommended respiratory protective equipment (**a full-face mask with P3 filters (APF 40)**), combined with relevant RMMs are sufficient to prevent inhalation exposure and protect the professionals against the irritation properties of the lime on the respiratory tract for outdoor application.

This point has been extensively discussed during the WG I 2022; the majority of the Member states agreed with this approach.

Overall conclusion

Disinfection of sewage sludge and manures

The risk for human health is considered as acceptable **only for the fully automated process** (including loading and disposal of empty bags) considering the following PPE are worn:

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

Moreover, it is also likely that the addition of calcium oxide to sewage leads/manures leads to the production of ammonia gas, which may be of some concern.
It is very difficult to predict the likely air concentrations that would prevail in treatment plants and whether they are likely to exceed such exposure limits. It may be possible to monitor air concentrations and assess the requirement for respiratory protective equipment and/or engineering controls based on this, but in the absence of this kind of information, it is recommended that air fed or canister RPE as indicated for protection against lime dust should be worn.
This might, in any case, be indicated to protect against strong, unpleasant odours as well as toxic gases.

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

- The pouring of the burnt lime into the treatment unit must be done fully automatically.
- Considering the use of big bags (a half to 1.2 tone), the loading into the treatment unit and the disposal of empty bags must be performed using a telehandler (including a closed cabin).
- The cleaning of the treatment unit must be avoided or performed with an automated process with no exposure of the professional.
- Wear protective gloves and protection coverall during the manipulation of treated sewage sludge and manures.
- During the treatment of sewage sludge and manures, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EU OEL of 14 mg/m^3 for this gas.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- Use in a well ventilated area.

Disinfection of indoor and outdoor floor surfaces

The risk for human health is considered acceptable for the loading the application and the disposal of empty bags considering the following PPE:

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

In addition to above-mentioned PPE, the following RMM are needed:

- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (including the loading, the application, the disposal of empty bags, the acting time and the following removal of the biocidal product and its residues from the ground).
- During the loading of small bags (25 kg), thoroughly empty out the bags in order to minimize the remaining powder;
- Fold carefully the small bag in order to avoid any spills.
- Considering the use of big bags (a half to 1.2 tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- Use in a well ventilated area.

Risk for non-professional users

Non-professional uses are not claimed.

Risk for the general public

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

Risk for consumers via residues in food

Regarding intended uses on sewage sludge (TP2 use#1) and manure (TP3 use#2), no dietary exposure is expected.
Regarding intended uses on floors indoor in livestock accommodations or transportations (TP3 use#3) and uses on floors of outdoor animal enclosures (TP3 use#4), no dietary exposure is expected considering the risk mitigations measures ((“*Animals should not be present during all the treatment duration” and “feed and drinking water must be carefully covered or removed during the application of the product”*).

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

Not applicable

2.2.7 Risk assessment for animal health

See Annex 1 (section 3.7 Other)

2.2.8 Risk assessment for the environment

EULA OXI-LIME 23 is a PT2 and PT3 product containing calcium oxide, Burnt lime (CAS 1305-78-8) that is applied for the:

- ✓ disinfection of sewage sludge (PT2),
- ✓ disinfection of manure (PT3),
- ✓ disinfection of indoor floor of animal accommodations (PT3),
- ✓ disinfection of indoor floor of animal transportation (PT3),
- ✓ disinfection of floors of animal outdoor enclosures (PT3).

The product is composed at 100% of the active substance, which is a naturally occurring inorganic salt. No environmental SoCs were identified for the EULA OXI-LIME 23 and no metabolites are formed that would need to be addressed in a risk evaluation for the environment. The following risk assessment is therefore based on the data obtained from the active substance only (CAR, Calcium oxide, Burnt lime CAS 1305-78-8, Product Type 2: Disinfectants and algaecides not intended for direct application to humans or animals and 3: Veterinary hygiene, RMS UK, May 2016).

Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime (Ca(OH)2).

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Ecotoxicological data about the biocidal product EULA OXI-LIME 23 are not available. Therefore, all data pertaining to the active substance are derived from the Calcium oxide CAR, Burnt lime (2016).

Further Ecotoxicological studies

No data required.

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

No data available.

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

No data available.

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

No data available.

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

Further information on the secondary ecological effect is not required.

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

Indirect routes:
- ✓ to soil and groundwater from uses in manure, on floor of animal accommodations and in sewage sludge.

Direct routes:
- ✓ to soil and groundwater from use in animal outdoor enclosures,
- ✓ to STP from use in animal transportation.

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

No data available.

Leaching behaviour (ADS)

No data available.

Testing for distribution and dissipation in soil (ADS)

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

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

Distribution

Burnt lime would simply dissociate to its respective ion constituents (Ca^{2+} and OH^-) where they would form part of existing chemical cycles in the natural environment. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+} and OH^- ions in nature.

Dissipation

Burnt lime would simply dissociate to its respective ion constituents (Ca^{2+} and OH^-) where they would form part of existing chemical cycles in the natural environment. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+} and OH^- ions in nature.

Testing for distribution and dissipation in air (ADS)

Since burnt lime is expected to have a vapour pressure well below 10^{-5} Pa, exposure via air is not expected.

Summary table of half-lives identified relevant metabolites and transformation products in air

No data available.

Dissipation

No data available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant for the use of EULA OXI-LIME 23.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant for the use of EULA OXI-LIME 23.

PNECs

The following table contains a summary of PNECs of the active substance Calcium oxide for the respective compartments (Calcium oxide CAR, Burnt lime, 2016). Since hydrated lime was the only form tested in the fate and effects studies, toxicity has been expressed in the form of the hydrated lime equivalents.

Summary of PNECs of the active substance Calcium oxide				
Compartment	**Species**	**Endpoint**	**Safety factor**	**PNEC (Hydrated lime equivalents)**
Surface water	*Daphnia magna*	48h EC_{50} = 49.1	100	0.491 mg/L
Sediment	-	-	-	Not relevant
Microorganisms (STP)	*Activated sludge*	3h EC_{50} = 300.4 mg/L	100	3.004 mg/L
Soil	*Spinacia oleracea*	21d $NOEC_{plant}$ = 1080 $mg.kg^{-1}$ dw*	10	108 $mg.kg^{-1}$ dw*
Bird	-	-	-	Not relevant
Mammal	-	-	-	Not relevant

*For the effects assessment of the soil compartment, endpoints are presented in terms of mg a.s/kg dry weight (dw) of soil. This is consistent with the application rates for the PT2 uses all being expressed as rates per dry solid weight of sludge. For consistency, dry weight has been used for the PT3 use patterns.

According to the CAR, various MS recommended a risk assessment based on a qualitative approach, particularly since the dissociation products of the lime variants (Ca^{2+}, Mg^{2+} and OH^-) form parts of existing chemical cycles in the natural environment. In addition, for the terrestrial compartment, the contribution to the total environmental loading of lime from the biocidal use may be much less significant than from the routine agricultural use of lime used to amend soil pH and maintain soil fertility (a use of the active substance that is outside the scope of the BPR).

Thus, the PNEC values will not be always used in the risk assessment (especially for the terrestrial compartment). As proposed during the assessment of the active substance at the European level, a qualitative assessment will be conducted. For the terrestrial compartment, it involves the calculation of lime emissions on arable land due to the biocidal claimed uses and the comparison with routine agricultural use of lime to control soil pH. According to EU wide good agricultural practices, the guideline recommends application rates to neutralise agricultural soil up to 16 tons/ha per year (as CaO) in lime deficient soils.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Application to sewage sludge
ESD(s) used	Not applicable.
Approach	Qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Distribution in the environment	Vol IV Part B+C (2017)
Groundwater simulation	No

Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes Service life: No
Remarks	

Assessed PT	PT 3
Assessed scenarios	Scenario 2.1: Application to manure, Scenario 2.2: Application on indoor floor of animal accommodations, Scenario 3: Application on indoor floor inside animal transportations, Scenario 4: Application on floors of outdoor animal enclosures.
ESD(s) used	Scenario 2.1: ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 ✓ ESDTP18, Emission scenario document for Insecticides for stables and manure storage systems, 2006 Scenario 2.2 and 3: ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 Scenario 4: Not applicable
Approach	Semi-qualitative assessment is performed in accordance with the approach used in the active substance CAR.
Distribution in the environment	Vol IV Part B+C (2017)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenario 2, 3 and 4: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

Scenario 1 (PT2): disinfection of sewage sludge in an open mixer

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

The dry product is mixed with sewage sludge in an open mixer by professionals. After the disinfection process, the treated sludge is spread on agricultural fields. Therefore, an indirect exposure to soil is considered.

This use has been assessed in the CAR of the active substance Burnt Lime PT2, with the following application rate in comparison with the product EULA OXI-LIME 23:

Application rate of active substance in sewage sludge			
	Representative product of the CAR Burnt Lime, 2016	**EULA OXI-LIME 23 product**	**Remarks**
Fraction of a.s in the product (-)	1	1	-
Maximum application rate of the product (in % of dry solid weight of sludge)	120	150 (i.e 1.5 kg product/kg of dry solid weight of sludge)	-
Application rate of the a.s (in % of dry solid weight of sludge)	120	150	= Fraction of a.s in the product x Maximal application rate of the product

It has been demonstrated that the use of the representative product of the CAR generates applications of lime in agricultural soil lower than 16t/ha/year. The same reasoning can be used for the product EULA OXI-LIME 23 (see table below).

Application rate of active substance in agricultural fields		
	Representative product of the CAR Burnt Lime, 2016	**EULA OXI-LIME 23 product**
Input		
Application rate of the a.s for the use described in the CAR	120% of dry solid weight of sludge	150% of dry solid weight of sludge
Maximum application rate of sludge in agricultural land per year (as a worst case)	5000 kg dry solid sludge/ha/year	
Output		
Amount of lime added to the sludge during the treatment	6000 kg	7500 kg
Total dry weight of treated sludge after the treatment (considering the dry sludge and the lime treatment)	11000 kg	12500 kg
Application of a.s per ha per year due to the final 5000 kg of actual sludge + lime landed in agricultural field	5000/11000 * 6000 = 2.7 t/ha/year	5000/12500*7500 = 3.0 t/ha/year

As the use of EULA OXI-LIME 23 will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of EULA OXI-LIME 23 on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 2 (PT3): disinfection of animal accommodation

For the two following uses:

- 2.1: disinfection of manure (outdoor for all animals, and indoor for poultry, i.e. manure gathered in a specific area inside animal housing) and
- 2.2: disinfection of indoor floor of animal accommodations,

the product is mixed or released in manure after application. The mix burnt lime/manure is removed when accommodations are cleaned and sent to manure storage for use in fields or for incineration. The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:
"Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water".

The manure could be spread on fields, therefore the soil compartment is indirectly exposed to the active substance.

All parameters (area of accommodations, number of animals…) considered are from ESDTP3, 2011 and ESDTP18 for stables and manure storage systems, 2006. For an easier reading of the PAR, only worst-case situations are presented:

- ✓ For cattle: veal calves emissions,
- ✓ For poultry: turkeys emissions.

Scenario 2.1: disinfection of manure

The dry product is mixed with a manure, litter or manure/litter mixture, outdoor in a manure storage silo/pit (for any type of animal accommodations) or is gathered in a specific area inside the animal house and treated inside (for poultry only).

It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

In order to estimate this, the following parameters are calculated:

1) **The concentration of a.s in manure** after the application of the product.

Then,

2) **The maximum application rate of manure in grassland and arable land**, based on the nitrogen immission standard. The concentration of nitrogen in manure are calculated according to ESDTP3 and ESDTP18 for stables adapted parameters.

Finally,

3) **The maximum application rate of substance in agricultural soil**, considering the concentration of a.s in manure after the application, and the maximum application rate of manure.

The concentration rate of active substance in manure is calculated as follow:

1) Concentration of a.s in manure after the application of product				
	Symbol	**Value**	**Unit**	**Remarks**
		EULA OXI-LIME 23 product Scenario 2.1		
Fraction of a.s in the product	Fbioc	1	[-]	-
Maximum application rate of product in manure	-	100	[kg/m^3 of manure]	-
Concentration of a.s in manure after the application of product	**-**	**100**	[kg/m^3 of manure]	**=** Fraction of a.s in the product x Maximum application rate of product in manure

As no scenario exists for this use, some parameters from ESDTP3, (2011) and ESDTP18 for stables (2006) were adapted to calculate the maximal application rate of manure in agricultural soil.

2) Application rate of manure in arable and grassland					
Parameters	**Symbol from ESDTP3/18**	**Value**		**Unit**	**Remarks**
Input					
		Scenario 2.1 - Manure			
		Veal calves	**Turkey**		
Amount of nitrogen produced per animal per day	$Qnitrog_{i1}$	0.02382	0.00482	[kg/day /animal]	ESDTP3, 2011
Amount of manure produced per animal per day	-	0.007	0.00036	[m^3/animal/d]	ESDTP18, 2006 Table in Appendix 5 with conversion of L to m^3
Maximum emission standard for nitrogen on grassland	Qn, grassland	170		[kg/ha/ year]	ESDTP3, 2011
Maximum emission standard for nitrogen on arable land	Qn, arable land	170		[kg/ha/ year]	ESDTP3, 2011
Intermediate Calculations					
Concentration of nitrogen in the manure	-	3.40	13.39	[kg/m^3]	<u>Concentration of nitrogen in the manure</u> = Amount of nitrogen produced per animal per day / Amount of manure produced per animal per day
Output					

Maximum application rate of manure on grassland	-	**49.96**	**12.69**	[m^3/year/ha soil]	Maximum application rate of manure on grassland or arable land = Maximum emission standard for nitrogen on grassland or arable land / Concentration of nitrogen in the manure
Maximum application rate of manure on arable land	-	**49.96**	**12.69**	[m^3/year/ha soil]	

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

3) Application rate of active substance in arable land and grassland				
Input				
Parameters	**Value**		**Unit**	**Remarks**
	Scenario 2.1 - Manure			
	Veal calves	**Turkey**		
Concentration of a.s in manure	100	100	[kg/m^3 of wet manure]	-
Maximum application rate of manure on grassland and arable land	49.96	12.69	[m^3/year/ha soil]	-
Output				
3) Maximum application rate of active substance on grassland or arable land per year per hectare	**5.00**	**1.27**	[T/year/ha]	= Concentration of a.s in manure x Maximum application rate of manure on grassland and arable land x 0.001

As the use of EULA OXI-LIME 23 will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of EULA OXI-LIME 23 on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 2.2: disinfection of indoor floor of animal accommodations

The dry product is applied on concrete or mud floor before a production cycle, at a frequency that depends on sanitary breaks of animal cycles.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Burnt lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:
"Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water". Therefore, for poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

Calculations are done according to scenario "Disinfection of animal housing" from ESDTP3 (2011). It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Input					
Type of House	cat-subcat (i1)	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype (i2)	Disinfectant	Disinfectant	[-]	D
Emission to STP	$Elocal_{wastewater}$	Not relevant	Not relevant	[-]	O
Amount of product prescribed to be used per m²	Qprod	0.8	0.8	[kg/m²]	S
Fraction of active substance in the product	Fbioc	1	1	[-]	S
Area of the housing for application (floor only)	$AREA_{i1}$	160*	3330*	[m²]	D
Amount of active ingredient to be used for one application	Qai-prescri1,i2,i3	128	2664	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	4**	2**	[-]	D
Biocide application interval	Tbioc-int	91**	182**	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D

Concentration of a.s in manure after the last application					
Parameter	**Symbol**	**Value**		**Unit**	**S/D/O**
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	Nanimal $_{i1}$	80	10000	[-]	D
Amount of nitrogen per animal	Qnitrog $_{i1}$	0.02382	0.00482	[kg/d]	D
IF NITROGEN IMMISSION STANDARDS ARE APPLIED					
Nitrogen immission standard for one year - grassland	$Q_{N,grassland}$	170	170	[kg.ha^{-1}]	D
Nitrogen immission standard for one year - arable land	$Q_{N,arable\_land}$	170	170	[kg.ha^{-1}]	D
Intermediate Calculations					
Fraction of a.s released to slurry/manure	Fslurry/manure	0.5	0.2+0.3=0.5	[-]	
Number of biocide applications – grassland / arable land	Napp-manure grassland and arable land	1**	1**	[-]	O
Amount of active ingredient in manure - grassland / arable land	Qai-grass/arab$_{i1,i2,i3,i4}$	64	1332	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	Qnitrog-grass$_{i1,i4}$	101	2555	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	Qnitrog-arab$_{i1,i4}$	404	10218	[kg]	O
Outputs					
Soil exposure via manure spreading					
Annual application rate per hectare (arable land)	-	26.9	22.2	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	108***	88.6***	[kg/yr/ha]	O

* The risk assessment was carried out taking into account the area to be treated claimed by the applicant (foor only). For completeness, calculations were also conducted with the slatted area+floor areas. Considering these additional surfaces has no impact on the conclusion.

** As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manure$_{gr}$ and Napp-manure$_{ar}$ = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emission.

*** Worst-case used in the risk assessment.

As the use of EULA OXI-LIME 23 will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility,

no further calculations are necessary to assess the impact of the use of EULA OXI-LIME 23 on soil.

Moreover, according to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path.

Scenario 3 (PT3): disinfection of indoor floor of animal transportation

The dry product is applied on the floor inside of the vehicle every day after every transport. In the ESD for PT03 (2011), the main emission pathway is an emission to the wastewater, but an emission to air may also take place. Based on a low vapour pressure (<<1.0E-05 Pa), negligible exposure *via* the atmosphere is expected and therefore not further assessed.

To calculate the emissions to the STP of active substances such as lime is difficult because of the nature of the substance and the lack of data about their behavior in the STP, as this pathway was not assessed at the approval stage.

The doc IIA of the CAR (2016) specifies that adding lime up to 1000 mg/L in activated sludge test media causes high rises in pH (>12) which reduces to pH 10.6 after 3h. Other studies in different water media conducted with the same dose conclude that the reduction of the pH to background values can last up to 7 days. Such pH changes in the STP over such times (3h as much as 7 days) would result in the elimination of microorganisms and disruption of its functioning.

Although a complete quantitative risk assessment is not possible due to a lack of data, the $Elocal_{wastewater}$ is calculated to estimate a PEC_{STP} and compare it with doses used in the activated sludge test of the CAR.

The calculation of the $Elocal_{wastewater}$ is done according to the ESDTP3, 2011, and presented in the table below:

Emission calculations				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Area of trucks (mammal transports)	AREAmam	4546	[m²]	ESDTP03, 2011
Area of trucks (poultry transports)	AREApoul	1120	[m²]	ESDTP03, 2011
Area of containers (poultry transports)	AREAcont	3355	[m²]	ESDTP03, 2011
Content of active ingredient in formulation	Fbioc	1	[-]	ESDTP03, 2011
Amount of product prescribed to be used per m²	Qprodi2,i3	800	[g/m²]	S
Dilution factor (for preparation of the working solution from the formulation	Fdil	1	[-]	ESDTP03, 2011
Fraction released to waste water	Fstpi2i3i4	0.9	[-]	ESDTP03, 2011

Number of disinfectant applications in one year	Napp-bioc	365	[-]	ESDTP03, 2011
Output				
Emission from one application to a standard STP or an on-site waste water treatment plant (mammal)	**Elocal wastewateri2i3i4 mammal**	**3273**	[kg/d]	
Emission from one application to a standard STP or an on-site waste water treatment plant (poultry)	**Elocal wastewateri2i3i4 poultry**	**3222**	[kg/d]	
PEC_{STP} calculation				
Input				
Fraction of release to water from the STP	Fwater	1*****	[-]	
Effluent discharge rate of STP	EFFLUENTstp	2000000	[L/d]	Vol IV Part B+C; 2017
Conversion factor from burnt to hydrated lime (CAR of Burnt Lime)	Fb->h	1.321******	[-]	
Output				
PEC_{STP} resulting of one application to a standard STP or an on-site waste water treatment plant (mammal)	**$PEC_{STP\ mammal}$**	**2.16**	[g/L]	
PEC_{STP} resulting of one application to a standard STP or an on-site waste water treatment plant (poultry)	**$PEC_{STP\ poultry}$**	**2.13**	[g/L]	

*As the Koc is set to 0 kg/L and no information is available about biodegradation in STP, a fraction of release to water from the STP (Fwater) of 100% is considered.

** Since hydrated lime was the only form tested in the fate and effects studies, toxicity has been expressed in the form of the hydrated lime equivalents. Therefore, PECs for burnt lime should be converted to hydrated lime form to be compared to the PNECs.

As both PEC_{STP} are higher than the doses assessed in the CAR (and more than 500 times higher than the $PNEC_{STP}$ of 3.004 mg/L), high rises of the pH in the STP are expected. Therefore a release to the STP of the product after its use for animal transport disinfection leads to non-acceptable risks.

According to the applicant, a common practice to remove the lime consists in brushing the resulting dry waste before starting new transport to recycle them as agricultural liming material.

To prevent any releases to the STP from the disinfection of animal transport, the following two RMM are applied:
"Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant or directly to surface water".

Scenario 4 (PT3): disinfection of floor of outdoor animal enclosures

The dry product is applied on the ground of outdoor animal enclosures.

As for manure and sludge spreading, 16 tons/ha /year of a.s is the maximum amount of lime that can be spread on soil at a maximum. An application rate of 0.8 kg product/m² or 0.8 kg a.s/m² of soil corresponds to an application rate of 8 tons of a.s/ha. Therefore, only 2 applications per year at a maximum should be authorised. Higher application frequencies would lead to non-acceptable risks.

As a note, in accordance with a French opinion[13], the disinfection of the rangeland using such biocidal active substances is only carried out when the farms have been detected infected. Expert considers that an at least 6 weeks of fallowing is mandatory after the treatment.
In routine, zootechnical measures are recommended.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
Use		Scenario	Fresh-water	Freshwater sediment	STP	Air	Soil	Groundwater
TP2	Disinfection of sewage sludge	Scenario 1	No	No	No	No	Yes	Yes
TP3	Disinfection of manure	Scenario 2.1	No	No	No	No	Yes	Yes
	Disinfection of indoor floor surfaces of animal accommodations	Scenario 2.2	No	No	No	No	Yes	Yes
	Disinfection of animal transportation area	Scenario 3	Yes	Yes	Yes	No	Yes	Yes
	Disinfection of floors of outdoor animal enclosures	Scenario 4	No	No	No	No	Yes	Yes

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	56.08	g/mol	(CAR, 2016)
Vapour pressure	<1.0E-05	Pa	Not conducted as melting point above 300°C. It can be assumed the vapour pressure is $<10^{-5}$ Pa. (CAR 2016)
Water solubility (at 10°C)	1.31	g/l	(CAR, 2016)
Log Octanol/water partition coefficient	<<3	Log 10	(CAR, 2016)

13 AVIS du 14/10/16 révisé le 08/03/17* de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) relatif aux « procédés efficaces de désinfection des parcours en exploitations de volailles »

Organic carbon/water partition coefficient (Koc)	0	l/kg	Worst-case specified in the CAR of 2016
Henry's Law Constant	-	$Pa/m^3/mol$	Not applicable (CAR, 2016)
Biodegradability	-		Not applicable (CAR, 2016)
DT_{50} for biodegradation in surface water	-	d or hr (at 12ºC)	When dissolved in water, Burnt lime dissociates into Ca^{2+} and OH^-, which are chemically and biologically not further degradable (CAR, 2016)
DT_{50} for hydrolysis in surface water	-	d or hr (at 12ºC /pH)	When dissolved in water, Burnt lime dissociates into Ca^{2+} and OH^-, which are chemically and biologically not further degradable (CAR, 2016)
DT_{50} for photolysis in surface water	-	d or hr	Not applicable, see Hydrolysis (CAR, 2016)
DT_{50} for degradation in soil (T0 to T=6h after application of lime in soil)	0.752	hr	(CAR, 2016)
DT_{50} for degradation in soil (T=6h to T=+∞ after application of lime in soil)	372	hr	(CAR, 2016)

Calculated PEC values

For uses assessed in scenarios:
- 1 (treatment of sewage sludge),
- 2.1 (treatment of manure),
- 2.2 (treatment of indoor animal floor accommodations) and
- 4 (treatment of outdoor animal enclosures):

As all the uses generate lower emissions than the routine agricultural use of lime applied to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of EULA OXI-LIME 23 on soil. A qualitative assessment is deemed sufficient as proposed during the assessment of the active substance at the European level.

For use assessed in scenario 3 (treatment of vehicle for animal transport), only PEC_{STP} is calculated (see Emission estimation section):
- For mammals: PEC_{STP} = 2.16 g/L
- For poultry: PEC_{STP} = 2.13 g/L

Groundwater

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

The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, Ca^{2+} ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwater.

Primary and secondary poisoning

Primary poisoning

As the product is a powder mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca^{2+}, Mg^{2+}, and OH^-) in the environment.

2.2.8.3 Risk characterisation

Atmosphere

For burnt lime, exposure via air (and subsequent phototransformation in air) would be negligible based on its structure and its expected low vapour pressure (<<1.0E-05 Pa).

Due to the negligible exposure no formal risk assessment of air compartment is considered necessary.

Aquatic compartment (surface water, sediment and sewage treatment plant)

For uses assessed in scenario:

- ✓ 1 (treatment of sewage sludge),
- ✓ 2.1 (treatment of manure),
- ✓ 2.2 (treatment of animal indoor floor accommodations) and
- ✓ 4 (treatment of animal outdoor enclosures):

According to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment

(surface water, sediment) in case of the run-off emission pathMoreover, the following RMM will be included to prevent any releases to the STP: "Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water".

For use assessed in scenario 3 (treatment of indoor floor of animal transportation), a risk assessment for the STP compartment is conducted for mammal and poultry:

Uses	PEC_{STP} (mg/L)	$PNEC_{STP}$ (mg/L)	PEC/PNEC
Scenario 3 – indoor floor of animal transportation - Mammals	2160	3.004	**719.3**
Scenario 3 – indoor floor of animal transportation - Poultry	2130	3.004	**709.3**

Thus, unacceptable risks are foreseen for the STP compartment for this use.
The following RMM will be included to prevent any releases to the STP:
"Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant or directly to surface water".

Terrestrial compartment

All the uses of EULA OXI-LIME 23 that lead to emissions to soil will generate application rate of lime on agricultural soil lower than the routine agricultural use of lime spread to correct soil pH and maintain soil fertility (16T/ha/year, see table below).

Uses	Emissions to soil (agricultural land, in T/ha/year)	
PT2		
1	3	
PT3	Veal calves	Turkeys
2.1	5	1.27
2.2	0.108	0.089
3	n.r.	n.r.
4	n.r.	16

n.r: not relevant

Therefore, the use of EULA OXI-LIME 23 leads to acceptable risk to the terrestrial compartment.

Groundwater

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

The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, Ca^{2+} ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwater.

Primary and secondary poisoning

Primary poisoning

As the product is a powder mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca^{2+}, Mg^{2+}, and OH^-) in the environment.

Aggregated exposure (combined for relevant emission sources)

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

In the CAR of the active substance, it is recommended to verify the pH of the soil to be amended or the pH of the spread sludge/manure in order not to have a pH disruption.
It is considered that this verification is part of good spreading/amendments practices. For example, in France several norms and regulation ensure the correct spreading of lime treated materials on agricultural fields, including soil pH monitorings. Hence eCA considers that such RMM is not necessary nor relevant in the SPC of the biocidal product EULA HYDRA-LIME 23.

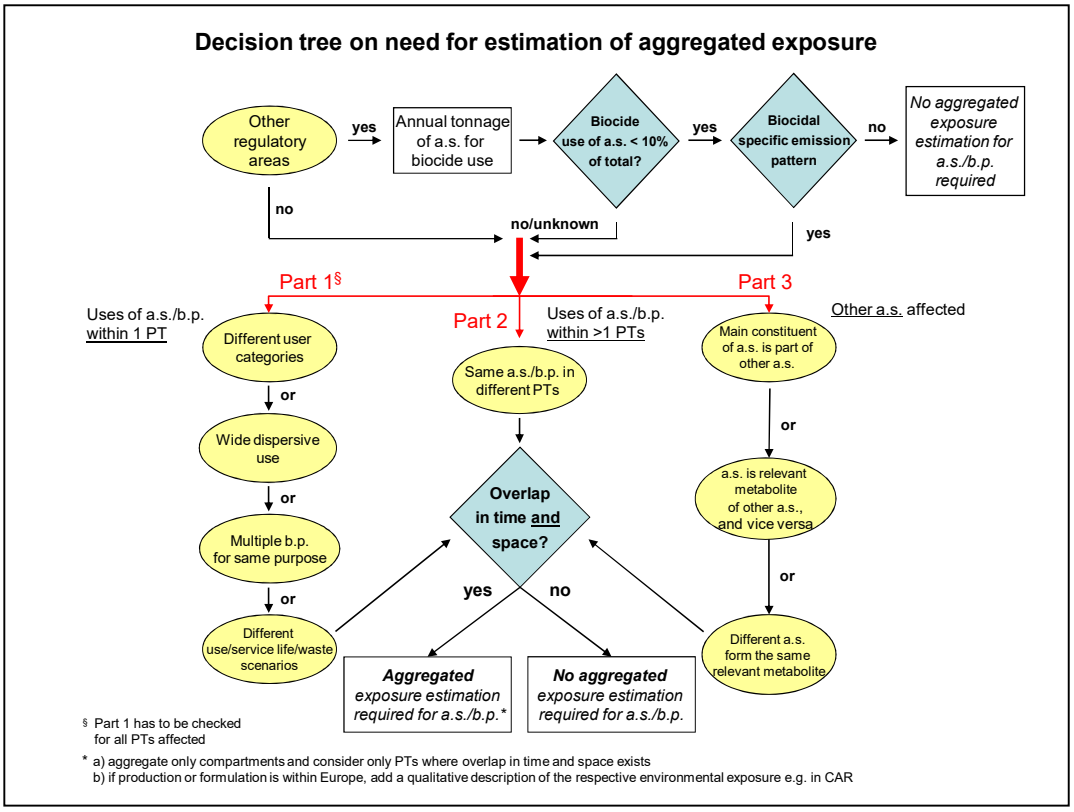


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product

Acceptable risks are foreseen for the following uses:

In PT2:

- ✓ disinfection of sewage sludge,

In PT3, considering the following RMM "Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water.":

- ✓ disinfection of manure,
- ✓ disinfection of indoor floor of animal accommodations and transportation,

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

- ✓ disinfection of floors of outdoor animal enclosures.

3 Annexes[14]

3.1 List of studies for the biocidal product

Author(s)	Year and Report date	Annex II/III requirements and IUCLID section	IUCLID document name	Title and Report number	Type of publication	Source (where different from company) and Study sponsor	GLP	Data Protection Claimed (Yes/No)
Author: [redacted]	Year: 1995	**Annex II/III requirement:** Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	IUCLID Document name: Appearance (at 20°C and 101.3 kPa) - active substance reference	Title: CD Römpp Chemie Lexikon – Version 1.0 No report number provided	Type of publication: review article or handbook		no	No
No author provided	No year provided	**Annex II/III requirement:** Acidity, alkalinity **IUCLID Section No.** 3.2	IUCLID Document name: Acidity, alkalinity - active substace reference	Title: Hydrated Lime active substance dossier: Doc. No.: 215-001; CB3.5/01 No report number provided	Type of publication: study report			No
No author provided	No year provided	**Annex II/III requirement:** Storage stability tests **IUCLID Section No.** 3.4.1	IUCLID Document name: Storage stability tests- active substance reference	Title: Burnt Lime active substance dossier: Doc. No.: 245-001; CB3.7/01 No report number provided	Type of publication: study report			No
No author provided	No year provided	**Annex II/III requirement:** Light	IUCLID Document name: Reactivity	Title: Burnt Lime active substance dossier: Doc. No.:	Type of publication: study report			No

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

		IUCLID Section No. 3.4.2.1	towards container material - active substance reference	245-001; CB3.7/01 No report number provided				
Author: [redacted]	Year: 2017	**Annex II/III requirement:** Technical characteristics of the biocidal product **IUCLID Section No.** 3.5	IUCLID Document name: Particle size distribution, dustibility and sieve data_EN 459-1	Title: PSD/laser diffraction data No report number provided	Type of publication: other company data		no	No
Author: [redacted]	Year: 2012	**Annex II/III requirement:** Corrosive to metals **IUCLID Section No.** 4.16	IUCLID Document name: Corrosive to metals_ CTL 2012	Title: Corrosion Testing per OSHA Regulations CFR 1910.1200 Appendix B No report number provided	Type of publication: study report	Company Owner: Corrosion Probe, Inc. 12 Industrial Park Rd. P.O. BOX 178 Centerbrook, CT 06409-0178		No
Author: [redacted]	Year: 1999	**Annex II/III requirement:** Corrosive to metals **IUCLID Section No.** 4.16	IUCLID Document name: Corrosive to metals_ BAM 1999	Title: Beurteilung der korrosion von kalkmilch hinsichtlich ihrer einstufung als atzender stoff der Klasse 8 “atzende stoffe” im sinne der transportlichen vorschriften. No report number provided	Type of publication: study report	Company Owner: Bundesverband der Deutschen Kalkindustrie e.V. Postfach 51 05 50, 50 941 Koln Germany	not specified	No
Author: ISO (the International Organization for	Year: 2013	**Annex II/III requirement:** METHODS OF	IUCLID Document name: Analytical	Title: ISO 17091:2013 Workplace air —	Type of publication: publication			No

Standardization)		DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	methods for determination in air	Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide — Method by measurement of corresponding cations by suppressed ion chromatography Report no. ISBN 978 0 580 77732 5				
Author: [redacted]	Year: 2003	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-1 from AS A5.10.01 Schirm et al. Hygienisation of biowaste. 2003 (Phase 3 - PT 2 - simulated use)	Title: Development of a safe method to hygienise bio-waste with lime Report no. 336-0201	Type of publication: publication	Source: Forschungsgemainschaft Kalk, 1/03/ C 023 Jan 2003 Company Owner: NA	not specified	No
Author: [redacted]	Year: 2004	**Annex II/III requirement:** Efficacy data to support these claims, including any available	IUCLID Document name: 6.7-2 from AS A5 10.02 Capizzi-Banas et al Liming as an	Title: Liming as an advanced treatment for sludge sanitisation: helminth eggs elimination - Ascaris as a model	Type of publication: publication	Source: Water Research 38: 3251-3258: Doc. No. 392-024 Company Owner: NA	not specified	No

		standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	advanced treatment for sludge sanitisation. 2004 (Phase 3 - PT 2)	Report no. NA				
Author: [redacted]	Year: 1984	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-3 From AS A5 10.03 Pfuderer G Hygenic aspects related to the treatment and use of sewage sludge. 1985 (Phase 2 - PT 2)	Title: Hygenic aspects related to treatment and use of sewage sludge Report no. NA	Type of publication: publication	Source: Ed P. L'Hermite, Elsevier, pp 85-97; Doc No 392-035 Company Owner: NA	not specified	No
Author: [redacted]	Year: 2008	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols,	IUCLID Document name: 6.7-6 - Evaluation of Liming in liquid and solid manure (Phase 2 - PT 2 and 3), Daugshies, 2008	Title: Evaluation of liming in liquid and solid manure Report no. not assigned	Type of publication: study report	Source: NA Company Owner: EuLA	not specified	No

		laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7						
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-7 Calcium oxide, Clean conditions, EN 14349 Phase 2 Step 2 (non porous surface test), MSL, 2018	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) Report no. J000714-1	Type of publication: study report	Source: NA Company Owner: EuLA, Brussels, Belgium	not specified	yes
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used	IUCLID Document name: 6.7-8 Calcium oxide, Dirty conditions EN 14349 Phase 2 Step 2 (non porous surface test, MSL, 2018	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	Type of publication: study report	Source: NA Company Owner: EuLA, Brussels, Belgium	not specified	yes

		including performance standards where appropriate and relevant **IUCLID Section No.** 6.7		conditions (Phase 2 Step 2) Report no. J000714-1				
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-9 Calcium dihydroxide Clean EN 14349 Phase 2 Step 2 (non porous surface test), MSL, 2018	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) Calcium Hydroxide, clean conditions Report no. J000714-01	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	yes
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance	IUCLID Document name: 6.7-10 Calcium dihydroxide Dirty EN 14349 Phase 2 Step 2 (non porous surface test, MSL, 2018	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, Calcium hydroxide dirty conditions (Phase 2	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	yes

		standards where appropriate and relevant **IUCLID Section No.** 6.7		Step 2) Porous surfaces Report no. J000714-2				
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-11 Calcium oxide, Clean conditions, EN 16437 Phase 2 Step 2 (porous surface test), MSL, 2018	Title: Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on porous surfaces without mechanical action (Phase 2 Step 2) CaO Clean Report no. J000714-2	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	yes
Author: [redacted]	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and	IUCLID Document name: 6.7-12 Calcium dihydroxide Clean EN 16437 Phase 2 Step 2 (porous surface test, MSL, 2018-	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, Calcium hydroxide dirty conditions (Phase 2 Step 2) Porous surfaces	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	yes

		relevant **IUCLID Section No.** 6.7		Report no. J000714-2				
Author: [redacted]	Year: 2008	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-13 - Evaluation of Liming in liquid manure - 90 day - Phase 2 (PT 3), Daugshies, May 2008	Title: Evaluation of the effect of liming in liquid pig and cattle manure on Ascaris suum eggs Report no. NA	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	yes
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	IUCLID Document name: 6.7-14 Calcium Oxide_Simulated test_ Modified NF T 72-281, (PT 3) Bacteria, Yeast Fungi, High Level Soil, Strohl, 2019	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) Report no. RE-1102/0219	Type of publication: study report	Source: NA Company Owner: EuLA, Rue Des Deux Eglises 26 box 2, 1000 Bruxelles, Belgium	not specified	yes

		IUCLID Section No. 6.7						
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-14 Calcium oxide Modified NF T 72-281,Bacteria, Yeast and Fungi, Veterinary High Level Soil, RE-1102/ 0219 Carre, Final, 2019	Title: Test Report No RE-1102/0219 Determination of microbicide activity of EuLA oxi-lime 23 according to a methodology issued to NF T 72-281 Report no. RE-1102/0219	Type of publication: study report	Source: NA Company Owner: EuLA, 1000 Brussels, Belgium	not specified	yes
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-14A Calcium oxide Modified NF T 72-281, Fungi, Aspergillus brasiliensis, Veterinary Low Level Soil, RE-1302/ 0919/A , Carre, Final, 2019	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) Report no. RE-1302/919/A	Type of publication: study report	Source: NA Company Owner: EuLA. 1000 Brussels, Belgium	not specified	yes

Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-14B Calcium oxide Modified NF T 72-281, Virus - Porcine Parvovirus, Veterinary High Level Soil, RE-1297/ 0819, Carre, Final, 2019	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) Report no. RE-1297/0819	Type of publication: study report	Source: NA Company Owner: EuLA, 1000 Brussels, Belgium	not specified	yes
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-15 Calcium dihydroxide_Simulated test_Modified NF T 72-281, (PT3) Bacteria, Yeast Fungi, High Level Soil, Strohl, 2019	Title: Test Report No RE-1143/0419 Determination of microbicide activity of 2 powders: hydra-lime and oxi-lime according to a methodology issued to NF T 72-281 - Powder Two - Calcium Hydrxide (hydra-lime) Report no. RE-1143/0419	Type of publication: study report	Source: NA Company Owner: EuLA, Rue des deux Eglises 26 Box 2, 1000 Bruxelles, Belgium	not specified	yes
Author: [redacted]	Year: 2019	**Annex II/III requirement:**	IUCLID Document name:	Title: EFFECTIVENESS	Type of publication: study	Company Owner: Lhoist o behalf of EuLA	no	yes

		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	6.7-16 Calcium oxide - Phase 3: Field Trial - PT 3 Poultry - RITTMO 18-445R	STUDY OF A BIOCIDE PRODUCT FOR TREATMENT OF POULTRY (FARM TRIAL) No report number provided	report			
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-17 Calcium oxide - Phase 3: Field Trial - PT 3 Poultry - RITTMO 19-415R	Title: EFFIACY STUDY OF A BIOCIDAL PRODUCT FOR THE TREATMENT OF POULTRY HOUSING No report number provided	Type of publication: study report	Company Owner: Lhoist on behalf of EuLA	no	yes
Author: [redacted]	Year: 2019	**Annex II/III requirement:** Efficacy data to support these	IUCLID Document name: 6.7-18 Calcium oxide - Phase 3:	Title: EFFICACY STUDY OF A BIOCIDAL PRODUCT	Type of publication: study report	Company Owner: Lhoist on behalf of EuLA	no	yes

		claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Field Trial - PT 3 Pigs - RITTMO 19-413R	Treatment of swine husbandry building No report number provided				
[redacted]	Year: 2020			Test report WA no.: 161-1/20	Type of publication: study report	ARGE Kalk GbR	no	yes
[redacted]	Year: 2020			Test report WA no.: 161-2-k2/20	Type of publication: study report	ARGE Kalk GbR	no	yes
[redacted]	Year: 2021			Determination of physico-chemical properties for several products. Report no Mo6493	Type of publication: study report	ARGE Kalk GbR	no	yes
Author: No author provided	Year: 2022			Calcium Dihydroxide Hydra Lime 23 & Calcium Oxide - OXI Lime 23 UN Transportation Testing 2022/101/JMF	Type of publication: study report	EuLA	no	yes

3.2 Output tables from exposure assessment tools

Loading of the product to sewage sludges and manures


ART modélisation-MANURES SLUDGES


RISKOFDERM MANURES SLUDGES

Application on indoor floor surfaces


ART- indoor floor surfaces.zip


RISKOFDERM floor surfaces.zip

Application on outdoor floor surfaces


ART- outdoor.zip

3.3 New information on the active substance

Supporting document presented by FR CA during the WG I 2022 – Use of the ULs as TRV


WG I2022-TOX_eCA_Ca 2+ syst

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[15]

3.6 Confidential annex

3.7 Other

Annex 1 – Risk assessment for animal health

Note to the reader: the risk assessment for animal health was not been peer reviewed and agreed by the WG members (WG I 2022)

According to the information provided by the applicant, the biocidal product is always removed after the treatment of the floor surfaces of animal accommodations, transportation and outdoor enclosures. Animals are not present during the treatment (which includes the application, the contact time of 48h and the removal of the product by sweeping).
Animals are not expected to be directly in contact with residues as the floor has to be covered with fresh straw before the re-entry. Moreover, after a contact time of 48h, no lime residues is expected on floor surfaces but only reaction products (with no irritant properties expected) that are swept at the end of the treatment. Considering that, no local RA is performed.
Regarding systemic RA, it is not considered relevant taking into account that animal exposure via feed is excluded by the addition of a specific RMM to remove feed during the treatment. Furthermore, the Ca^{2+} and Mg^{2+} intake from the product is considered negligible compared to those from the normal feeding of livestock.

15 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.