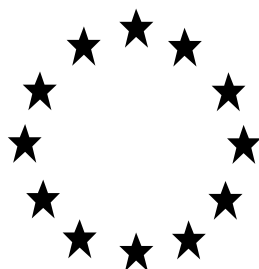


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A  
BIOCIDAL PRODUCT FOR UNION  
AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



EULA HYDRA-LIME 23

Product types 2-3

Calcium dihydroxide

Case Number in R4BP: BC-JR038510-32

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 HYDRA-LIME 23.

### General

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

The biocidal product EULA HYDRA-LIME 23, containing 100% calcium dihydroxide<sup>1</sup> is a product type (PT) 2 and 3 intended to be used for disinfection of sewage sludge and manures, of bedding materials, of indoor and outdoor floor surfaces of animal accommodation walls by brush. The biocidal product EULA HYDRA-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 applicant, a 15 months shelf-life can be accepted as well for the product.

The product is not classified for any physical hazard properties.

The product is 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.

### Labelling:

Protect from humidity.

Do not store at a temperature above 30°C.

### Efficacy

The product EULA HYDRA-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 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 should be calculated by the users based on the dry weight of the substrate.

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

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<sup>1</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2016/1935 of 4 November 2016 approving calcium dihydroxide (hydrated 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 during the exposure time.

The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users 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 (including limewashing of walls) and transportation, floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus.

The effective application rate is of 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.

- ✓ For the disinfection of bedding materials (PT3), against bacteria, yeast, fungi and virus. No specific efficacy data on bedding materials was presented to support this claim. A read-across with manure, considered as a worst case, was proposed but the EFF WG (WG I 2022 meeting) concluded that the demonstration of the efficacy is not acceptable. The efficacy is therefore not supported by the data presented in the dossier and the use is not proposed for authorisation.

## **Human Health**

The product EULA HYDRA-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<sup>2+</sup> and Mg<sup>2+</sup> during application combined with the dietary intake is still below the Upper Limit values set for Ca<sup>2+</sup> and Mg<sup>2+</sup> 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) with the following PPE:

- gloves;
- protection 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 likely that the addition of calcium dihydroxide to sewage or manures 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<sup>3</sup> for this gas.

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

- The pouring of the hydrated lime into the treatment unit must be done fully automatically.
  - Considering the use of big bags (500-1000 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/manure.
  - 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, transportation and bedding materials**

The risk for human health is considered acceptable for loading, 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:

- Considering the use of big bags (500-1000 kg), 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 minimize the remaining powder;
  - For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
  - 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 animal accommodation walls by brush**

The risk for human health is considered acceptable for the loading 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).

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

- gloves;
- protective coverall;
- respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter).

Moreover, the following RMM are needed:

- Considering the use of big bags (500-1000 kg), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin);
- Minimisation of splash and spills during application of water suspended lime.
- Do not let bystander (including co-workers and children) touch the treated surfaces until complete drying.
- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (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.

### **Animal Health**

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

- Animals should not be present during all the treatment duration.
- Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals. 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.
- Do not let animal re-enter the accommodations before complete drying of surfaces
- 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<sup>2+</sup>, the dietary risk for consumer related to the intended uses is negligible.

### **Environment**

The product EULA HYDRA-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 animal bedding material,
- ✓ disinfection of indoor walls of animal accommodations,
- ✓ disinfection of indoor floor 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 dihydroxide 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.



<b>Uses</b>	<b>Target</b>	<b>Conditions of use</b>	<b>Conclusions</b>
Disinfection of sewage sludge	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Indoor Professional The product is mixed with the sewage sludge in an open mixer.	<b>Acceptable, except for yeast, fungi and virus</b>
Disinfection of manure	Bacteria, yeast, fungi, viruses, Endoparasites: helminth eggs	Indoor Professional The product is mixed with the manure	<b>Acceptable except for yeast and fungi</b>
Disinfection of indoor floor surfaces of animal accommodations and transportation	Bacteria, yeast, fungi, viruses	Indoor Professional Direct application.	<b>Acceptable</b>
Disinfection of animal bedding materials	Bacteria, yeast, fungi, viruses	Indoor Professional Direct application.	<b>Not Acceptable</b> <b>No efficacy studies submitted</b>
Disinfection of animal accommodations; limewashing of walls	Bacteria, yeast, fungi, viruses	Indoor Professional The product is suspended in water prior its application by brushing on the walls	<b>Acceptable</b>
Disinfection of floors of outdoor animal enclosures	Bacteria, yeast, fungi, viruses	Outdoor Professional Direct application	<b>Acceptable</b>

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	Country (if relevant)
EuLA Hydra-lime 23	Union Authorisation

##### 2.1.1.2 Authorisation holder

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

##### 2.1.1.3 Manufacturer(s) of the products

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

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

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

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

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

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

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

<b>Name of manufacturer</b>	Carmeuse Holding Srl
<b>Address of manufacturer</b>	Str.Carierei Nr.127A, 500047 Brasov, Romania
<b>Location of manufacturing sites</b>	Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Pravat, 117805 Campulung, Romania.

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

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

<b>Name of manufacturer</b>	Carmeuse SA
<b>Address of manufacturer</b>	Rue du Château 13a, 5300 Seilles, Belgium
<b>Location of manufacturing sites</b>	Rue du Val Notre Dame 300, 4520 Moha, Belgium. Rue du Château 13a, 5300 Seilles, Belgium.

<b>Name of manufacturer</b>	Carmeuse Slovakia s.r.o.
<b>Address of manufacturer</b>	Slavec, 049 11 Slavec, Slovakia
<b>Location of manufacturing sites</b>	závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia

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

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

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

<b>Name of manufacturer</b>	Chaux de Boran
<b>Address of manufacturer</b>	Route de Boran, 60 640 Précý-Sur-Oise, France
<b>Location of manufacturing sites</b>	Route de Boran, 60 640 Précý-Sur-Oise, France

<b>Name of manufacturer</b>	Chaux de Bretagne
<b>Address of manufacturer</b>	53 600 Evron, France
<b>Location of manufacturing sites</b>	53 600 Evron, France

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

<b>Name of manufacturer</b>	Clogrennane Lime LTD
<b>Address of manufacturer</b>	Clogrennane Lime LTD, Clogrennane, Carlow, R93 EV26, Ireland
<b>Location of manufacturing sites</b>	Clogrennane, Carlow, R93 EV26, Ireland

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

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

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

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

<b>Name of manufacturer</b>	Lhoist Faxe Kalk A/S
<b>Address of manufacturer</b>	Hovedgaden 13, 4654 Faxe Ladeplads, Denmark
<b>Location of manufacturing sites</b>	Gl. Strandvej 14, 4640 Faxe, Denmark

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

<b>Name of manufacturer</b>	Lusical
<b>Address of manufacturer</b>	Valverde, 2025-201 Alcanede, Portugal
<b>Location of manufacturing sites</b>	Valverde, 2025-201 Alcanede, Portugal

<b>Name of manufacturer</b>	Nordkalk AB
<b>Address of manufacturer</b>	Box 901 SE-731 29 Köping Sweden
<b>Location of manufacturing sites</b>	Nordkalk AB, Köping, Kungsängsvägen 22, SE-731 36 Köping, Sweden Nordkalk AB, Landskrona, Verkstadsgatan, SE-261 35 Landskrona, Sweden Nordkalk AB, Luleå, Viktoriavägen 5, SE-974 37 Luleå, Sweden

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

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

<b>Name of manufacturer</b>	SMA Mineral AB
<b>Address of manufacturer</b>	SE-682 27 Filipstad, Sweden
<b>Location of manufacturing sites</b>	Luleå Lime Plant, C/O SSAB Europe, SE-971 88 Luleå, Sweden. Boda Lime Plant, Kärvsåsen Kalkverksvägen 15, SE-795 96 Boda kyrkby, Sweden. Rättvik lime plant, Kalkvagen 7 SE-795 32 RÄTTVIK, Sweden. SSAB Industriområde, Kalkverket, SE-613 80 Oxelösund, Sweden. Mo Industripark, Verkstedsoypa, NO-8626 Mo i Rana, Norway.

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

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

<b>Name of manufacturer</b>	Tarmac, Lime and Powders
<b>Address of manufacturer</b>	Tunstead House, Wormhill, Buxton, Derbyshire, SK17 8TG, UK
<b>Location of manufacturing sites</b>	Tunstead Quarry, Wormhill, Buxton, Derbyshire, SK17 8TG, UK

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

<b>Name of manufacturer</b>	Wietersdorfer & Peggauer Zementwerke GmbH
<b>Address of manufacturer</b>	Wietersdorf 1, 9373 Klein St. Paul, Austria

<b>Location of manufacturing sites</b>	Alois-Kern-Straße 1, 8120 Peggau, Austria
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<b>Name of manufacturer</b>	Zakłady Wapiennicze Lhoist S.A.
<b>Address of manufacturer</b>	ul. Wapiennicza 7, 46-050 Tarnów Opolski, Poland
<b>Location of manufacturing sites</b>	ul. Fabryczna 22, 47-316 Górażdże, Poland ul. Bolesława Chrobrego 77B, 59-550 Wojcieszów, Poland

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

<b>Name of manufacturer</b>	SMA Mineral AS
<b>Address of manufacturer</b>	Postbox 500, NO-8601 Mo I Rana, Norway
<b>Location of manufacturing sites</b>	Mo Industripark, Verkstedssøypa, NO-8626 Mo i Rana, Norway

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

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

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

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

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

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

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

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

<b>Name of manufacturer</b>	Carmeuse Holding Srl
<b>Address of manufacturer</b>	Str.Carierei Nr.127A, 500047 Brasov, Romania
<b>Location of manufacturing sites</b>	Str Principala 1, 337457 Com. Soimus, Romania. Valea Mare Pravat, 117805 Campulung, Romania.

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

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

<b>Name of manufacturer</b>	Carmeuse SA
<b>Address of manufacturer</b>	Rue du Château 13a, 5300 Seilles, Belgium
<b>Location of manufacturing sites</b>	Rue du Val Notre Dame 300, 4520 Moha, Belgium. Rue du Château 13a, 5300 Seilles, Belgium.

<b>Name of manufacturer</b>	Carmeuse Slovakia s.r.o.
<b>Address of manufacturer</b>	Slavec, 049 11 Slavec, Slovakia
<b>Location of manufacturing sites</b>	závod Vápenka Slavec, Slavec 179, 049 11 Slavec, Slovakia

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

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

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

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

<b>Name of manufacturer</b>	Chaux de Bretagne
<b>Address of manufacturer</b>	53 600 Evron, France
<b>Location of manufacturing sites</b>	53 600 Evron, France

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

<b>Name of manufacturer</b>	Clogrennane Lime LTD
<b>Address of manufacturer</b>	Clogrennane Lime LTD, Clogrennane, Carlow, R93 EV26, Ireland
<b>Location of manufacturing sites</b>	Clogrennane, Carlow, R93 EV26, Ireland

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

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

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

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

<b>Name of manufacturer</b>	Lusical
<b>Address of manufacturer</b>	Valverde, 2025-201 Alcanede, Portugal
<b>Location of manufacturing sites</b>	Valverde, 2025-201 Alcanede, Portugal

<b>Name of manufacturer</b>	Nordkalk AB
<b>Address of manufacturer</b>	Box 901 SE-731 29 Köping Sweden
<b>Location of manufacturing sites</b>	Nordkalk AB, Köping, Kungsängsvägen 22, SE-731 36 Köping, Sweden Nordkalk AB, Landskrona, Verkstadsgatan, SE-261 35 Landskrona, Sweden Nordkalk AB, Luleå, Viktoriavägen 5, SE-974 37 Luleå, Sweden

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

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

<b>Name of manufacturer</b>	SMA Mineral AB
<b>Address of manufacturer</b>	SE-682 27 Filipstad, Sweden
<b>Location of manufacturing sites</b>	Luleå Lime Plant, C/O SSAB Europe, SE-971 88 Luleå, Sweden. Boda Lime Plant, Kärvsåsen Kalkverksvägen 15, SE-795 96 Boda kyrkby, Sweden. Rättvik lime plant, Kalkvagen 7 SE-795 32 RÄTTVIK, Sweden.

	SSAB Industriområde, Kalkverket, SE-613 80 Oxelösund, Sweden. Mo Industripark, Verkstedsoypa, NO-8626 Mo i Rana, Norway.
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<b>Name of manufacturer</b>	SMA Mineral Burgas Var LTD
<b>Address of manufacturer</b>	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. №52
<b>Location of manufacturing sites</b>	8002, Bulgaria, Burgas, dis. Pobeda, Chataldzha str. №52

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

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

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

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

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

### 2.1.2 Product composition and formulation

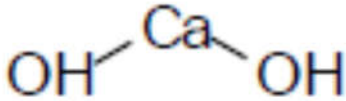
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

#### 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 (%)
Calcium dihydroxide	Calcium dihydroxide	Active substance (technical)	1305-62-0	215-137-3	100

### 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 dihydroxide. According to the ED conclusions in the BPC opinions (ref. BPC OPI PT2, BPC OPI PT3, 2016) from the active substance approval, hydrated 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  
 WP : Wettable Powder (use 5 - Disinfection of animal accommodations; limewashing of walls)

## 2.1.3 Hazard and precautionary statements

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

<b>Classification</b>	
Hazard category	Skin irritation, category 2 Serious eye damage, category 1 STOT SE, category 3
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
<b>Labelling</b>	
Signal words	GHS05, GHS07

<b>Classification</b>	
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
Precautionary statements	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of water/... P321: Specific treatment (see ... 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. P405: Store locked up. P501: Dispose of contents/container in accordance with national regulation.
Note	

### 2.1.4 Authorised use(s)

#### 2.1.4.1 Use description

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

<b>Product Type</b>	2
<b>Where relevant, an exact description of the authorised use</b>	
<b>Target organism (including development stage)</b>	Bacteria Endoparasites: helminth eggs
<b>Field of use</b>	Indoor. The product is dosed into the sewage sludge and mixed by means of a blender.
<b>Application method(s)</b>	Automatic direct application
<b>Application rate(s) and frequency</b>	Ready to use product The dry product is mixed with the sewage sludge in an open mixer. The product should be loaded by fully automated processes.  The dose must be sufficient to maintain a pH of > 12 during the contact time needed.

	Contact time: 24h to several weeks for endoparasites: helminth eggs
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1000 kg

#### 2.1.4.2 Use-specific instructions for use

- The dose must be sufficient to maintain a pH of > 12 during the contact time needed.
- Application rate: 0.2 – 2 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

#### 2.1.4.3 Use-specific risk mitigation measures

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

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

-

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

-



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

-

#### 2.1.4.7 Use description

Table 6. Use # 2 – **Disinfection of manure**

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	
<b>Target organism (including development stage)</b>	Bacteria, Viruses, Endoparasites: helminth eggs
<b>Field of use</b>	Indoor The product is dosed into the manure and mixed by means of a blender.
<b>Application method(s)</b>	Automatic direct application.
<b>Application rate(s) and frequency</b>	Ready to use The product is mixed with the manure. The product should be loaded by fully automated processes.  The dose must be sufficient to maintain a pH of > 12 during the contact time needed.  Contact time: 72h (bacteria, virus) to 90 days (helminth eggs)
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1000 kg

#### 2.1.4.8 Use-specific instructions for use

<ul style="list-style-type: none"> <li>✓ The dose must be sufficient to maintain a pH of &gt; 12 during the contact time needed.</li> <li>✓ Remove the manure from the animal house.</li> </ul> <p>Application rate:</p> <ul style="list-style-type: none"> <li>✓ 1. Do not apply more than 100 kg lime /m<sup>3</sup> of manure,</li> <li>✓ 2. After the necessary contact time, dispose of the lime treated manure according to local legislation.</li> </ul>
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#### 2.1.4.9 Use-specific risk mitigation measures

<ul style="list-style-type: none"> <li>- The loading of lime powder into the treatment unit and the application must be done fully automatically.</li> <li>- 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</li> </ul>
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- a closed cabin).
- During the loading of the product and the disposal of empty bags , wear :
    - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
    - o a protective coverall (coverall material to be specified by the authorisation holder within the product information),
    - o a respiratory mask at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter).
  - 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<sup>3</sup> for this gas.
  - Wear protective gloves and protection coverall during the manual handling of treated manures.
  - The cleaning of the unit treatment must be avoided or performed with an automated process with no exposure of the professional.
  - Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or directly to surface water.

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

-

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

-

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

-

**2.1.4.13** Use description

Table 2. Use # 3 – **Disinfection of indoor floor surfaces of animal accommodations and transportation**

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	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.
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	Ready to use 800 g Ca(OH) <sub>2</sub> / m <sup>2</sup> Frequency in animal housing: Before each production cycle Frequency in animal transportation: After each animal transport  Contact time: 48h
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1000 kg Paper sacks (with PP or PE inner layer): 25 kg

#### 2.1.4.14 Use-specific instructions for use

The product is spread directly onto the floors of animal accommodations and transportation, using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.

A. On concrete floors:

1. Wash the installation with running water,
2. Sprinkle approx. 800 g of Ca(OH)<sub>2</sub> per m<sup>2</sup> to cover the damp ground and add 0.9 L/m<sup>2</sup> of water
3. Leave to act for at least 48 h.

B. On beaten-earth floors:

1. Brush and wet the floor,
2. Sprinkle approx. 800 g of Ca(OH)<sub>2</sub> per m<sup>2</sup> on the damp ground and add 0.9 L/m<sup>2</sup> of water
3. Leave to act for at least 48 h.

#### 2.1.4.15 Use-specific risk mitigation measures

- During the loading, the application of the product on floor and the disposal of empty bags, wear :
  - o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - o a protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Considering the use of big bags (a half to one 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.
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.

- During the disposal of the product after the application, wear :
  - o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - o protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Animals should not be present during all the treatment duration.
- Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application of the product
- Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or directly to surface water.

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

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**2.1.4.17** 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.

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

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**2.1.4.19** Use description

Table 4. Use # 5 – **Disinfection of animal accommodations; limewashing of walls**

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	

<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Direct application with a brush. The product is suspended in water and the mixture painted onto the walls of animal accommodations
<b>Application rate(s) and frequency</b>	The product is suspended in water (50% w/v) prior its application by brushing on the walls  800 g Ca(OH) <sub>2</sub> / m <sup>2</sup>  Contact time 48 hours  Frequency: Before each production cycle
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1000 kg

#### 2.1.4.20 Use-specific instructions for use

For one layer:

- ✓ Application method for 150 to 200 m<sup>2</sup> of wall (depending on the porosity of the wall):
  - ✓ 1. Clean the surface with running water before the application of the product.
  - ✓ 2. Introduce 25 kg of hydrated lime into 50 L of water,
  - ✓ 3. Let the mixture rest for 12h,
  - ✓ 4. Mix the resulting slurry and brush onto the wall.
  - ✓ 5. Leave to act for at least 48 h

The application rate is 125-167 g Ca(OH)<sub>2</sub> / m<sup>2</sup> for a single layer. A final application rate of 800 g Ca(OH)<sub>2</sub> / m<sup>2</sup> is required, therefore 5-7 coats should be applied, depending on the porosity of the wall.

Stir before and during application

Considering the use of big bags (a half to one tone), the product must be first fully automatically transferred to a medium lower volume tank. Then, the product is manually load for the medium tank to a bucket.

#### 2.1.4.21 Use-specific risk mitigation measures

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

- within the product information),
  - a respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter).
- Considering the use of big bags (a half to one tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin).
- Minimisation of splash and spills during application.
- Do not let bystander (including co-workers and children) touch treated surfaces until complete drying.
- 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.
- Animals should not be present during all the treatment duration.
- Do not let animal re-enter the accommodations before complete drying of surfaces.
- Feed and drinking water must be carefully covered or removed during the application of the product

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

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

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

-

**2.1.4.25** Use description

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

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	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.
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	Ready to use

	800 g Ca(OH) <sub>2</sub> /m <sup>2</sup> Contact time 48 hours Frequency: maximum two applications per year
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk powder Big bags or sacks (with PP or PE inner layer): 500 - 1000 kg Paper sacks (with PP or PE inner layer): 25 kg

#### 2.1.4.26 Use-specific instructions for use

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

#### 2.1.4.27 Use-specific risk mitigation measures

- During the loading, the application of the product and the disposal of empty bags, wear:
  - o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - o a protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Considering the use of big bags (a half to one 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.
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- During the disposal of the product after the application, wear :
  - o a respiratory protective equipment at least APF 40 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P3 filter);
  - o chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
  - o a protective coverall (coverall material to be specified by the authorisation holder within the product information).
- Do not exceed two applications per year.
- Animals should not be present during all the treatment duration.
- Remove residues of the biocidal product on the ground by thorough sweeping before re-entry of animals.
- Feed and drinking water must be carefully covered or removed during the application

of the product

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

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**2.1.4.29** 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

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

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## **2.1.5 General directions for use**

**2.1.5.1** Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc).
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- For outdoor uses of the product, do not apply in case of wind or rain.

**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, 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 – 1000 kg	Body cover: Polypropylene white Anti-UV treatment according to ISO 21898 : 2004; or paper Lining: Type: Polyethylene	Closure with ribbon or ligament	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 provide by the applicant. The big-bag/sacks should be adapted to be opened and transferred with an automatized closed 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 1. Use # 1 – Disinfection of sewage sludge

<b>Product Type</b>	2
<b>Where relevant, an exact description of the authorised use</b>	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.
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses, nematode eggs
<b>Field of use</b>	Indoor, outdoor
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	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. 0.2 – 2.0 kg product / kg dry weight of substrate; Typical dry solids content - 12-25% in sewage sludge and 1-6% in liquid manures The dose must be high enough to achieve a pH of > 12 for a minimum of 3 hours. Note; the rate may vary between application
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk Big bags or sacks: 500 - 1000 kg Paper sacks: 25 kg

Table 2. Use # 2 – Disinfection of manure

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use.

<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses, nematodes eggs
<b>Field of use</b>	Indoor, outdoor
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	<p>Remove the manure or litter from the animal house.</p> <ol style="list-style-type: none"> <li>1. For prevention: Add approximately 10 kg lime/m<sup>3</sup> of litter or manure.</li> <li>2. For treatment: Add approx. 100 kg lime/m<sup>3</sup> of litter or manure</li> <li>3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water.</li> <li>4. Stockpile the lime treated manure.</li> <li>5. After at least 24h, dispose of the lime treated manure according to local legislation.</li> </ol> <p>Application of lime to litter or manure inside animal houses</p> <ol style="list-style-type: none"> <li>1. For Prevention: Spread approx. 10 kg/m<sup>3</sup> (2 kg of lime /m<sup>2</sup> for 20 cm litter) on the litter or manure inside the poultry house</li> <li>2. For treatment: Spread approx. 100 kg/m<sup>3</sup> (20 kg of lime /m<sup>2</sup> of 20 cm litter) on the litter or manure inside the animal house</li> <li>3. The mixture should be moistened and any self-ignition that might occur should be extinguished with water</li> <li>4. Remove the lime/manure or lime/litter mixture from the animal house</li> <li>5. Homogenise the lime/manure or litter mixture</li> <li>6. Stockpile the lime treated manure</li> <li>7. After at least 24 h, dispose the lime treated manure according to the local legislation</li> </ol>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	<p>Bulk Big bags or sacks: 500 - 1000 kg</p> <p>Paper sacks: 25 kg</p>

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

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	The product is spread directly onto the floors of animal accommodations (poultry, cattle, sheep)
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	Disinfection of indoor floor surfaces of animal accommodations and transportation. The product is spread onto the floors of animal accommodations using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.

	<p>a. On concrete floors</p> <ol style="list-style-type: none"> <li>1. Wash the installation with running water</li> <li>2. Spread approx. 800 g of product per m<sup>2</sup> to cover the damp ground and add 0.9 L/m<sup>2</sup> of water.</li> <li>3. Leave to act for at least 2 h</li> </ol> <p>B. On mud floors</p> <ol style="list-style-type: none"> <li>1. Brush the floor</li> <li>2. Sprinkle approx. 800 g of product per m<sup>2</sup> on the damp Ground and add 0.9 L/m<sup>2</sup> of water.</li> <li>3. Leave to act for at least 24 h</li> </ol>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk Big bags or sacks: 500 - 1000 kg Paper sacks: 25 kg

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

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	The product is spread directly onto animal bedding materials (straw, sawdust, woodchip)
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	Cattle: Spread onto mulched or soiled bedding, do not apply alone to animal stalls. Use 1 to 1.5 kg per livestock unit per week in straw area. 200 to 300 g per stall once or twice a week Sheep/goats: 110 to 200 g/m <sup>2</sup> per head/week Poultry: 100 - 200 g/m <sup>2</sup> 1-2 times per week
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk Big bags or sacks: 500 - 1000 kg Paper sacks: 25 kg

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

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	The product is diluted in water and the mixture painted onto the walls of accommodations (poultry, cattle, sheep)
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Direct application with a brush
<b>Application rate(s) and frequency</b>	For one layer: Application method for 150 to 200 m <sup>2</sup> of wall (depending on the porosity of the wall):

	<ol style="list-style-type: none"> <li>1. Introduce 25kg of hydrated lime into 50l of water</li> <li>2. Let the mixture rest for 12h</li> <li>3. Mix the resulting slurry and brush onto the wall</li> </ol> <p>The application rate is 125-167 g Ca(OH)<sub>2</sub> / m<sup>2</sup> for a single layer. A final application rate of 800 g Ca(OH)<sub>2</sub> / m<sup>2</sup> is required, therefore 5-7 coats should be applied, depending on the porosity of the wall.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk Big bags or sacks: 400 - 1000 kg Paper sacks: 25 kg

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

<b>Product Type</b>	3
<b>Where relevant, an exact description of the authorised use</b>	The product is spread directly onto the surface of animal enclosures
<b>Target organism (including development stage)</b>	Bacteria, yeast, fungi, viruses
<b>Field of use</b>	Outdoor
<b>Application method(s)</b>	Direct application
<b>Application rate(s) and frequency</b>	<p>At the beginning of a production cycle it is recommended to spread 800 g/m<sup>2</sup> of the product onto the ground and apply water to the soil.</p> <p>At the end of the production cycle it is recommended to remove any remaining material from the soil.</p> <p>Leave to act for at least 24 hours before bringing in the animals.</p> <p>When the flock is in place, reapply if the ground becomes muddy or unstable.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Bulk Big bags or sacks: 500 - 1000 kg Paper sacks: 25 kg

## 2.2.2 Physical, chemical and technical properties

The product is 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) or in 50%w/v in water.

The content of hydrocarbons or H304 co-formulants in the product is  $\leq 10\%$  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) <sub>2</sub> 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	$\geq 97.0\%$	Relative density: 2.2 Bulk density: 0.4 g/mL Tap density: 0.5 g/mL	AS dossier: A3.1.3/02 A3.1.3/03	Accepted in the CAR of active substance
Storage stability test – <b>accelerated storage</b>	Waiver		Lime products are not degradable. If stored in damp conditions the products may react, but there is no loss of the active substance. A storage stability study is therefore not appropriate for this type of material.		No accelerated storage study was provided. In consequence, the mitigation measure is added:

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
					<b>Product do not store above 30°C.</b>
Storage stability test – <b>long term storage at ambient temperature</b>	not indicated	As described in Section B2	See AS dossier (product PRECAL 50N): Bagged material must be stored under dry conditions because Burnt lime is hygroscopic. The uptake of CO <sub>2</sub> and water by Precal 30S stored in paper bags was measured for a period of 24 weeks (extrapolated to 26weeks which correspond to 6 months). The water content of the product raised from 0.5 to 6% (w/w) During storage, no hard lumps are formed.	AS Dossier 3.7	Based on AS dossier, a shelf life of 6 months is acceptable. For the use : Disinfection of animal accommodations; limewashing of walls, the product is diluted in water at 50% w/v before use. According to guidance on the Biocidal products regulation, vol I, suspensibility, persistent foaming and wet sieve test should be provided. However, the product is a milk lime, similar to a sludge. The diluted product is therefore very viscous and performance of the tests seems to be limited. Moreover, viewing the application use

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
					<p>(product is applies by brushing and rests 12h to finish by a solid coat on the wall) the required tests are not relevant and no other data is required. A mitigation measure is nevertheless preconize: stirring before and during the application. The biocidal product (= active substance) is not reactive with water nor hygroscopic as CaO has already reacts with water to form Ca(OH)<sub>2</sub> (see manufacturing process of active substance). Nevertheless, as the product is a powder, it should be <b>protect from humidity</b> to avoid aggregation.</p>
	CIPAC MT184	Cabio Bac WKH Bag – Ca(OH) <sub>2</sub>	A new study was provide to follow some technical properties during 12months storage The material packaging is not known.	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> 2021 Study Mo6493*	The tested product is not an Eula product but the results can be taken into



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	Comments
	CIPAC MT53.3  CIPAC MT 171.1	100% Ca(OH) <sub>2</sub>	Test	Initial	3months	9months	12months		account as it is 100% of Ca(OH) <sub>2</sub> (same composition than Eula product).  Suspensibility is low as the active substance (Ca(OH) <sub>2</sub> ) is not miscible in water. Nevertheless, as the product is diluted in water at high concentration (50%w/v) to form a sludge, it is considered acceptable for this kind of product.
			Suspensibility (20%w/v)	18%	10%	10%	8%		
			Wettability	30sec	27sec	21sec	28sec		
			Dustiness	118 Dusty	147 Dusty	140 Dusty	64 Dusty		
	Norm EN 459-2  CIPAC MT31	WKH, 100% Ca(OH) <sub>2</sub>		Initial	After 15months in big-bags		2020, WA-Nr.: 161-2-k2/20*	Acceptable The tested product is not an Eula product but the results can be taken into account as it is 100% of Ca(OH) <sub>2</sub> (same composition than Eula product).  The particle size shows that no aggregation is	
			Mean content (%w/w)						
			Ca(OH) <sub>2</sub>	93.2	3.3	6.5			
			CO <sub>2</sub>	1.42	0.5	0.5			
			MgO	12.6	0.26% NaOH	0.25% NaOH			
			pH	12.6	12.5				
			Alkalinity	0.26% NaOH	0.25% NaOH				
			Particle size	D10: 1.5µm	D10: 1.6µm	D10: 1.6µm			
				D50: 8.6µm	D50: 9.1µm	D50: 9.1µm			
				D90: 26µm	D90: 29µm	D90: 29µm			
				D100: 86µm	D100: 86µm	D100: 86µm			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
					observed during storage. Moreover, the content of active substance as other forms is stable.
Effects on content of the active substance and technical characteristics of the biocidal product - <b>light</b>	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 of the biocidal product - <b>temperature and humidity</b>	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 (decomposition at 450°C according to the CAR).		In view of the nature of the biocidal product/active substance, effects of temperature and humidity on content of the active substance and technical characteristics of the biocidal product should be follow as the humidity as an impact on the active substance. A mitigation sentence <b>'protect from</b>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
					<b>humidity'</b> is added on the label to avoid agglomerates.
Effects on content of the active substance and technical characteristics of the biocidal product - <b>reactivity towards container material</b>	No Guideline followed	Ca(OH) <sub>2</sub>	<p>No significant difference in the packaging (bags) was noted after 24 weeks of storage (extrapolated to 26weeks which correspond to 6 months).</p> <p>The corrosion study indicates that aluminium and stainless steel packaging is suitable for transport and storage of the product.</p> <p>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.</p> <p>Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime based products (e.g. milk of lime)</p> <p>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.</p>	AS Dossier: Doc. No.: 245-001; CB3.7/01	<p>Product is stored in paper bags (with PP or PE inner layer). Therefore, packaging is suitable but to avoid the formation of agglomerates, the product should be <b>protect from humidity</b>.</p> <p>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.</p> <p>Therefore as the product is sell as a solid product, no reactivity towards the contained material is expected.</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
Wettability	Waiver		Not applicable		
Suspensibility, spontaneity and dispersion stability	Waiver		Not applicable		
Wet sieve analysis and dry sieve test	EN 459-1 Particle size $\geq 2$ mm shall be determined by dry sieving in accordance with EN 459-2:2010, 6.1 and particle size $< 2$ mm by air-jet	$\text{Ca(OH)}_2 \geq 80\%$ (active substance Reference Specification)	<p>The product conforms to the requirement of EN 459 -1 in that residues of <math>\leq 2\%</math> by mass must be greater than 0.2 mm in size and <math>\leq 7\%</math> must be greater than 0,09 mm in size.</p> <p>The products are defined as being very dusty powders.</p> <p>The dry product is a fine powder that is insoluble in water. Dry sieve tests show that the majority of the particles are <math>&lt; 0.09</math> mm. The products are mixed with water to form a slurry. When using the milk of lime for painting of walls, the liquid is mixed to a smooth consistency to ensure even coverage. The product has been shown not to form lumps during 24 weeks of storage in paper bags. Any lumps that may form on addition to water will be mixed out before use. As the product does not dissolve once the water evaporates the fine particles will remain on the wall. A wet sieve test is therefore scientifically unnecessary as the particle size has already been determined in the dry sieve tests.</p> <p>For information, a raw wet sieve test according to EN 12518 (no official study) was provided on the product BIOCALCO M50 (corresponding to 50% of active substance in water): 1.5%w/w of dry matter was retained on a 90<math>\mu\text{m}</math> sieve.</p>	EN 459-1 Anon; PSD/laser diffraction data (2017)	Accepted in AS dossier Justification is accepted. The norm EN-459-1 precise that the hydrated lime particle size is $< 90\mu\text{m}$ .

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments	
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 $\geq 2$ 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.	Ca(OH) <sub>2</sub> $\geq$ 80% (active substance Reference Specification)	The product conforms to the requirement of EN 459 -1 in that residues of $\leq 2\%$ by mass must be greater than 0.2 mm in size and $\leq 7\%$ must be greater 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 Anon; PSD/laser diffraction data (2017)	Accepted in AS dossier.	
	Sartorius Model MA40, electronic moisture analyser	Calcium Dihydroxide Hydra Lime 23 Batch number BE1121.6.1				Acceptable, the particle size of the product is under 63 $\mu$ m.
			Particle size distribution ( $\mu$ m)			
			D10	0.73		
			D50	3.2		
		D90	8.3			
		Moisture	0.68%			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
Flowability/Pourability/Dustability	EN 459-1 Particle size $\geq 2$ 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.	$\text{Ca(OH)}_2 \geq 80\%$ (active substance Reference Specification)	The product conforms to the requirement of EN 459 -1 in that residues of $\leq 2\%$ by mass must be greater than 0.2 mm in size and $\leq 7\%$ must be greater than 0.09 mm in size. The products are defined as being very dusty powders.	EN 459-1 PSD/laser diffraction data (2017)	Accepted in AS dossier.
Burning rate — smoke generators			Not relevant for DP nor WP products		
Burning completeness — smoke generators			Not relevant for DP nor WP products		
Composition of smoke — smoke generators			Not relevant for DP nor WP products		
Spraying pattern — aerosols			Not relevant for DP nor WP products		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	Comments
Physical compatibility	Waiver		According to long-time experience, Hydrated lime (and consequently the Hydrated 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			Not relevant		See storage study Moreover, the product is not expected to be mixing with another product.
Degree of dissolution and dilution stability	Waiver		Not applicable		
Surface tension			Not applicable to solids		
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. ██████████ Biogenius Report no Mo6493. 2021-05-27
- Test report WA no.: 161-1/20. ██████████ IKM Institut für Kalk- und Mörtelforschung e.V. Annastr. 67-71 29-11-2020
- Test report WA no.: 161-2-k2/20. ██████████ 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 (tested products are 100% of active substance).

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

The product is an off-white powdery solid of naturally occurring origin The dusts are within the inhalable/respirable range. Based on the storage stability study provided, the product when stored at room temperature and away from moisture can be considered stable for a period of 15 months. For the use - Disinfection of animal accommodations; limewashing of walls-, the product is diluted in water at 50% w/v. According to guidance on the Biocidal products regulation Vol I, suspensibility, persistent foaming and wet sieve test should be provided.

However, the product is a milk lime, similar to a sludge. The diluted product is therefore very viscous and performance of the tests seems to be limited.


Moreover, viewing the application use (product is applied by brushing and rests 12h to finish as a solid coat on the wall) the required tests are not relevant and no other data is required. A mitigation measure is nevertheless established: "stir before and during the application".

**Implication for the labelling:** Protect from humidity  
Shelf-life: 15 months  
Do not store above 30°C  
Stir before and during application (for the use limewashing of walls only)


### 2.2.3 Physical hazards and respective characteristics


Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Comment
Explosives	Waiver		Not explosive According to the CLP regulation, "A substance or mixture is not classified as explosive when there are no chemical groups associated with explosive properties present in the molecule". As Ca-(OH) <sub>2</sub> is not considered is not a chemical group having explosive properties, the product is not considered classified.	AS dossier IIIA 3.15	Acceptable Not explosive product according to CLP regulation
	Waiver based on composition	Calcium dihydroxide Ca(OH) <sub>2</sub> Batch BE1110.144.3	There are no chemical groups within the structure that would imply explosive properties according to the manual of recommendation on Transport of dangerous goods.	██████████ 2010 Project number 2937/0006	
Flammable solids	Waiver		According to CLP regulation, "For inorganic material, testing may be waived in cases where the substance is commonly known to	AS dossier IIIA 3.11	Acceptable



Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Comment
			<p><i>be not flammable (i.e. stable salts or metal oxides) or where a flammability hazard can be excluded by any other scientific reasoning."</i></p> <p>As Ca-(OH)<sub>2</sub> is a metal dihydroxide totally inert, the product is not considered having flammable properties.</p>		Not flammable according to CLP regulation
	EEC A10 (Test N.1)	Calcium dihydroxide Ca(OH) <sub>2</sub> Batch BE1110.144.3	The substance does not ignite within the 2min screening test.	 2010 Project number 2937/0006	
Self-reactive substances and mixtures	Waiver		<p>The melting point is &gt; 2500 °C. Therefore it can be excluded that Ca(OH)<sub>2</sub> is instable at high temperatures.</p> <p>Ca(OH)<sub>2</sub> is produced from CaO, itself produced from limestone (CaCO<sub>3</sub>) at 900 – 1300 °C. It can be concluded that Ca(OH)<sub>2</sub> is stable at least at this temperature range and that SADT test would not show an exothermic peak.</p> <p>Therefore, the substance is not considered having self-reactive nor self-heating properties.</p>	AS dossier	Acceptable Not self-reactive according to CLP regulation
Pyrophoric liquids	Waiver		Not relevant		
Pyrophoric solids	Waiver		<p>In Ca(OH)<sub>2</sub>, Calcium and Oxygen are in their respective preferred oxidation state.</p> <p>The active substance and hence the products are not pyrophoric.</p> <p>Moreover, the substance is not known having pyrophoric properties as Ca(OH)<sub>2</sub> is produced from CaO, itself produced from limestone (CaCO<sub>3</sub>) at 900 – 1300 °C. It can</p>	AS dossier	Acceptable and accepted in AS Dossier

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Comment									
			be concluded that Ca(OH) <sub>2</sub> is stable at least at this temperature range.											
Self-heating substances and mixtures	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that Ca(OH) <sub>2</sub> is instable at high temperatures. Ca(OH) <sub>2</sub> is produced from CaO, itself produced from limestone (CaCO <sub>3</sub> ) at 900 – 1300 °C. It can be concluded that Ca(OH) <sub>2</sub> 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	Acceptable Not self-heating according to CLP regulation									
	UN Test N.4	Calcium Dihydroxide Hydra Lime 23 Batch number BE1121.6.1	After 24h in an "Fan Assisted" oven at an isothermical temperature of 140°C, the sample does not self-heat more than 140°C. <table border="1"> <thead> <tr> <th>Basket Size (mm cube)</th> <th>Test Temperature (°C)</th> <th>Test System</th> <th>Test Item Weight (g)</th> <th>Ignition Yes / No</th> </tr> </thead> <tbody> <tr> <td>100</td> <td>140</td> <td>9</td> <td>501.2</td> <td>No</td> </tr> </tbody> </table>	Basket Size (mm cube)	Test Temperature (°C)	Test System	Test Item Weight (g)	Ignition Yes / No	100	140	9	501.2	No	<div style="background-color: black; width: 100px; height: 20px; margin-bottom: 5px;"></div> Report N° S3016011300R 1/2022
Basket Size (mm cube)	Test Temperature (°C)	Test System	Test Item Weight (g)	Ignition Yes / No										
100	140	9	501.2	No										
Substances and mixtures which in contact with water emit flammable gases	Waiver		In contact with water, the active substance and hence the products will not emit flammable gases. Ca(OH) <sub>2</sub> is made from calcium oxide and is already hydrated and inert.	AS dossier	Acceptable									
Oxidising solids	Waiver		Not oxidising According to the CLP regulation, " <i>Before submitting a substance or a mixture to the full test procedure, an evaluation of its chemical structure may be very useful as it</i>	AS dossier IIIA 3.16	Acceptable according to CLP regulation									

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Comment
			<p><i>may prevent unnecessary testing. The following text provides a guideline for the theoretical evaluation of potential oxidising properties on the basis of its composition and chemical structure."</i></p> <p>Moreover, "in cases where an examination of structural formula establishes beyond reasonable doubt that the active ingredient is incapable of reacting exothermically with combustible material, it is acceptable to provide such information as justification for the non-determining of oxidising properties."There is no chemical evidence to assume oxidising properties for Ca(OH)<sub>2</sub> because in Ca(OH)<sub>2</sub>, Calcium and Oxygen are in their respective preferred oxidation state and Ca(OH)<sub>2</sub> is an inert material.</p>		
	Waiver based on composition	Calcium dihydroxide Ca(OH) <sub>2</sub> Batch BE1110.144.3	The substance is inorganic and does not contain halogens.	 2010 Project number 2937/0006	
Organic peroxides			Not applicable		
Corrosive to metals	waiver		Not required		The test is not required for solid product.
Auto-ignition temperatures of products	Waiver		Not applicable		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Comment
(liquids and gases)					
Relative self-ignition temperature for solids	Waiver		The melting point is > 2500 °C. Therefore it can be excluded that Ca(OH) <sub>2</sub> is instable at high temperatures. Ca(OH) <sub>2</sub> is produced from CaO, itself produced from limestone (CaCO <sub>3</sub> ) at 900 – 1300 °C. It can be concluded that Ca(OH) <sub>2</sub> is stable at least at this temperature range and that SADT test would not show an exothermic peak. Therefore, the substance is not considered having self-ignition properties. Moreover, the substance/product is not flammable.	AS dossier	Acceptable
	EEC A16	Calcium dihydroxide Ca(OH) <sub>2</sub> Batch BE1110.144.3	No self-ignition point below 400°C	 2010 Project number 2937/0006	
Dust explosion hazard	Waiver		In Ca(OH) <sub>2</sub> , Calcium and Oxygen are in their respective preferred oxidation state and is not explosive as the substance is not combustible or flammable. In addition, the absence of a dust explosion hazard is supported by the use of inert limestone dust to prevent dust explosions in coal mining.	AS dossier	Acceptable

### Conclusion on the physical hazards and respective characteristics of the product

The product is not classified for other physical hazard properties.

### 2.2.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Active substance (CaO, MgO)	Gravimetric, Volumetric, EDTA, Pyrophosphate, Insoluble matter	N/A	N/A	N/A	See Table below			N/A	ASTM C25-99 (1999)
Active substance (Na, Mg)	X-ray spectrometric analysis  Ca as % CaO       Mg as % MgO	5							ASTM C1271-99 (1999)
					53,347 53,683 54,304 55,599 55,837		0,28 % 0,30 % 0,23 % 0,20 % 0,26 %		
					0,176 0,216 0,637 0,919 1,406		8,52 % 2,78 % 1,10 % 1,09 % 3,49 %		
Active substance (calcium, magnesium,	ICP AA	Duplicate							ASTM CC 1301 – 95 (1995)

<i>oxide and hydroxide)</i>									(Reapproved 2001)
<i>Active substance</i>	Titration		N/A	Reproducibility: 12.64%			2.30		EN12945
<i>Active substance</i>	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 are 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 are 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<sup>2+</sup> and Mg<sup>2+</sup> 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<sup>++</sup>, Mg<sup>++</sup>, K<sup>+</sup> and Na<sup>+</sup> cations – Agitation method".

However, given that these ions occur naturally in soil and hydrated lime is commonly used for agricultural liming it would not be possible to determine the source of these ions as being from biocidal use. In addition, the biocidal use of hydrated lime allows for

application of the treated sewage or manure to agricultural land (as a replacement for agricultural liming). Given this, the normal requirement for more detailed analysis of the active/residues in soil is 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		
<i>Active substance</i>	Ion chromatography	0.01 mg to 5 mg		No differentiation between the hydroxides and salts detectable by this method.					ISO 17091:2013

#### Analytical methods for water

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

#### Analytical methods for animal and human body fluids and tissues

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

#### Analytical methods for monitoring of active substances and residues in food and feeding stuff

Any analysis for the active/residues in food/feedstuffs would not be able to establish the origin of the ions as being naturally occurring, from liming or following use as a biocide. Established standard methods for the determination of Hydrated lime components ( $Mg^{2+}$  and  $Ca^{2+}$ ) in animal feeding stuffs are described in the following standards;

DIN EN (Deutsche Norm; Entwurf) 15505 "Foodstuffs – Determination of trace elements – Determination of sodium, magnesium and calcium by flame atomic absorption spectrometry (AAS) after microwave digestion; German version prEN 15505:2006",

DIN EN (Deutsche Norm; Entwurf) 15510 "Animal feeding stuffs – Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES; German version prEN 15510:2006",

Given the uses of hydrated lime on agricultural land & the nature of the active/residues the requirement for more detailed analysis of the active/residues in food or feedstuffs would seem unnecessary.

#### **Conclusion on the methods for detection and identification of the product**

The analytical methods for the active substance are applicable to the products.

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



## 2.2.5 Efficacy against target organisms

### 2.2.5.1 Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algacides not intended for direct application to humans or animals

PT3: Veterinary hygiene

The biocidal product EULA HYDRA-LIME 23 is a dustable power, intended for use in the disinfection of sludge prior to spreading on the land or prior incineration (PT2), and applied on hard surfaces, bedding materials, 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 bedding materials, manure and sewage sludge, this will likely be directly into the substrate.

The product is for professional users only.

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

Disinfectant product 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 (yeastocidal 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 Calcium dihydroxide are known:

1) Increased alkalinity - Addition of sufficient quantities of Lime to organic waste brings about a rapid and sustained increase in pH, to a level > 12. The high concentration of free OH<sup>-</sup> 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<sub>3</sub>) - 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<sub>4</sub><sup>+</sup>) into free / non-ionised ammonia gas (NH<sub>3</sub>). Ammonia gas diffuses into bacterial cells, altering

chemical equilibrium between intra-and extra-cellular environments, and impeding essential enzymatic function to bring about cell death. Free non-ionised ammonia has also been shown to be destructive to viruses. However, only in closed systems, in which loss of gaseous ammonia is prevented, can concentrations relevant for a synergistic effect with high pH be reached.

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

#### 2.2.5.5 Efficacy data

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

Both active substance and products may be referred to as "Lime". Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime (Ca(OH)<sub>2</sub>). The raw material for all lime-based products is limestone, which is composed almost exclusively of calcium carbonate (CaCO<sub>3</sub>).

- Calcium oxide (CaO) is also known as burnt lime or quicklime, obtained from the calcination (removal of CO<sub>2</sub>) above 900°C of limestone.
- Calcium dihydroxide (Ca(OH)<sub>2</sub>) is also known as hydrated lime or slaked lime, obtained from the hydration (addition of water) of quick lime.

Calcium oxide produces calcium dihydroxide in contact with water.

Effect of calcium oxide is due to both to pH and heat increase (release of heat as a result of hydration of calcium oxide) and only pH increase for calcium hydroxide. Therefore efficacy results obtained with calcium oxide have been taken into account for calcium hydroxide in the studies where the temperature rise associated with the hydration of quicklime is limited.

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

##### ➤ **Use # 1 – Disinfection of sewage sludge (PT2)**

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

First, sewage substrate was combined, with a range of inocula (*Salmonella*, *Streptococci*, *E.coli*, *Clostridium perfringens*, Bovine parvovirus, ECBO and *Ascaris suum*) and the biocidal product (study 6.7-01). The product test tested is Burnt lime but as low temperatures are also involved in this study, efficacy results can be used for Hydrated lime.

Temperature and pH were measured over time, the amount of lime required was calculated as a percentage of the dry content of the sewage sludge.

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

=>pH above 12 is needed and contact time needed to obtain a sufficient efficacy decreased with a rise in temperature.

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

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

Regarding virus, for the disinfection of sewage sludge, the 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 dihydroxide (pH=12.59). For calcium oxide, temperature measured is 60° and 70°C, and for calcium hydroxide, the liquid manure is heated at 60°C for the *Ascaris suum* testing.

For calcium hydroxide, in liquid pig and cattle manure:

- For bacteria, more than 7 log reduction are observed for a contact time of 72H without heating;
- For virus, more than 5 log reduction are observed for a contact time of 72H without heating;
- For *Ascaris suum* eggs, 100 % inhibition of development are obtained for a contact time of 60 minutes, at the temperature of 60 °C.

A second simulated-use test (6.7-13) has been carried out only on liquid manure (pig and cattle manure), treated with calcium dihydroxide against *Ascaris suum* eggs (pH obtained is higher than 12, no heating applied). For endoparasites: helminth eggs (*Ascaris suum*), respectively 100 % inhibition of development are obtained for pig manure and 98% for cattle manure, with a contact time of 90 days (pH measured is higher than 12, liquid manure not heated)

Based on these studies, it can be concluded, that:

- Calcium dihydroxide, at a pH > 12, is efficient against bacteria and virus, for a contact time of 72 hours and against *Ascaris suum* eggs after 90 days in liquid pig and cattle manures.

Since liquid manure differs only from solid manure with the content of water, similar efficacy of calcium hydroxyde is expected in solid manure.

Based on these efficacy data, the efficacy of calcium dihydroxide is demonstrated for the disinfection of manure, against bacteria, virus, and helminth eggs. Effective treatment is due to the raised pH (>12), that should be maintained during the contact time needed with regard to the situation.

It should be noticed that as no effect of temperature is expected for Calcium dihydroxide, contact time is longer than the one with calcium oxide.

No data has been provided for yeast and fungi.

From the efficacy study, the quantity of lime to be applied should be enough to reach a pH>12 in all the cases. Two recommendations are presented by the applicant, one for routine application (10 kg lime/m<sup>3</sup> of manure) and one in case of outbreak (100 kg lime/m<sup>3</sup> of manure). Since application rate should be adapted to the type of manure in order to achieve a pH>12, the SPC should only specify that 100 kg lime/m<sup>3</sup> of manure should not be exceeded whatever the circumstances of manure treatment.

➤ **Use # 4 – Disinfection of bedding materials (PT3)**

No specific study has been submitted by the applicant for this use. A read across with manure treatment studies has been proposed.

At EFF WG-I-2022, in relation with the distribution properties, the availability of water for the reaction of lime in the matrix that could differ from manure, the EFF WG concluded the demonstration of the efficacy based on the read across with manure studies was not acceptable. The efficacy of this use is then not supported by the efficacy data presented in the dossier

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

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference																																													
Disinfectant for sewage sludge	PT2 – Use 1	Burnt Lime specified according to the "Building Lime Standard" EN 459-1 as "CL 90". Calcium Oxide content was 93.7%. The reactivity was defined as T60 = 2.5 minutes and Tmax = 73°C. Mean density was 0.95kg/L.	<p><u>Bacteria</u> (<math>2,3.10^3 - 23.10^6</math> CFU/g)</p> <p><i>Salmonella senftenberg</i> (<i>H<sub>2</sub>S positive DSM 10062 SIT 100, H<sub>2</sub>S negative DSM 10062 SIT 112</i>), <i>Streptococci</i>, <i>Clostridium perfringens DSM 765</i>, <i>E.coli DSM 498</i></p> <p><u>Virus</u> (<math>2,3.10^5 - 6,16.10^6</math> TID50 / ml) <i>Bovine parvovirus</i>, <i>ECBO</i></p> <p><u>Nematodes</u> <i>Ascaris suum</i> eggs</p> <p>Culture collection, except <i>Ascaris</i> eggs source unknown</p>	<p>Simulated study</p> <p>Direct mixing of sewage sludge with the biocidal product</p> <p>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).</p> <p>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 <i>Ascaris</i> eggs.</p> <p>For the industrial scale test, the mix was pumped and piled for storage. Samples were taken from the stored material at intervals, to determine the numbers of viable bacteria, viruses or <i>Ascaris</i> eggs.</p>	<p>0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solids</p> <p>Contact time: 1-24 hours, until 8 weeks for <i>Ascaris suum</i></p> <p>temperatures and pH values were recorded over the time</p>	<p>0.9 – 1.1 kg burnt lime / kg dried sludge</p> <p>Small scale test : pH&gt;12.9</p> <table border="1"> <thead> <tr> <th>Substrate</th> <th>Virus</th> <th>Bacteria</th> <th>Worm eggs</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Sewage sludge (22% dry matter)</td> <td>not tested</td> <td>pH &gt; 12.9 T<sub>max</sub>: 26°C</td> <td>24 hours pH &gt; 12.9 T<sub>max</sub>: 17°C</td> </tr> <tr> <td>AR: 0.9 T<sub>max</sub>: 57°C</td> <td>&gt; 10 hours pH &gt; 12.9 T<sub>max</sub>: 57°C</td> <td>0.5 hours pH &gt; 12.9 T<sub>max</sub>: 57°C</td> </tr> <tr> <td>AR: 1.1 T<sub>max</sub>: 71°C</td> <td>2 hours pH &gt; 12.9 T<sub>max</sub>: 71°C</td> <td>0.5 hours pH &gt; 12.9 T<sub>max</sub>: 71°C</td> </tr> <tr> <td rowspan="4">Paunch contents (16% or 28% dry matter)</td> <td>AR: 1.25 T<sub>max</sub>: 35°C</td> <td>&gt;24 hours AR: 0.2 T<sub>max</sub>: 22°C</td> <td>24 hours AR: 1.25 T<sub>max</sub>: 35°C</td> </tr> <tr> <td>AR: 1.56 T<sub>max</sub>: 55°C</td> <td>&gt;24 hours AR: 0.3 T<sub>max</sub>: 22°C</td> <td>1 hour AR: 1.56 T<sub>max</sub>: 55°C</td> </tr> <tr> <td>AR: 0.7 T<sub>max</sub>: 64°C</td> <td>&gt; 10 hours AR: 0.6 T<sub>max</sub>: 22°C</td> <td>1 hour AR: 0.7 T<sub>max</sub>: 64°C</td> </tr> <tr> <td>AR: 0.9 T<sub>max</sub>: 74°C</td> <td>5 hours AR: 1.25 T<sub>max</sub>: 35°C</td> <td>&lt; 1 hour AR: 0.9 T<sub>max</sub>: 74°C</td> </tr> </tbody> </table> <p>Industrial scale test:</p> <table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </table> <p>Efficacy criteria achieved: 5 log reduction bacteria 4 log reduction viruses 3 log reduction nematode eggs</p>	Substrate	Virus	Bacteria	Worm eggs	Sewage sludge (22% dry matter)	not tested	pH > 12.9 T <sub>max</sub> : 26°C	24 hours pH > 12.9 T <sub>max</sub> : 17°C	AR: 0.9 T <sub>max</sub> : 57°C	> 10 hours pH > 12.9 T <sub>max</sub> : 57°C	0.5 hours pH > 12.9 T <sub>max</sub> : 57°C	AR: 1.1 T <sub>max</sub> : 71°C	2 hours pH > 12.9 T <sub>max</sub> : 71°C	0.5 hours pH > 12.9 T <sub>max</sub> : 71°C	Paunch contents (16% or 28% dry matter)	AR: 1.25 T <sub>max</sub> : 35°C	>24 hours AR: 0.2 T <sub>max</sub> : 22°C	24 hours AR: 1.25 T <sub>max</sub> : 35°C	AR: 1.56 T <sub>max</sub> : 55°C	>24 hours AR: 0.3 T <sub>max</sub> : 22°C	1 hour AR: 1.56 T <sub>max</sub> : 55°C	AR: 0.7 T <sub>max</sub> : 64°C	> 10 hours AR: 0.6 T <sub>max</sub> : 22°C	1 hour AR: 0.7 T <sub>max</sub> : 64°C	AR: 0.9 T <sub>max</sub> : 74°C	5 hours AR: 1.25 T <sub>max</sub> : 35°C	< 1 hour AR: 0.9 T <sub>max</sub> : 74°C	Application rate (kg Lime / kg dry matter in substrate)	Temperature (°C)	Ascaris eggs	BPV	Salmonella senftenberg	Streptococci	0.9	50-55	0.5 hours	24 hours	0.25 hours	0.5 hours	1.0-1.1	65-75	0.25 hours	0.5-2 hours	0.25 hours	0.25 hours	6.7-01
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Disinfectant for sewage sludge	PT2 – Use 1	Milk of lime (Ca(OH) <sub>2</sub> suspension in water Dry hydrated lime (Ca(OH) <sub>2</sub> Burnt lime (CaO)	<p><u>Nematodes</u> <i>Ascaris suum</i> eggs (Sludge from pig slaughter houses)</p> <p>Sludge A: 924 ± 295 eggs per 10 g solid</p> <p>Total solids: 33%</p>	<p>Simulated-use tests:</p> <p>1), Artificially contaminated milk of lime was heated to 50°C, 55°C and 60°C.</p> <p>2) Naturally contaminated sewage sludges were treated with slaked lime (40% weight slaked lime</p>	Contact time : 5-160 minutes pH ≥ 12	<p>Inactivation threshold: duration required to reach a level of inactivation at which no viable egg was detected per g of solid sludge (TS)</p> <p>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</p>	6.7-02																																													

			<p>Sludge B 132 ± 108 eggs per 10 g solid Total solids: 15%</p>	<p>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 temperature was reached, bags containing Ascaris eggs were inserted in it.</p>		<p>- 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)</p> <p>=&gt; 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</p>	
Disinfectant for sewage sludge	PT2 – use 1	Calcium dihydroxide (10% Ca(OH) <sub>2</sub> in water: milk of lime)	<p><u>Bacteria</u> <i>Salmonella senftenberg</i> (10<sup>8</sup> CFU/mL) Coliforms (10<sup>6</sup> CFU/mL)</p>	<p>Simulated tests  Direct mixing of sewage sludge with the biocidal product</p>	<p>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.</p>	<p>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.</p>	6.7-03 RI=2

					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.		
Disinfectant for manure and litter, bedding materials	PT3 – Use 2	Calcium dihydroxide (liquid manure)  Calcium oxide (solid manure)  (EuLA specifications)	<u>Bacteria</u> (lab collection) <i>Salmonella senftenberg 775W</i> (H2S negative) <i>Enterococcus faecium</i> For each bacteria: 5.10 <sup>8</sup> CFU/ml,  <u>Virus</u> <i>Bovine Parvovirus</i> The virus host cells were MDCK cells  <u>Nematodes</u> <i>Ascaris suum</i> 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 <i>A. suum</i> 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) <sub>2</sub> ) at 72H and 96H contact time: Virus: > 5 log reduction Bacteria: > 7 log reduction <i>Ascaris suum</i> 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 <i>Ascaris suum</i> eggs: 100% development inhibition	6.7-06  RI=2
Disinfectant for manure	PT3 – Use 2	Calcium dihydroxide (EuLA specification)	Nematodes <i>Ascaris suum</i> eggs (recovered from adult female worms) 2 ml egg suspension in gaze-bags (200000 eggs)	Simulated test Direct mixing of manure with the biocidal product  Stockpiled lime treated manure and contaminated with gaze-bags of eggs  At the end of the trial the treated aliquots were compared to untreated	Liquid manure: Contact time: 30/60/90 days	Contact time: 90 days  liquid pig manure: 100 % development inhibition liquid cattle manure: 98 % development inhibition	6.7-13  RI = 2



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			(unlimed) controls and log reduction calculated			
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➤ **Uses 3/5/ 6 surface disinfection (PT3)**

For PT3 uses (disinfection of indoor floor surfaces of animal accommodations and transportation, animal accommodations (limewashing of walls), and of floors of outdoor animal enclosures), both phase 2 steps 1 and 2 tests should be normally submitted according to Vol II part B/C efficacy guidance.

Nevertheless, for efficacy testing of veterinary hard surfaces, the tiered approach was not suitable for lime and should be adapted in order to demonstrate the efficacy of the products used in the form of a powder or a thick milk applied to a surface.

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

- ✓ Laboratory suspension tests (phase 2, step 1 tests) have been withdrawn, as not 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 dihydroxide-based product at the application rate of 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.
  - ⇒ Bactericidal activity is not demonstrated on porous surfaces, according to EN 16437, at 10 °C, with a contact time of 60 min, in clean conditions (3 g/L BSA), with Calcium dihydroxide-based product at the application rate of 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.

Under EN standard conditions, the product shows only limited performance at the application ratios tested, due to the small surface area treated and the large amount of product and water to be applied. It has been agreed that the EN tests protocols are not valid for this type of product due to the application method, the insolubility of the product and the mode of action.

In order to 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, 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 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.  
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 the application rate of 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.
- ⇒ 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), used as ready to use, at the application rate of 800 g Ca(OH)<sub>2</sub>/m<sup>2</sup>.

To complete results from laboratory and simulated-use tests, field studies 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 treatment 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 / m<sup>2</sup> of floor (2018) and 600 g CaO / m<sup>2</sup> (2019).

Both studies were conducted into two phases:

The first phase consisted in identifying and quantifying the pathogens present in the breeding with the current practices of vacuum-sanitary, in order to evaluate existing pathogenic pressure.

The second phase consisted in evaluating the effectiveness of CaO under real conditions of disinfectant treatment 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/m<sup>2</sup> 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 / m<sup>2</sup> of floor. The floor is moistened with a water pressure washer before treatment. For the sake

of similarity between "control" and "treated" housing, the "witness" housing were also sprayed with a water pressure washer.

Microorganisms monitored during these studies are: aerobic microorganisms at 30°C, *Escherichia coli* B glucuronidase positive at 44 °C, spores of *Clostridium perfringens*, intestinal enterococci, enterobacteria presumed at 30 ° C, *Pseudomonas sp.*, yeasts and moulds, and *Aspergillus sp.*

=>As a result, a slight mortality of microorganisms in untreated area due to the cleaning the water pressure washer was noticed. In the treated surfaces, a reduction of the order or more than 2/3 logs is obtained for aerobic microorganisms, *Pseudomonas sp.*, yeast and moulds. Abatement is less for other microorganisms since populations in untreated areas are present in small quantities (*E. coli*, *Clostridium perfringens*, intestinal enterococci). The applied dose of 600 g/m<sup>2</sup> gives similar results to 800 g/m<sup>2</sup>.

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

These field studies have been conducted on concrete floors. Treatment of beaten-earth floors have been also claimed and the applicant points out that both types of surface are in effect largely semi-porous structures and arguable very similar. This one is shown in a thesis of the Sheffield Hallam University<sup>2</sup> 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.

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<sup>2</sup> <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
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Proteus vulgaris</i> ATCC 13315	EN 14349 modified  Test coupons: 3.14 cm <sup>2</sup> with 251 mg of powder applied To obtain an application rate: equivalent to 800 g/m <sup>2</sup> product mixed with 2000 ml/m <sup>2</sup> water	3 g/L BSA)  T°C : 10°C TC : 30 min  800 g/m <sup>2</sup>	Pass >4 log reduction	6.7-09 RI = 2
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Proteus vulgaris</i> ATCC 13315	EN 14349 modified  Test coupons: 3.14 cm <sup>2</sup> with 251 mg of powder applied to obtain an application rate: equivalent to 800 g/m <sup>2</sup> product mixed with 2000 ml/m <sup>2</sup> water	Dirty conditions (10 g/L BSA + 10 g/L yeast extract)  T°C : 10°C TC : 30 min  800 g/m <sup>2</sup>	Fail >4 log reduction sur <i>P.aeruginosa</i> , <i>E.hirae</i> and <i>P.vulgaris</i>  <4 log reduction sur <i>S.aureus</i>	6.7-10 RI = 3
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Proteus vulgaris</i> ATCC 13315	EN 16437 modified  Test coupons: 2 cm <sup>2</sup> with 160 mg of powder applied to obtain an application rate: equivalent to 800 g/m <sup>2</sup> product mixed with 2000 ml/m <sup>2</sup> water	3 g/L BSA)  T°C : 10°C TC : 60 min  800 g/m <sup>2</sup>	FAIL <i>P.aeruginosa</i> and <i>P.vulgaris</i> =>4log reduction  <i>S.aureus</i> and <i>E. hirae</i> <4log reduction	6.7-12 RI = 3
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<i>Enterococcus hirae</i> CIP 58.55 <i>Pseudomonas aeruginosa</i> DSM 939 <i>Staphylococcus aureus</i> DSM 799  <i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> ATCC 16404	Simulated test The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms.	Dirty conditions (10 g/L BSA + 10 g/L yeast extract)  T°C : 15-22°C  Contact time: 2h <i>Pseudomonas aeruginosa</i> <i>Candida albicans</i>  Contact time: 24 h Remaining organisms	Calcium Hydroxide  PASS Bactericidal (> 4 log reduction): <i>Pseudomonas aeruginosa</i> 2 hours contact time	6.7-15 RE-1143/0419 RI = 2

			<p>Strains have been chosen in accordance with those used in the standard EN tests: EN16437, EN16438</p> <p>Test suspensions prepared in accordance with NF T 72-281</p>	<p>The organisms are placed on carriers (mosaic tiles) and air-dried.</p> <p>The tiles are placed in the test room and 0.25 L/m<sup>2</sup> water added (no pressure);</p> <p>The test material was applied and another aliquot of water as above to give total water of 0.5L/m<sup>2</sup></p> <p>Survivors counted in accordance with NF T-72-281</p> <p>Log reduction calculated by comparison between test carriers and control carriers</p> <p>Efficacy criteria: Bacteria 3 log reduction Yeasts/fungi: 3 log reduction</p>	<p>Test material: Ca(OH)<sub>2</sub>: 800g/m<sup>2</sup></p>	<p>PASS Bactericidal (&gt; 4 log reduction): <i>Enterococcus hirae</i> <i>Stapylococcus aureus</i> 24 hours contact time</p> <p>PASS Yeasticidal (&gt; 3 log reduction): <i>Candida albicans</i> 2 hours contact time</p> <p>FAIL: Not Fungicidal (&lt;1 log reduction) <i>Aspergillus brasiliensis</i></p>	
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<p><i>Aspergillus brasiliensis</i> DSM 1988</p> <p>Strain has been chosen in accordance with those used in the standard EN test: EN16438</p>	<p>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.</p> <p>The organisms are placed on carriers (ceramic tiles) and air-dried.</p> <p>The tiles are placed in the test room and 0.25 L/m<sup>2</sup> water added (no pressure);</p>	<p>Clean conditions (3 g/L BSA)</p> <p>T°C : 15-22°C</p> <p>Contact time: 24h <i>Aspergillus brasiliensis</i></p> <p>Test suspensions prepared in accordance with NF T 72-281</p> <p>Test material: Ca(OH)<sub>2</sub>: 800 g/m<sup>2</sup></p>	<p>PASS Fungicidal (&gt;3 log reduction)</p>	<p>6.7-15A RE-1303/0919/A RI = 2</p>

				<p>The test material was applied and another aliquot of water as above to give total water of 0.5L/m<sup>2</sup></p> <p>Survivors counted in accordance with NF T-72-281</p> <p>Log reduction calculated by comparison between test carriers and control carriers</p> <p>Veterinary LowLevel Soil conditions (3.0 g/L bovine albumin)</p> <p>Efficacy criteria: Fungi: 3 log reduction</p>			
Surface disinfectant	PT3- Uses 3/4/5	Calcium dihydroxide	<p>Porcine parvovirus</p> <p>Strain has been chosen in accordance with those used in the standard EN test: prEN17122.</p>	<p>Simulated test</p> <p>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.</p> <p>The organisms are placed on carriers (ceramic tiles) and air-dried.</p> <p>The tiles are placed in the test room and 0.25L/m<sup>2</sup> water added (no pressure);</p> <p>The test material was applied and another aliquot of water as above to give total water of 0.5L/m<sup>2</sup></p> <p>Survivors counted in accordance with NF T-72-281</p> <p>Log reduction calculated by comparison between test carriers and control carriers</p>	<p>Dirty conditions (10 g/L BSA+ 10 g/L yeast extract)</p> <p>T°C : 15-22°C</p> <p>Contact time: 2h</p> <p>Porcine parvovirus</p> <p>Test suspensions prepared in accordance with NF T 72-281</p> <p>Test material: Ca(OH)<sub>2</sub>: 800 g/m<sup>2</sup></p>	<p>PASS: Virucidal (&gt;3 log reduction)</p> <p>Porcine parvovirus</p>	<p>6.7-15B RE-1298/0819 RI = 2</p>

				Veterinary High Level Soil conditions Efficacy criteria: Virus; 3 log reduction																																																																																																			
Surface disinfectant	PT3- Uses 3/4/5	Calcium oxide	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 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, ie 6 zones of 1x1 m For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried. 2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored	Phase 1 control Standard treatment  Phase 2: 800 g of CaO / m <sup>2</sup> of soil Contact time: 48 h Temp: ambient (max 31.4 deg C)	100% CaO at 800 g/m <sup>2</sup> (48h contact time):  > Log 4 reduction for all organisms analysed  Reduction greater than 4 Log for microorganisms monitored with high initial concentrations (greater than 4 Log <sub>10</sub> ).	6.7-16 RITTMO 18-445R RI = 2																																																																																																
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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</p>	<p>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</p> <p>pH = 11 after 48H exposure and after hydration.</p> <p>The soil temperature is increased by 3.1 °C between the start of the test and the end of the quicklime intake.</p> <p>traces of ammonium (NH3) were measured in the breeding room (between 2 and 6ppm) during product treatment</p> <table border="1" data-bbox="1160 507 1794 774"> <thead> <tr> <th colspan="5">Elevage Avicole mars 2019</th> </tr> <tr> <th></th> <th>Initial state /m<sup>2</sup></th> <th>FINAL state without treatment /m<sup>2</sup></th> <th>Reduction without treatment Log<sub>10</sub></th> <th>Reduction without treatment %</th> </tr> </thead> <tbody> <tr> <td>Dénombr. microorganismes aérobies 30°C</td> <td>1,9E+08</td> <td>4,5E+07</td> <td>0,6</td> <td>75,8</td> </tr> <tr> <td>Dénombr. des entérobactéries présumées</td> <td>1,0E+04</td> <td>2,2E+03</td> <td>0,7</td> <td>78,5</td> </tr> <tr> <td>Dénombrement d'Escherichia coli</td> <td>2,7E+03</td> <td>1,3E+02</td> <td>1,3</td> <td>95,2</td> </tr> <tr> <td>Dénombrement de Pseudomonas spp</td> <td>5,5E+04</td> <td>3,7E+04</td> <td>0,2</td> <td>31,9</td> </tr> <tr> <td>Spores de Clostridium perfringens</td> <td>9,8E+02</td> <td>4,7E+01</td> <td>1,3</td> <td>95,2</td> </tr> <tr> <td>Dénombrement de levures et moisissures</td> <td>3,2E+05</td> <td>3,8E+04</td> <td>0,9</td> <td>87,8</td> </tr> <tr> <td>Dénombrement d'Aspergillus</td> <td>6,8E+04</td> <td>1,0E+03</td> <td>1,8</td> <td>98,5</td> </tr> <tr> <td>Dénombrement d'entérocoques intestinaux</td> <td>1,8E+04</td> <td>3,0E+04</td> <td>-0,2</td> <td>-68,7</td> </tr> <tr> <td>Rech. de Staphylocoques à coagulase positive</td> <td>Absent</td> <td>Absent</td> <td>Absent</td> <td>Absent</td> </tr> </tbody> </table> <table border="1" data-bbox="1160 799 1794 1050"> <thead> <tr> <th colspan="5">Elevage Avicole mars 2019</th> </tr> <tr> <th></th> <th>INITIAL state /m<sup>2</sup></th> <th>FINAL state D600 /m<sup>2</sup></th> <th>reduction D600 Log<sub>10</sub></th> <th>reduction D600 %</th> </tr> </thead> <tbody> <tr> <td>Dénombr. microorganismes aérobies 30°C</td> <td>1,9E+08</td> <td>6,8E+04</td> <td>3,4</td> <td>99,96</td> </tr> <tr> <td>Dénombr. des entérobactéries présumées</td> <td>1,0E+04</td> <td>&lt; 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10 cfu/m<sup>2</sup>).</p> <p>Populations of aerobic microorganisms, intestinal enterococci and Pseudomonas have a reduction of more than 3 Log.</p> <p>Staphylococci are not detected</p> <p>Initial level s of organisms low with some less than Log3.</p>	
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Dénombr. microorganismes aérobies 30°C	1,9E+08	6,8E+04	3,4	99,96																																																																																																																	
Dénombr. des entérobactéries présumées	1,0E+04	< 10	3,0	99,90																																																																																																																	
Dénombrement d'Escherichia coli	2,7E+03	< 10	2,4	99,63																																																																																																																	
Dénombrement de Pseudomonas spp	5,5E+04	< 10	3,7	99,98																																																																																																																	
Spores de Clostridium perfringens	9,8E+02	< 10	2,0	98,98																																																																																																																	
Dénombrement de levures et moisissures	3,2E+05	6,5E+03	1,7	97,94																																																																																																																	
Dénombrement d'Aspergillus	6,8E+04	< 100	2,8	99,85																																																																																																																	
Dénombrement d'entérocoques intestinaux	1,8E+04	< 10	3,2	99,94																																																																																																																	
Rech. de Staphylocoques à coagulase positive	Absent	Absent	Absent	Absent																																																																																																																	
Surface disinfectant	PT3– Uses 3/4/5	Calcium oxide	Organisms monitored:  Escherichia coli B glucuronidase Clostridium Perfringens intestinal enterococci enterobacteria Pseudomonas spp Aspergillus Salmonella Staphylococci Coagulase	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	600 or 800 g of CaO / m <sup>2</sup> 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)	100% CaO at 600 g/m <sup>2</sup> (40h contact time):  >2/3 Log for aerobic microorganisms, Pseudomonas spp, yeast and moulds	6.7-18 RITTMO 19-431R RI = 2																																																																																																														

Yeasts  
Moulds

Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods

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 / m<sup>2</sup> of product, and a last housing unit treated with 800 g / m<sup>2</sup> 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 crust is removed from the soil using a shovel rinsed in ethanol and air-dried. 2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored

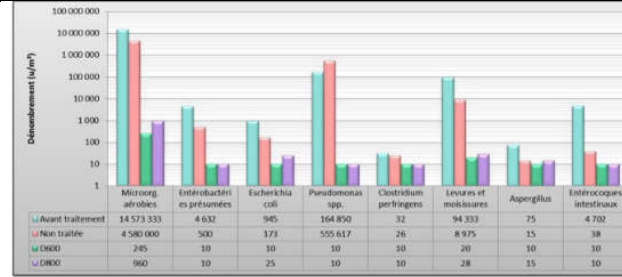


Figure 5 : Population count of different microorganismes before traitement and after treatment in treated and non-treated areas.

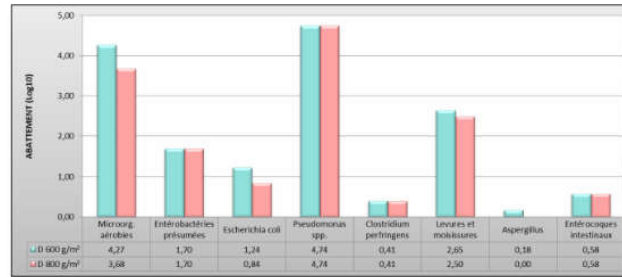


Figure 6 : Reduction (log<sub>10</sub>) of microbe populations between treated and non-treated zones 40h after treatment

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

No significant difference between 600 and 800 g/m<sup>2</sup> application in terms of reduction.

**Conclusion on the efficacy of the product**

The product EULA HYDRA-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 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

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

Regarding virus, for the disinfection of sewage sludge, the 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 endoparasite (helminth eggs).

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time.

The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

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

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

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

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

Nevertheless, for the disinfection of bedding materials (PT3), against bacteria, yeast, fungi and virus, the EFF WG (WG I 2022 meeting) concluded that the demonstration of the efficacy based on a read across with manure studies was not acceptable. The efficacy of this use is then not supported by the efficacy data presented in the dossier.

### 2.2.5.6 Occurrence of resistance and resistance management

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

Also the other effects described:

- Increase in free / non-ionised ammonia (NH<sub>3</sub>)

- 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

No study was conducted. The classification of the product is determined following information available in the CAR on hydrated lime 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**

<b>Conclusion used in Risk Assessment – Skin corrosion and irritation</b>	
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**

<b>Conclusion used in Risk Assessment – Eye irritation</b>	
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**

<b>Conclusion used in the Risk Assessment – Respiratory tract irritation</b>	
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**

<b>Conclusion used in Risk Assessment – Skin sensitisation</b>	
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 according to the 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)***

<b>Conclusion used in Risk Assessment – Respiratory sensitisation</b>	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	No new data on skin 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*

<b>Value used in the Risk Assessment – Acute oral toxicity</b>	
Value	Not acutely toxic by 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*

<b>Value used in the Risk Assessment – Acute inhalation toxicity</b>	
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*

<b>Value used in the Risk Assessment – Acute dermal toxicity</b>	
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**

<b>Value(s) used in the Risk Assessment – Dermal absorption</b>	
Substance	Hydrated lime
Value(s)	100%
Justification for the selected value(s)	According to the CAR of hydrated lime, 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 is no substance of concern in the product.

#### **2.2.6.2 Exposure assessment**

EULA HYDRA-LIME 23 is used for disinfection of sewage sludge (PT2), of manures and bedding materials and of floor and walls surfaces of animal accommodations, transportation and outdoor enclosures (PT3) by professionals.

Hydrated lime powder is packed in small sack of 25 kg, in big bags of 500 to 1000 kg and in powder tanker containing up to 30 T.

For the disinfection of sewage sludge and manures, the hydrated 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 manures with a blender in a fully automated process.

For the disinfection of floor surfaces of animal accommodations (indoor and outdoor), the hydrated lime powder is loaded into a wheelbarrow or a low impact spreader for the manual and semi-automated application tasks.

A brush application as a water suspended lime (lime powder in water) is also possible on walls of animal accommodations.

Considering the different modes 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 for these different operations are considered.

### Adverse effects -ammonia

The addition of hydrated lime leads to an increase of the alkalinity of the treated substrates (sewage sludge, manures or litter) and consequently a potential release of ammonia gas due to the natural content in nitrogen compounds in the substrates. The increase of the level of ammonia gas in air may be of concern and 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 needed. The following contents in the product EULA HYDRA-LIME 23 are considered for exposure assessment:

Calcium and magnesium contents in EULA HYDRA-LIME 23	
Ca(OH) <sub>2</sub> (nominal)	100 %
Mg(OH) <sub>2</sub>	3.79 %
<b>Ca (equivalent) (max.)</b>	54.1 %
<b>Mg (equivalent) (max.)</b>	2 %

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 Ca(OH)<sub>2</sub>.

### Identification of main paths of human exposure towards active substance from its use in biocidal product

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



**List of scenarios**

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

13.	Application (Manual)	<b>Primary exposure</b> - Manual spreading of dry product onto animal enclosure using a shovel - outdoor	Professionals
14.	Loading (Semi-automated)	<b>Primary exposure</b> - 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)	<b>Primary exposure</b> - Semi- automatic application of dry product onto animal enclosure - outdoor	Professionals
16.	Disposal	<b>Primary exposure</b> - Disposal of empty bags	Professionals
17.	Disposal	<b>Primary exposure</b> - Disposal of lime product after application	Professionals
<b>Disinfection of animal accommodations walls using a brush (Use #5)</b>			
18.	Mixing & loading	<b>Primary exposure</b> – Semi-automated transfer of the product from big bags to a medium volume tank	Professionals
19.	Loading (Manual)	<b>Primary exposure</b> - Manual loading of the product from the medium volume tank to a bucket	Professionals
20.	Loading (Manual)	<b>Primary exposure</b> - Manual loading of the product from small bags to a bucket	Professionals
21.	Application	<b>Primary exposure</b> – Manual application by brush	Professionals
22.	Cleaning equipment	<b>Primary exposure</b> - Cleaning of the brush equipment	Professionals
23.	Disposal	<b>Primary exposure</b> - Disposal of empty bags	Professionals
24.	Contact with treated surfaces	<b>Secondary exposure – Dermal exposure</b> After brush on surfaces, secondary dermal exposure may occur during the contact with wet surfaces	Professionals and general public
25.	Contact with treated surfaces	<b>Secondary exposure – Dermal exposure</b> After application, secondary dermal exposure may occur during the contact with dried surfaces	Professionals and general public
26.	Contact with treated surfaces	<b>Secondary exposure – Dermal and oral exposure</b> After brush on surfaces, secondary dermal and oral exposure may occur during the contact with the wet surfaces	General public
27.	Contact with treated surfaces	<b>Secondary exposure – Dermal and oral exposure</b> secondary dermal and oral exposure may occur during the contact with dried surfaces well after the application	General public

### **Industrial exposure**

No industrial use for this product.

### **Professional exposure**

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

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

<b>Description of Scenario [1]</b>			
<p>EULA HYDRA-LIME 23 is available in small bags of 25 kg for manual loading to sewage sludge and manures.</p> <p>The bags are manually opened (thanks to a knife) and emptied in the storage container (hopper) of the unit of treatment. Workers are not protected by any cab. The lime is then transferred to the sludge mixer through a screw conveyor (closed system). The actual mixing can occur before or after dewatering.</p> <p>The same assumption is made for the treatment of manures where bags of 25 kg calcium hydroxide are opened and emptied manually in an open area.</p> <p>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).</p> <p>A dermal exposure of <b>56.9 mg bp/min</b> (75th percentile) is calculated.</p> <p>It has to be noted that exposure value for body is not available with this model (only hand exposure value).</p> <p>Gloves are taken into consideration in Tier 2.</p> <p>A field study for the measurement of potential inhalation exposure has been submitted by EULA in the CAR on the active substance<sup>3</sup>.</p> <p>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.</p> <p>The results of this study are as follows.</p> <p>When normalised over 8 hours, a daily exposure to inhalable dust was 0.27 to <b>2.58</b> mg of bp/m<sup>3</sup>, with an average of 1.07 mg/m<sup>3</sup>. The value retained from the study for the assessment is therefore equal to 2.58 mg pb/m<sup>3</sup>.</p> <p>For Tier 2, a respiratory mask (APF 40) is taken into account.</p>			
	Parameters <sup>1</sup>	Value	References
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data

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

	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	10	General time duration for a M&L scenario in accordance with the CAR on active substance PT 2
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> ) – full shift	2.58	Field study from the CAR PT 2
	Inhalation exposure (mg/m <sup>3</sup> ) – task only	23.2	Field study from the CAR PT2
	Dermal absorption value	100 %	Active substance data (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14 , 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14 , 2017
Tier 2	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
	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	2.33E-01	5.13E+00	5.36E+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 [1]	Tier 1/no PPE	9.03E-03	1.99E-01	2.08E-01

**Local effect - calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
Scenario [1]	Tier 1/no PPE	2.32E+01
Scenario [1]	Tier 2/ respiratory mask (RPE40)	5.80E-01

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

**Description of Scenario [2]**

EULA HYDRA-LIME 23 is available in big bags from 500 to 1000 kg for semi-automated loading of the 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)** and 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% of 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 75<sup>th</sup> percentile is equal to (see Annex 3.2 for reports):

For full shift:

- **0.27 mg/m<sup>3</sup> and 1.8 mg/m<sup>3</sup> for telehandler** for outdoor and indoor activities, respectively.
- **0.62 mg/m<sup>3</sup> and 4.3 mg/m<sup>3</sup> for forklift** for outdoor and indoor activities, respectively.

For task only:

- **1.1 mg/m<sup>3</sup> and 7.3 mg/m<sup>3</sup> for telehandler** for outdoor and indoor activities, respectively.
- **2.5 mg/m<sup>3</sup> and 17 mg/m<sup>3</sup> for forklift** for outdoor and indoor activities, respectively

The values estimated during the task only are chosen for inhalation exposure as a worst-case.

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure – telehandler (with a closed cabin) indoors (mg/m <sup>3</sup> ) task only	1.1	ART model
	Inhalation exposure – forklift indoors (mg/m <sup>3</sup> ) task only	17	ART model
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)

	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
	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	3.88E-01	5.13E+00	5.52E+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 [2]	Tier 1/no PPE	1.47E-02	1.99E-01	2.14E-01

#### Local effect –calcium hydroxide

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 2/ respiratory mask (RPE40)	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 manure**

**Description of Scenario [3]**

EULA HYDRA-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 (75<sup>th</sup> 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 75<sup>th</sup> percentile is equal to (see Annex 3.2 for reports):

For full shift:

- **0.97 mg/m<sup>3</sup>**

For task only:

- **3.9 mg/m<sup>3</sup>**

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Dermal exposure – Hand only (mg/min)	7.97	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.97	ART model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	3.9	ART model
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017



Tier 2	Gloves	PF = 95% (solid)	HEEG Opinion 9, 2010
	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	8.75E-02	7.19E-01	8.06E-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 [3]	Tier 1/no PPE	3.40E-03	2.79E-02	3.13E-02

#### Local effect –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [3]	Tier 1/no PPE	3.90E+00
Scenario [3]	Tier 2/ respiratory mask (RPE 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 hydroxide, 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 less than 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/m<sup>3</sup>** is taken into account.

A task duration of 30 min is considered.

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	30	Default value for this task
	Product density (tap density)	0.5 g/mL	Applicant's data
	Inhalation exposure (mg/m <sup>3</sup> )	23.2	Field study from CAR PT2
	Dermal absorption	100%	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /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**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [4]	Tier 1/no PPE	1.31E-01	1.49E+01	1.50E+01
Scenario [4]	Tier 2 /gloves + coated coverall	1.31E-01	2.01E+00	2.14E+00

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [4]	Tier 1/no PPE	5.08E-03	5.79E-01	5.84E-01
Scenario [4]	Tier 2/gloves	5.08E-03	2.40E-01	2.45E-01

**Local effect –calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
Scenario [4]	Tier 1/no PPE	2.32E+01
Scenario [4]	Tier 2/ 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 75<sup>th</sup> percentile is equal to (see Annex 3.2 for reports):

For full shift:

- **0.015** mg/m<sup>3</sup> (outdoor);
- **0.051** mg/m<sup>3</sup> (indoor).

For task only:

- **0.39** mg/m<sup>3</sup> (outdoor);
- **2.5** mg/m<sup>3</sup> (indoor).

As a worst-case approach, only indoor value is retained for the risk assessment.

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
	CaO concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2%	Applicant's data
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.015 (out) 0.051 (in)	ART model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	0.39 (out) 2.5 (in)	ART model
	Inhalation rate (m <sup>3</sup> /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**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [5]	Tier 1/no PPE	4.7E-03	-	4.7E-03

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [5]	Tier 1/no PPE	1.74E-04	-	1.74E-04

**Local effect – calcium hydroxide**

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

### Combined Exposure (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 lime powder in the unit treatment is usually performed by the truck driver and not the professional that's why no combined exposure has been performed with this scenario.

#### Systemic effect – calcium

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 1+4 5	Tier 1/no PPE	3.66E-01	2.00E+01	2.02E+01
	Tier 2/ gloves for loading and gloves + coverall for cleaning	3.66E-01	2.27E+00	2.6E+00
Scenario 2+4+5	Tier 1/no PPE	5.2E-01	2.00E+01	2.02E+01
	Tier 2/gloves for loading and gloves+ coverall for cleaning	5.2E-01	2.27E+00	2.8E+00

#### Systemic effect – magnesium

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 1+4	Tier 1/no PPE	5.2E-03	5.71E+00	5.71E+00
	Tier 2/ gloves	5.2E-03	4.97E-01	5.0E-01
Scenario 2+4	Tier 1/no PPE	5.2E-03	7.78E-01	7.83E-01
	Tier 2/ gloves	5.2E-03	2.50E-01	2.55E-01

**Scenario [6]: Disposal of treated sludge and manure****Description of Scenario [6]**

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

## Disinfection of floor surfaces of animal accommodations (indoor), animal transportation and animal beddings (Uses # 3&4)

### Scenario [7]: Loading – Manual loading into a wheelbarrow for disinfection of floor and bedding materials.

#### 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<sup>3</sup>
- For task only (10min), **110** mg/ m<sup>3</sup>.

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

	Parameters	Value	References
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	2	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017



Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	APF = 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	1.80E-01	5.13E+00	5.31E+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 [7]	Tier 1/no PPE	7.00E-03	1.99E-01	2.06E-01

#### Local effect –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [7]	Tier 1/no PPE	1.10E+02
Scenario [7]	Tier 2/ RPE (APF 40)	2.75E+00

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

After the transfer of the 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 occur.

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<sup>2</sup> 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<sup>2</sup>. 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:

$$\text{Round trips} = 58 \text{ m} / 0.5 \text{ m} = 116.$$

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

$$d = \sqrt{\text{surface area} \times \text{round trips}}$$

$$d = \sqrt{3330 \text{ m}^2 \times 116}$$

$$d = 6\,693.9 \text{ m (rounded to } \mathbf{6.7 \text{ km}}).$$

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<sup>2</sup>, a task time duration of 160 min is taken into account. This leads to a surface/time ratio of 20.8 m<sup>2</sup>/min (3330 m<sup>2</sup> / 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 splitted 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<sup>2</sup>.

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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup> has been taken account in the model. This volume corresponds approximately to the surface of 390 m<sup>2</sup> multiplied by a height of 2.7 m calculated from the ESD PT 3 data<sup>4</sup>.

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

<sup>4</sup> 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<sup>2</sup> is presented in the ESD associated to a floor area of 390 m<sup>2</sup>. 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<sup>2</sup> meaning that a single wall is of 52.5 m<sup>2</sup> 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<sup>3</sup>
- For task only (19 min): **110** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	19	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	4.3	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	110	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

### Calculations for Scenario [8a]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [8a]	Tier 1/no PPE	3.88E-01	2.09E+01	2.13E+01
Scenario [8a]	Tier 2/gloves	3.88E-01	1.05E+00	1.43E+00

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [8a]	Tier 1/no PPE	1.51E-02	8.11E-01	8.26E-01
Scenario [8a]	Tier 2/gloves	1.51E-02	4.06E-02	5.56E-02

**Local effect – calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Scenario [8a]	Tier 1/no PPE	1.10E+02
Scenario [8a]	Tier 2/ RPE (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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup> 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<sup>3</sup> is calculated taking into account a maximal floor surface area of 3330 m<sup>2</sup> and a height of 5.8 m calculated from the ESD PT 3 data<sup>5</sup>.

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<sup>3</sup>;
- For task only (160 min): **97** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	160	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	32	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	97	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017

<sup>5</sup> 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<sup>2</sup> is presented in the ESD associated to a floor area of 3330 m<sup>2</sup>. 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<sup>2</sup> meaning that a single wall is of 330 m<sup>2</sup> 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.

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

### Calculations for Scenario [8b]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from professional uses</b>				
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	2.89E+00	1.76E+02	1.79E+02
Scenario [8b]	Tier 2 /gloves + RPE (APF 40)	7.21E-02	8.80E+00	8.87E+00

#### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
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	1.12E-01	6.83E+00	6.94E+00
Scenario [8b]	Tier 2/gloves	1.12E-01	3.42E-01	4.54E-01

#### Local effect –calcium hydroxide

<b>Summary table: local exposure from professional uses</b>		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m3)
Scenario [8b]	Tier 1/no PPE	9.70E+01
Scenario [8b]	Tier 2/ 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<sup>2</sup>.

Taking into account the surface/time ratio of 20.8 m<sup>2</sup>/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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup> has been taken account in the modelling. This volume corresponds approximately to the mean surface of 160 m<sup>2</sup> multiplied by a height of 3.3 m calculated from the ESD PT 3 data<sup>6</sup>.

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<sup>3</sup>
- For task only (8 min): **140** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	8	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	2.4	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	140	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017

<sup>6</sup> 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<sup>2</sup> is presented in the ESD associated to a floor area of 160 m<sup>2</sup>. 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<sup>2</sup> meaning that a single wall is of 42.5 m<sup>2</sup> 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.

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

### Calculations for Scenario [8c]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from professional uses</b>				
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	2.16E-01	8.80E+00	9.02E+00
Scenario [8c]	Tier 2/gloves	2.16E-01	4.40E-01	6.56E-01

#### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
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	8.40E-03	3.42E-01	3.50E-01

#### Local effect–calcium hydroxide

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

**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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup> has been selected in the ART model. This volume corresponds approximately to the maximum surface of 1170 m<sup>2</sup> multiplied by a height of 3.7 m calculated from the ESD PT 3 data<sup>7</sup>.

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<sup>3</sup>;
- For task only (56 min): **97** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	56	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	11	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	97	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017

<sup>7</sup> 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<sup>2</sup> is presented in the ESD associated to a floor area of 1170 m<sup>2</sup>. 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<sup>2</sup> meaning that a single wall is of 125 m<sup>2</sup> 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.

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

### Calculations for Scenario [8d]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [8d]	Tier 1/no PPE	9.92E-01	6.16E+01	6.26E+01
Scenario [8d]	Tier 2/gloves	9.92E-01	3.08E+00	4.07E+00

#### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [8d]	Tier 1/no PPE	3.85E-02	2.39E+00	2.43E+00
Scenario [8d]	Tier 2/gloves	3.85E-02	1.20E-01	1.58E-01

#### Local effect –calcium hydroxide

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
Scenario [8d]	Tier 1/no PPE	9.70E+01
Scenario [8d]	Tier 2/ 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 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 (95<sup>th</sup> percentile) from the study are as follow:

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

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 hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
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 thanks to Big Bag emptying stations;
- semi-automatically raised and emptied into a tank for application of the product onto animal accommodation floor surfaces using a tractor.

Assuming that not all the farmers have *Big Bag emptying stations*, the second assumption has been retained in the risk assessment.

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<sup>3</sup>
- For task only (10min), **45** mg/ m<sup>3</sup>.

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

	Parameters	Value	References
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Dermal exposure – Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.94	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017	

Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	PF = 40	HEEG Opinion 9, 2010

### Calculations for Scenario [9]

#### 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 [9]	Tier 1/no PPE	8.48E-02	5.13E+00	5.22E+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 [9]	Tier 1/no PPE	3.29E-03	1.99E-01	2.02E-01

#### Local effect –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [9]	Tier 1/no PPE	4.50E+01
Scenario [9]	Tier 2/ RPE (APF 40)	1.13E+00



**Scenario [10]: Application– Semi-automated spreading of dry product onto floor surfaces of animal accommodation using a tractor - 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, 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<sup>2</sup> 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<sup>2</sup>. 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:

$d = \sqrt{\text{surface area} \times \text{round trips}}$   
 $d = \sqrt{3330 \text{ m}^2 \times 58}$   
 $d = 3347 \text{ m}$  (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<sup>2</sup>, a task time duration of 40 min is taken into account. This leads to a surface/time ratio of 83.25 m<sup>2</sup>/min (3330 m<sup>2</sup> / 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 lime powder contained in big bags (500-1000 kg) could be loaded into the tank of a tractor for a semi-automated application of 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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup> has been taken account in the model. This volume corresponds approximately to the real surface of 390 m<sup>2</sup> 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<sup>3</sup>
- For task only (5 min): **110** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	1.1	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	110	ART Model

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

### Calculations for Scenario [10a]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from professional uses</b>				
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	9.92E-02	8.93E-01	9.92E-01

#### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
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	3.85E-03	3.47E-02	3.85E-02

#### Local effect – calcium hydroxide

<b>Summary table: local exposure from professional uses</b>		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [10a]	Tier 1/no PPE	1.10E+02
Scenario [10a]	Tier 2/ 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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup>
- For task only (40 min): **45** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	3.8	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

**Calculations for Scenario [10b]****Systemic exposure - calcium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [10b]	Tier 1/no PPE	3.43E-01	7.14E+00	7.48E+00
Scenario [10b]	Tier 2a/gloves	3.43E-01	3.57E-01	7.00E-01

**Systemic exposure - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [10b]	Tier 1/no PPE	1.33E-02	2.77E-01	2.91E-01

**Local exposure –calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Scenario [10b]	Tier 1/no PPE	4.50E+01
Scenario [10b]	Tier 2/ 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<sup>2</sup>.

Taking into account the surface/time ratio of 66.6 m<sup>2</sup>/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<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup> has been selected in the ART modelling. This volume corresponds approximately to the minimal surface of 160 m<sup>2</sup> 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<sup>3</sup>
- For task only (2 min): **360** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	2	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	1.5	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	360	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010



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

Gloves + RPE - APF 40

PF = 40 %

HEEG Opinion 9, 2010

### Calculations for Scenario [10c]

#### 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 [10c]	Tier 1/no PPE	1.35E-01	3.57E-01	4.92E-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 [10c]	Tier 1/no PPE	5.25E-03	1.39E-02	1.91E-02

#### Local exposure –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [10c]	Tier 1/no PPE	3.60E+02
Scenario [10c]	Tier 2/ 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<sup>2</sup>/min calculated above, a task time duration of 14 min is calculated for the highest default surface value of 1170 m<sup>2</sup> 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup> has been selected in the ART modelling. This volume corresponds approximately to the mean surface of 1170 m<sup>2</sup> 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<sup>3</sup>
- For task only (14 min): **45** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	14	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	1.3	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

**Calculations for Scenario [10d]****Systemic exposure - calcium**

<b>Summary table: systemic exposure from non-professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [10d]	Tier 1/no PPE	1.17E-01	2.50E+00	2.62E+00

**Systemic exposure - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [10d]	Tier 1/no PPE	4.55E-03	9.70E-02	1.02E-01

**Local effect – hydroxide calcium**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Scenario [10d]	Tier 1/no PPE	4.50E+01
Scenario [10d]	Tier 2/ 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 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 hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
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 75<sup>th</sup> percentile is equal to (see Annex 3.2 for reports):

For full shift:

- **0.015** mg/m<sup>3</sup> (outdoor);
- **0.051** mg/m<sup>3</sup> (indoor).

For task only:

- **0.39** mg/m<sup>3</sup> (outdoor);
- **2.5** mg/m<sup>3</sup> (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.

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2%	Applicant's data
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.015 (out) 0.051 (in)	ART model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	0.39 (out) 2.5 (in)	ART model
	Inhalation rate (m <sup>3</sup> /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**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [11]	Tier 1/no PPE	4.7E-03	-	4.7E-03

### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [11]	Tier 1/no PPE	1.74E-04	-	1.74E-04

### Local effect – calcium dihydroxide

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
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**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 7+8a+11	Tier 1/no PPE	5.8E-01	2.60E+01	2.66E+01
	Tier 2/gloves	5.8E-01	1.30E+00	1.88E+00
Scenario 7+8b+11	Tier 1/no PPE	3.08E+00	1.81E+02	1.84E+02
	Tier 2/gloves for loading and gloves + mask APF 40 for application	2.76E-01	9.06E+00	9.33E+00
Scenario 7+8c+11	Tier 1/no PPE	4.19E-01	1.39E+01	1.43E+01
	Tier 2/gloves	4.19E-01	6.97E-01	1.12E+00
Scenario 7+8d+11	Tier 1/no PPE	1.19E+00	6.67E+01	6.79E+01
	Tier 2/gloves for loading and gloves + RPE APF 40 for application	2.27E-01	3.34E+00	3.57E+00

**Systemic effect – magnesium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 7+8a+11	Tier 1/no PPE	2.26E-02	1.01E+00	1.03E+00
	Tier 2/gloves	2.26E-02	5.05E-02	7.3E-02
Scenario 7+8b+11	Tier 1/no PPE	1.20E-01	7.03E+00	7.15E+00
	Tier 2/gloves	1.20E-01	3.52E-01	4.71E-01
Scenario 7+8c+11	Tier 1/no PPE	1.63E-02	5.41E-01	5.57E-01
Scenario 7+8d+11	Tier 1/no PPE	4.64E-02	2.59E+00	2.64E+00
	Tier 2/gloves	4.64E-02	1.30E-01	1.76E-01

**Semi-automated process (loading and application)****Systemic effect – calcium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 9+10a+11	Tier 1/no PPE	1.89E-01	6.02E+00	6.21E+00
	Tier 2/gloves	1.89E-01	3.01E-01	4.9E-01
Scenario 9+10b+11	Tier 1/no PPE	4.3E-01	1.23E+01	1.27E+01
	Tier 2/gloves	4.3E-01	6.14E-01	1.04E+00
Scenario 9+10c+11	Tier 1/no PPE	2.22E-01	5.49E+00	5.71E+00
	Tier 2/gloves	2.22E-01	2.74E-01	4.99E-01
Scenario 9+10d+11	Tier 1/no PPE	2.07E-01	7.63E+00	7.84E+00
	Tier 2/gloves	2.07E-01	3.81E-01	5.88E-01

**Systemic effect – magnesium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 9+10a+11	Tier 1/no PPE	7.3E-03	2.34E-01	2.41E-01
Scenario 9+10b+11	Tier 1/no PPE	1.67E-02	4.76E-01	4.93E-01
Scenario 9+10c+11	Tier 1/no PPE	8.7E-03	2.13E-01	2.22E-01
Scenario 9+10d+11	Tier 1/no PPE	8.0E-03	2.96E-01	3.04E-01

**Scenario [12]: – Disposal of lime product after floor disinfection****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 lime powder is swept off the treated floor and thrown into a suitable bag. It is the cleaning task.

During this cleaning task, dermal and inhalation exposure of the professional can occur.

For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 8a have been used.

For inhalation exposure, measurements of professionals during the cleaning task have been provided by the field study.

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

- For full shift (normalised over 8 hours): 0.23 mg /m<sup>3</sup>;
- For task only: 2.79 mg/ m<sup>3</sup>.

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	2.07E-02	2.09E+01	2.09E+01
	Tier 3a/ gloves	2.07E-02	1.05E+00	1.07E+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	8.05E-04	8.11E-01	8.12E-01
	Tier 3a/ gloves	8.05E-04	4.06E-02	4.14E-02

**Local effect – calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Field study	Tier 3/no RPE	2.79E+00
	Tier 3b/ RPE (APF 20)	2.79E-01

## Disinfection of floors of outdoor animal enclosures (Use # 6)

### **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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup>
- For task only (19 min), **45** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	19	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model

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

### Calculations for Scenario [13a]

#### Systemic exposure - calcium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated total uptake</b>
Scenario [13a]	Tier 1/no PPE	1.62E-01	2.09E+01	2.11E+01
Scenario [13a]	Tier 2/gloves	1.62E-01	1.05E+00	1.21E+00

#### Systemic exposure - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [13a]	Tier 1/no PPE	6.30E-03	8.11E-01	8.18E-01
Scenario [13a]	Tier 2/gloves	6.30E-03	4.06E-02	4.69E-02

**Local exposure – calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Scenario [13a]	Tier 1/no PPE	4.50E+01
Scenario [13a]	Tier 2/ respiratory mask (RPE40)	1.13E+00

**Description of Scenario [13b] :** Application– Manual spreading of dry product onto floor surfaces of animal enclosures\_ **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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 20.8 m<sup>2</sup>/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<sup>3</sup>
- For task only (160 min), **45** mg/ m<sup>3</sup>.

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

	Parameters <sup>1</sup>	Value	References
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	160	see calculation above
	Dermal exposure – Hand only (mg/min)	122	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	15	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	45	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

### Calculations for Scenario [13b]

#### 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 [13b]	Tier 1/no PPE	1.35E+00	1.76E+02	1.77E+02



<b>Summary table: systemic exposure from professional uses</b>				
Scenario [13b]	Tier 2 /gloves + RPE (APF 40)	3.38E-02	8.80E+00	8.83E+00

### Systemic exposure - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
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	5.25E-02	6.83E+00	6.88E+00
Scenario [13b]	Tier 2/gloves	5.25E-02	3.42E-01	3.94E-01

### Local exposure – hydroxide calcium

<b>Summary table: local exposure from professional uses</b>		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m3)
Scenario [13b]	Tier 1/no PPE	4.50E+01
Scenario [13b]	Tier 2/ 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].

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### **Scenario [14]: Semi automated loading into the tank of a tractor for disinfection of outdoor floor enclosures**

#### **Description of Scenario [14]**

The product is available in big bags from 500 to 1000 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<sup>3</sup>
- For task only (10min), **8.8** mg/ m<sup>3</sup>.

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

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Dermal exposure - Hand only (mg/min)	56.9	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.18	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	8.8	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
Tier 2	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	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	1.62E-02	5.13E+00	5.15E+00

### Systemic effect – magnesium

Summary table: systemic exposure from professional uses				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [14]	Tier 1/no PPE	6.30E-04	1.99E-01	2.00E-01

### Local effect –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [14]	Tier 1/no PPE	8.80E+00
Scenario [14]	Tier 2/ 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup>
- For task only (5 min): **11** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	5	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.12	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017

<b>Description of Scenario [15a] : Application- Semi-automatic spreading of dry product onto floor surfaces of animal enclosure _ Minimum surface area outdoor</b>			
Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	Respiratory protection	APF = 40	HEEG Opinion 9, 2010

### Calculations for Scenario [15a]

#### Systemic effect - calcium

<b>Summary table: systemic exposure from non-professional uses</b>				
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	1.08E-02	8.93E-01	9.03E-01

#### Systemic effect - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
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	4.20E-04	3.47E-02	3.51E-02

#### Local effect – hydroxide calcium

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



**Description of Scenario [15b] : Application– Semi-automatic spreading of dry product onto floor surfaces of animal enclosures \_ 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<sup>2</sup> proposed by the applicant in the SPC and the application rate of 83.25 m<sup>2</sup>/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<sup>3</sup>
- For task only (40 min): **11** mg/ m<sup>3</sup>.

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

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	40	see calculation above
	Dermal exposure – Hand only (mg/min)	19.8	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.96	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	11	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	HEAd hoc Recommendation no. 14, 2017
	Body weight (kg)	60	HEAd hoc Recommendation no. 14, 2017
Tier 2	Gloves	PF = 95 % (solid)	HEEG Opinion 9, 2010
	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	8.66E-02	7.14E+00	7.23E+00
Scenario [15b]	Tier 2/gloves	8.66E-02	3.57E-01	4.44E-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 [15b]	Tier 1/no PPE	3.36E-03	2.77E-01	2.81E-01

### Local effect – hydroxide calcium

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [15b]	Tier 1/no PPE	1.10E+01
Scenario [15b]	Tier 2/ 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].

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**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**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [16]	Tier 1/no PPE	4.7E-03	-	4.7E-03

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [16]	Tier 1/no PPE	1.74E-04	-	1.74E-04

**Local effect – calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
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)****Manual process (M&L and application)****Systemic effect – calcium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 7+13a+16	Tier 1/no PPE	8.17E-01	2.64E+01	2.72E+01
	Tier 2/gloves	8.17E-01	1.32E+00	2.14E+00
Scenario 7+13b+16	Tier 1/no PPE	5.34E+00	1.84E+02	1.89E+02
	Tier 2/gloves for loading and gloves + mask APF 40 for application	3.31E-01	9.20E+00	9.53E+00

**Systemic effect – magnesium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 7+13a+16	Tier 1/no PPE	3.17E-02	1.02E+00	1.05E+00
	Tier 2/gloves	3.17E-02	5.12E-02	8.29E-02
Scenario 7+13b+16	Tier 1/no PPE	2.07E-01	7.14E+00	7.35E+00
	Tier 2/gloves for loading and gloves + mask APF 40 for application	1.29E-02	3.57E-01	3.70E-01

**Semi-automated process (loading and application)****Systemic effect – calcium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 14+15a+16	Tier 1/no PPE	2.71E-02	6.02E+00	6.05E+00
	Tier 2/gloves	2.71E-02	3.01E-01	3.28E-01
Scenario 14+15b+16	Tier 1/no PPE	1.03E-01	1.23E+01	1.24E+01
	Tier 2/gloves	1.03E-01	6.14E-01	7.16E-01

**Systemic effect – magnesium**

<b>Summary table: estimated exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario 14+15a+16	Tier 1/no PPE	1.05E-03	2.34E-01	2.35E-01
Scenario 14+15b+16	Tier 1/no PPE	3.99E-03	4.76E-01	4.80E-01

**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 lime powder is swept off the treated floor and thrown into a suitable bag.

During this cleaning task, dermal and inhalation exposure of the professional can occur.

For inhalation exposure, the exposure measurements obtained for indoor activities described in the study have been used as a worst case approach.

For dermal exposure, it is assumed that the exposure during the cleaning would not be greater than during the manual application task using a shovel. Thus, the dermal value estimated from the RISKOFDERM Model for scenario 8a has been used.

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

- For full shift (normalised over 8 hours): 0.23 mg /m<sup>3</sup>;
- For task only: 2.79 mg/ m<sup>3</sup>.

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

**Calculations for Scenario [17]****Systemic effect - calcium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [17]	Tier 1/no PPE	3.88E-01	2.09E+01	2.13E+01
Scenario [17]	Tier 2/gloves	3.88E-01	1.05E+00	1.43E+00

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [17]	Tier 1/no PPE	1.51E-02	8.11E-01	8.26E-01
Scenario [17]	Tier 2/gloves	1.51E-02	4.06E-02	5.56E-02

**Local effect – calcium hydroxide**

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

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## Disinfection of animal accommodations walls using a brush (Use #5)

### Scenario [18]: Loading– Semi-automated loading of dry product from big bags to medium volume tank

#### **Scenario [18]: Semi-automated transfer of the product from big bags to a medium volume tank**

The product is available in large packaging (big bags from 500 to 1000 kg) for the application of milk of lime on walls by brush.

Transfer the product from this type of packaging to a very small bucket seems unlikely. Therefore, the product contained in big bags is expected to be first transferred automatically to a medium lower volume tank and then loaded into a bucket for application by brush on walls.

The RISKOFDERM Dermal Exposure Model is used to estimate dermal exposure by taking into account an application rate of 225 kg/min and a task duration of 10 min.

The resulting dermal exposure (75<sup>th</sup> percentile) is **7.97 mg/min**.

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): **0.1 mg bp/m<sup>3</sup>**
- For task only (10 min): **4.9 mg/ m<sup>3</sup>**.

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

A duration of 10 minutes is taken into consideration.

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Duration (min)	10	
	Dermal exposure – Hand only (mg/min)	7.97	RISKOFDERM Model
	Inhalation exposure (mg/m <sup>3</sup> )- full shift	0.1	ART Model
	Inhalation exposure (mg/m <sup>3</sup> )- task only	4.9	ART Model
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2	Gloves (solid)	PF = 95 %	HEEG Opinion 9, 2010
	Gloves + RPE – APF 40	PF = 40 %	

## Calculations for Scenario [18]

### 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 [18]	Tier 1/no PPE	9.02E-03	7.19E-01	7.28E-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 [18]	Tier 1/no PPE	3.50E-04	2.79E-02	2.82E-02

### Local exposure –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [18]	Tier 1/no PPE	4.90E+00
Scenario [18]	Tier 2/ RPE (APF 40)	1.23E-01

**Scenario [19] – Manual loading of the product from the lower volume tank to a bucket**

**Description of Scenario [19]**

After the semi-automated transfer of the product from the big bag to a lower volume tank, professional exposure may occur during the manual loading of the product from the medium volume tank to a bucket.

Potential exposure is predominantly to the hands, resulting from accidental touching of contaminated surfaces.

Inhalation exposure is also considered.

To assess dermal and inhalation exposure during this task, the Mixing and Loading Model 7 (BHHM, 2015) has been used as recommended in HEEG Opinion 1.

The indicative exposure value from the model are as follows :

- **101** mg/min (total body without gloves)
- **1.01** mg/min (total body with clothes and gloves)
- **0.94** mg/m<sup>3</sup> (inhalation).

A final application rate of 0.8 kg/m<sup>2</sup> of lime product has been submitted by the applicant. To treat a worst-case wall surface of 1320 m<sup>2</sup> (see ESD document for PT3), the professional has to use 0.8 kg/m<sup>2</sup>\*1320 m<sup>2</sup> = 1056 kg of lime powder.

Taking into account the claimed dilution of 25 kg of powder for 50 L of water, the volume of water to be added can be calculated as : (50 L\*1056 kg)/25 kg = **2 112** L of water.

So it means for the milk of lime:

	Dry matter	Density
Calculation	%	kg/L
=25 kg Ca(OH) <sub>2</sub> + 50L or kg	=25/(25+50)*100	
	33.3	1.22

Thus, the final volume of milk of lime necessary to treat a wall surface of 1320 m<sup>2</sup> is: (1056+2 112 )/1.22=**2596.7L** L.

The applicant did not submit any information regarding time duration for the loading of 2596.7 L of milk of lime before application on wall. Therefore, the exposure duration of the professional has been calculated based on several assumptions :

- Time spent for each loading in the bucket of 0.5 min,
- Volume of bucket = 20 L.

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

- t=**65** min ((2596.7L L/20 L) \* 0.5 min = 65 min).

The content of calcium and magnesium fractions in the product has been redefined considering the dilution of 25 kg of lime powder in 50 L of water.

With 25kg of calcium dihydroxide in 50L or kg of water it means a calcium dihydroxide content of 33.3%.

According to the calculations above, a dilution factor of **0.33** is applied for the calculation of calcium and magnesium fractions after dilution.

-Calcium fraction in milk of lime (after dilution):  $54.1 \times 0.33 = \mathbf{17.85\%}$

-Magnesium fraction in milk of lime (after dilution) :  $2.1 \times 0.33 = \mathbf{0.69\%}$

These new values were used to assess the systemic exposure of the operator during the task

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	33%	Applicant's data
	Assumed calcium fraction	17.9%	Applicant's data
	Assumed magnesium fraction	0.69%	Applicant's data
	Density of the milk of lime	1.22	Applicant's data
	Dilution factor	0.33	See calculation above
	Duration (min)	65	See calculation above
	Dermal exposure – total body (mg b.p/min)	101	HEEG Opinion 1
	Inhalation (mg b.p/m <sup>3</sup> )	0.94	HEEG Opinion 1
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tier 2	Dermal exposure – total body (mg b.p/min)	1.01 mg/min (total body)	HEEG Opinion 9, 2010
	Gloves penetration factor	Included in the model	
	Coverall penetration factor	Included in the model	

### Calculations for Scenario [19]

#### Systemic exposure - calcium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [19]	Tier 1/no PPE	3.78E-03	2.23E+01	2.23E+01
Scenario [19]	Tier 2/gloves + impermeable coverall	3.78E-03	2.23E-01	2.27E-01

**Systemic exposure - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [19]	Tier 1/no PPE	1.46E-04	8.64E-01	8.64E-01
Scenario [19]	Tier 2/gloves + impermeable coverall	1.46E-04	8.64E-03	8.79E-03

**Local exposure –calcium hydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
Scenario [19]	Tier 1/no PPE	3.10E-01
Scenario [19]	Tier 2/ RPE (APF 4)	7.76E-02

**Scenario [20] – Manual loading of the product from the small bags to a bucket****Description of Scenario [20]**

Considering the small bags of 25 kg, a direct loading of the product from the bag to a bucket is taken into account in this scenario.

To assess dermal and inhalation exposure during this task, the *Mixing and Loading Model 5* (BHHEM, 2015) has been used as recommended in HEEG Opinion 1.

The indicative exposure values from the model are as follows :

- **10.2** mg/kg a.s (hand without gloves),
- **0.66** mg/kg a.s (inhalation).

Considering the application rate of 0.8 kg/m<sup>2</sup> and the realistic worst-case wall area for veal sheds of 170 m<sup>2</sup> (ESD document for PT3) to be treated, the dose of lime powder to be used can be calculated as :

$$-170 \text{ m}^2 / 0.8 \text{ kg/m}^2 = 136 \text{ kg of product.}$$

The number of bags of 25 kg to use to reach this dose is:  $136 / 25 = 5.4$ .

Considering the time spent for each loading of bag of 0.5 min, the exposure duration of the professional during the loading of 5 bags of 25 kg of lime powder is :

$$-2.7 \text{ min (} 5.4 * 0.5 \text{ min} = 2.7 \text{ min)}$$

	<b>Parameters<sup>1</sup></b>	<b>Value</b>	<b>References</b>
Tier 1	Ca(OH) <sub>2</sub> concentration	100%	Applicant's data
	Assumed calcium fraction	54.1%	Applicant's data
	Assumed magnesium fraction	2.1%	Applicant's data
	Density	1.22	Applicant's data
	Duration	2.7 min	See calculation above
	Hand exposure (mg a.s./kg a.s handled)	10.2	TNsG part 2
	Inhalation (mg a.s./kg a.s. handled)	0.66	TNsG part 2
	Dermal absorption	100 %	Default value, CAR (for calcium and magnesium)
	Inhalation rate (m <sup>3</sup> /hour)	1.25	Recommendation no. 14, 2017
	Body weight (kg)	60	Recommendation no. 14, 2017
Tiers 2	Gloves	PF = 95%	HEEG Opinion 9, 2010

## Calculations for Scenario [20]

### Systemic exposure - calcium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [20]	Tier 1/no PPE	8.09E-01	1.25E+01	1.33E+01
Scenario [20]	Tier 2a/gloves	8.09E-01	6.25E-01	1.43E+01

### Systemic exposure - magnesium

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [20]	Tier 1/no PPE	3.14E-02	4.86E-01	5.17E-01
Scenario [20]	Tier 2a/gloves	3.14E-02	2.43E-02	5.57E-02

### Local exposure - calcium

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m<sup>3</sup>)</b>
Scenario [20]	Tier 1/no PPE	1.60E+03
Scenario [20]	Tier 2/ RPE (APF 40)	3.99E+01

**Scenario [21]: Application to the walls with a brush****Description of Scenario [21]**

Exposure of the professional to the product may occur during painting on walls using a brush.

Dermal exposure and inhalation exposure (splashes and aerosols) are expected during this task.

According to the HEAd Hoc Recommendation 10 (2016), dermal exposure is evaluated using Austrian/BfR study results and inhalation exposure using *Consumer Product Painting Model 3*.

Considering the worst-case wall surface to brush (1320 m<sup>2</sup> for turkey sheds), an exposure duration of 6 hours has been considered according to expert judgment and duration of application by brush mentioned by Excel spreadsheet for PT2-6-7-10-18 for brushing liquid in the *Biocides Human Health Exposure Methodology* (BHHEM, 2015).

Considering the product is a water-based products and that hydrated lime is low-volatile, the indicative exposure value from the model are as follows:

- Body: **1.7 µL/min**
- Hands: **4.07 µL/min**
- Inhalation: **1.63 mg/m<sup>3</sup>**

The new values of calcium and magnesium fractions after dilution were used to assess the systemic exposure of the operator (see scenario 16 for the detailed calculations).

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
Tiers 1	Ca(OH) <sub>2</sub> concentration after dilution	33%	See calculation above
	Assumed calcium fraction	17.9	See calculation above
	Assumed magnesium fraction	0.69	See calculation above
	Duration (min)	360	BHEEM, 2015 Expert judgment
	Density	1.22	Applicant's data
	Dermal exposure – Hand (µL /min)	4.07	Ad Hoc Recommendation 10 (2016)
	Dermal exposure – Body (µL /min)	1.70	Ad Hoc Recommendation 10 (2016)
	Inhalation (mg b.p/m <sup>3</sup> )	1.63	Ad Hoc Recommendation 10 (2016)
	Inhalation absorption	100%	Default value, CAR
	Dermal absorption	100%	Default value, CAR
	Inhalation rate (m <sup>3</sup> /h)	1.25	Ad Hoc Recommendation 14 (2017)
Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)	
Tier 2	Gloves	10% penetration	HEEG Opinion 9 (2010)
	Respiratory protection	APF 10	HEEG Opinion 9 (2010)



## Calculations for Scenario [21]

### 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 [21]	Tier 1/no PPE	3.65E-02	7.56E+00	7.60E+00
Scenario [21]	Tier 2/gloves	3.65E-02	2.76E+00	2.80E+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 [21]	Tier 1/no PPE	1.41E-03	2.91E-01	2.93E-01

### Local exposure –calcium hydroxide

Summary table: local exposure from professional uses		
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/m <sup>3</sup> )
Scenario [21]	Tier 1/no PPE	5.38E-01
Scenario [21]	Tier 2/ respiratory mask (RPE4)	1.34E-01



**Scenario [22]: Cleaning of the brush equipment**

According to the HEEG Opinion 11, it is expected that for water-based paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands.

EULA HYDRA-LIME 23 being a water-based product, no exposure during cleaning of the brush equipment is expected.

**Scenario [23]: Cleaning – Disposal of empty bags****Description of Scenario [23]**

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 [23]****Systemic effect - calcium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [23]	Tier 1/no PPE	4.7E-03	-	4.7E-03

**Systemic effect - magnesium**

<b>Summary table: systemic exposure from professional uses</b>				
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [23]	Tier 1/no PPE	1.74E-04	-	1.74E-04

**Local effect – calcium dihydroxide**

<b>Summary table: local exposure from professional uses</b>		
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake (mg/m3)</b>
Scenario [23]	Tier 1/no PPE	2.5
Scenario [23]	Tier 2b/ RPE (APF 40)	0.063

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

#### Systemic effect – calcium

<b>Summary table: estimated exposure from professional uses</b>				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario 18+19+20+23	Tier 1/no PPE	5.4E-02	3.06E+01	3.06E+01
	Tier 2/gloves + coverall	5.4E-02	3.02E+00	3.07E+00

<b>Summary table: estimated exposure from professional uses</b>				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario 20+21+23	Tier 1/no PPE	8.46E-01	1.96E+01	2.44E+01
	Tier 2/gloves	8.46E-01	3.09E+00	3.94E+00

#### Systemic effect – magnesium

<b>Summary table: estimated exposure from professional uses</b>				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario 18+19+20+23	Tier 1/no PPE	2.07E-03	1.18E+00	1.18E+00
	Tier 2/gloves + coverall	2.07E-03	1.16E-01	1.18E-01

<b>Summary table: estimated exposure from professional uses</b>				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario 20+21+23	Tier 1/no PPE	3.28E-02	7.55E-01	7.88E-01
	Tier 2/gloves	3.28E-02	1.18E-01	1.56E-01

**Non-professional exposure**

Product is intended to be used by professionals only.

**Exposure of the general public****Scenario [24]: Secondary exposure – Contact with wet surfaces- Post application**

<b>Description of Scenario [24]</b>			
<p>Dermal exposure of the professional (adult) touching the wet wall with hands just after lime washing can occur.</p> <p>Considering that the mixture of lime and water is a suspension strongly adhering to the wall to be efficiency, it can be compared to a paint. Therefore, the exposure assessment is performed according to the parameters of wet residus agreed in the HEAd Hoc Recommendation 5.</p> <p>The assumed calcium and magnesium fractions of the mixture has been considered in the calculation considering the dilution of the powder in the water (see above for more details).</p> <p>The dermal systemic dose, in mg a.s./kg b.w./d is calculated as follow: Systemic dose = (Amount of product in contact with skin* Skin contact factor*Transfer coefficient* Dermal abs)/Body weight.</p>			
	<b>Parameters</b>	<b>Value</b>	<b>References</b>
Tiers 1	Ca(OH) <sub>2</sub> concentration after dilution	33%	Applicant's data
	Assumed calcium fraction	17.9	See calculation above
	Assumed magnesium fraction	0.69	See calculation above
	Product application rate	800 g/m <sup>2</sup>	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
	Area of hands- palms only of both hands	410 cm <sup>2</sup>	
	Proportion of palm hands in contact with wet product	100%	Recommendation 5
Transfer coefficient from treated surfaces to hand	50%		

**Calculations for Scenario [24]****Systemic effect - calcium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [24]	-	4.89E+01	4.89E+01

**Systemic effect - magnesium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [24]	-	1.89E+00	1.89E+00

**Scenario [25]: Secondary exposure – Contact with dried surfaces -Post application****Description of Scenario [25]**

Dermal exposure of the professional (adult) touchings the dried wall with hands well after the application can occur.

Considering that the milk of lime is a suspension strongly adhering to the wall to be efficiency, it can be compared to a paint. Therefore, the exposure assessment is performed according to the parameters of dried residus agreed in the HEAd Hoc Recommendation 5.

The assumed calcium and magnesium fractions of the milk of lime has been considered in the calculation considering the dilution of the powder in the water.

The dermal systemic dose, in mg a.s./kg b.w./d is calculated as follow:

Systemic dose = (Amount of product in contact with skin\* Skin contact factor\*Transfer coefficient\* Dermal abs)/Body weight

	Parameters	Value	References
Tiers 1	Ca(OH) <sub>2</sub> concentration after dilution	33%	Applicant's data
	Assumed calcium fraction	17.9%	See calculation above
	Assumed magnesium fraction	0.69%	See calculation above
	Product application rate	800 g/m <sup>2</sup>	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)
	Area of hands-Palm only of both hands	410 cm <sup>2</sup>	
	Proportion of palm hands in contact with dried product	40%	HEAd Hoc Recommendation 5
	Transfert coefficient of paint from treated surface to hand	3%	

**Calculations for Scenario [25]****Systemic effect - calcium**

Exposure scenario	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [25]	-	1.17E+00	1.17E+00

**Systemic effect - magnesium**

Exposure scenario	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [25]	-	4.53E-02	4.53E-02



**Scenario [26] – Dermal and oral exposure to wet surfaces – Toddler**

<b>Description of Scenario [26]</b>			
<p>The secondary exposure of toddlers touching the wet treated wall with a hand to mouth transfer immediately after application is considered. Inhalation of volatilised residues after application (indoors) is considered to be negligible due to the low volatile properties of the active substance.</p> <p>Assessment is performed according the parameters agreed in HEAd Hoc Recommendation 5: "Non-professional use of antifouling paints: exposure assessment for a toddler".</p>			
	<b>Parameters</b>	<b>Value</b>	<b>References</b>
Tiers 1	Ca(OH) <sub>2</sub> concentration	33%	Applicant's data
	Assumed calcium fraction	17.9	See calculation above
	Assumed magnesium fraction	0.69	See calculation above
	Product application rate	800 g/m <sup>2</sup>	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Oral absorption	100%	Default value, CAR
	Toddler body weight (kg)	10	Ad Hoc Recommendation 14 (2017)
	Proportion of hands- palms only of both hands	115.2 cm <sup>2</sup>	
	Proportion of palm hand in contact with wet product	100%	HEAd Hoc Recommendation 5
	Transfer coefficient of wet product from treated surface to hand	50%	
	Transfer coefficient of wet product from treated surface to mouth	10%	

**Calculations for Scenario [26]****Systemic effect - calcium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated oral uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [26]	-	7.42E+01	8.25E+00	8.25E+01

**Systemic effect - magnesium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated oral uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [26]	-	2.86E+00	3.18E-01	3.18E+00

**Scenario [27] – Dermal and oral exposure to dried surfaces - Toddler****Description of Scenario [27]**

The secondary exposure of toddlers who touches the dried treated wall with a hand to mouth transfer well after the application is considered.

According to the Recommendation 5, it is possible to refine the Tier 1 assessment of dermal exposure and oral exposure through hand-to-mouth transfer of a toddler touching dried antifouling paint on a treated surface by using leaching data.

	<b>Parameters</b>	<b>Value</b>	<b>References</b>
Tiers 1	Ca(OH) <sub>2</sub> concentration	33%	Applicant's data
	Assumed calcium fraction	17.9	See calculation above
	Assumed magnesium fraction	0.69	See calculation above
	Product application rate	800 g/m <sup>2</sup>	Applicant's data
	Dermal absorption	100%	Default value, CAR
	Oral absorption	100%	Default value, CAR
	Toddler body weight (kg)	10	HEAd Hoc
	Proportion of hands- palms only of both hands	115.2 cm <sup>2</sup>	Recommendation 14 (2017)
	Proportion of palm hand in contact with dried product	40%	HEAd Hoc Recommendation 5
	Transfer coefficient of dried product from treated surface to hand	3%	
	Transfer coefficient of dried product from treated surface to mouth	50%	

**Calculations for Scenario [27]****Systemic effect - calcium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated oral uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [27]	-	1.78E+00	7.92E-01	2.57E+00

**Systemic effect - magnesium**

<b>Exposure scenario</b>	<b>Estimated inhalation uptake (mg/kg bw/d)</b>	<b>Estimated dermal uptake (mg/kg bw/d)</b>	<b>Estimated oral uptake (mg/kg bw/d)</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
Scenario [27]	-	6.87E-02	3.05E-02	9.92E-02

## **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<sup>2</sup> without ventilation.

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

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

It should be noticed that the submitted exposure data are measured data performed in the frame of the OEL regulation. Indeed, this type of report data has to be submitted regularly to ensure that the use of the lime is in line with the OEL regulation.

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

### **Worker selection**

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

Two HEGs have been determined based on the type of spreading: a shovel or a low impact spreader.

Another HEG was identified for the cleaning task. This post application task includes the collect of lime powder using a shovel and its emptying into a bag.

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

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

#### **Summary table : Construction of the Homogeneous Exposure Group**

HEG N°	Performed task	Number of measurements	Treatment area	Substance of interest
1	Manual application with a shovel	9	Indoor (37.8m <sup>2</sup> )	Calcium oxide
2	Semi-automated application with a low impact spreader	9	Indoor (37.8m <sup>2</sup> )	Calcium oxide
3	Cleaning	9	Indoor (37.8m <sup>2</sup> )	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<sup>8</sup>.

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).

<sup>8</sup> *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.*

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<sup>3</sup>)

Inhalation exposure has been calculated for each task.

As part of the biocidal assessment, the measured raw values are used. A summary of the results obtained is described in the table below.

**Table 1: Measured exposure concentrations (mg/m<sup>3</sup>) on the task duration per HEG**

	<b>HEG N°1 (manual application with a shovel)</b>	<b>HEG N°2 (application with a spreader)</b>	<b>HEG N°3 (surface cleaning)</b>
	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
<b>Mean</b>	<b>3.63</b>	<b>2.98</b>	<b>1.76</b>
<b>95th percentile</b>	<b>9.58</b>	<b>5.59</b>	<b>2.79</b>

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

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

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

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

**Table 2: Measured Exposure concentrations (mg/m<sup>3</sup>) on the full shift per HEG**

	<b>HEG N°1 (manual application using a shovel)</b>	<b>HEG N°2 (application with a spreader)</b>	<b>HEG N°3 (surface cleaning)</b>
	0.13	0.05	0.012
	0.017	0.029	0.044
	0.028	0.04	0.038

	0.036	0.06	0.073
	0.15	0.026	0.079
	0.033	0.11	0.06
	0.078	0.03	0.09
	0.034	0.05	0.04
	0057	0.03	0.04
<b>Mean</b>	<b>0.06</b>	<b>0.05</b>	<b>0.05</b>
<b>95th percentile</b>	<b>0.14</b>	<b>0.092</b>	<b>0.087</b>

### **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 m<sup>2</sup>. It has been assumed that the inhalation exposure of professionals during the application of lime product powder does not increase with the treated surface due to the good natural ventilation expected in animal accommodations, the moistening of the soil that is intended before treatment and considering the behaviour of the operator when applying the product (professional gesture and removal from the dust source).

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

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

## **Dietary exposure**

Regarding intended uses on sewage sludge (TP2 use#1) and manure (TP3 use#2), no dietary exposure is expected.

Regarding intended uses on floors and walls surface indoor in livestock accommodations or transportations (TP3 use#3 and use#5) and uses on floors of outdoor animal enclosures (TP3 use#6), no dietary exposure is expected considering the risk mitigation 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*").

Regarding intended uses on bedding materials (TP3 use#4), the animals may be in direct contact with the active substance. Therefore, an indirect exposure via food of animal origin might be expected for these uses.

eCA has asked the applicant to compare the quantities of active substance as a biocides, to those of already authorized uses in the plant protection framework, including fertilisers. Following this request, the applicant provided an assessment of animal exposure.

Nevertheless, in view of the toxicological properties of this active substance regarding oral exposure, but also the widely presence of calcium in food, eCA considers that those calculations are overestimated and not necessary to support this dossier.

### Information of non-biocidal use of the active substance

**Calcium hydroxide** is listed as a basic substance (approval date 01/07/2015) in accordance with Regulation (EC) No. 1107/2009. (Implementing Regulation (EU) No 540/2011). It is included in Annex IV to (EC) No. 396/2005 and thus no MRL are required from PPP uses.

Calcium hydroxide 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 hydroxide is also listed in annex II of regulation 1333/2008, as approved food additives at "quantum satis" and in annex II of regulation 1925/2006 as approved food supplements.

### Residue definitions

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

<b>Summary table of other (non-biocidal) uses</b>			
	<b>Sector of use<sup>1</sup></b>	<b>Intended use</b>	<b>Reference value(s)<sup>2</sup></b>
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

<sup>1</sup> e.g. plant protection products, veterinary use, food or feed additives

<sup>2</sup> e.g. MRLs. Use footnotes for references.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

The active substance is composed of  $\text{Ca}^{2+}$ , 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 exposure – calcium**

<b>Scenarios and values to be used in risk assessment</b>			
<b>Scenario number</b>	<b>Exposed group</b>	<b>Tier/PPE</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
<b>Disinfection of sewage sludge and manures (Uses # 1 &amp; 2)</b>			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	5.36E+00
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	5.52E+00
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	8.06E-01
Scenario [4] – cleaning of the treatment unit	Professionals	Tier 1/no PPE	1,50E+01
		Tier 2a/gloves	6.32E+00
		Tier 2b/ gloves + coated coverall	2.14E+00
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	4.7E-03
<b>Disinfection of floor surfaces of animal accommodations, transportation and animal bedding materials (Uses # 3&amp;4)</b>			
Scenario [7] – manual loading into the wheelbarrow	Professionals	Tier 1/no PPE	5.31E+00
Scenario [8a] – manual application – indoor – <b>Minimal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	2.13E+01
		Tier 2a/gloves	1.43E+00
Scenario [8b] – manual application – indoor – <b>Maximal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	1.79E+02
		Tier 2b/gloves + RPE (APF 40)	8.87E+00
Scenario [8c] – manual application – indoor – <b>Minimal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	9.02E+00
		Tier 2b/gloves + RPE (APF 40)	6.56E-01
Scenario [8d] – manual application – indoor – <b>Maximal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	6.26E+01
		Tier 2a/gloves	4.07E+00
Scenario [9] – semi automated loading into the tank of tractor	Professionals	Tier 1/no PPE	5.22E+00

Scenario [10a] – semi-automated application – indoor – <b>Minimal</b> floor surfaces – <b>Poultry</b>	Professionals	Tier 1/no PPE	9.92E-01
Scenario [10b] – semi-automated application – indoor – <b>Maximal</b> floor surfaces – <b>Poultry</b>	Professionals	Tier 1/no PPE	7.48E+00
		Tier 2a/gloves	7.00E-01
Scenario [10c] – semi-automated application – indoor – <b>Minimal</b> floor surfaces – <b>Cattle</b>	Professionals	Tier 1/no PPE	4.92E-01
Scenario [10d] – semi-automated application – indoor – <b>Maximal</b> floor surfaces – <b>Cattle</b>	Professionals	Tier 1/no PPE	2.62E+00
Scenario [11] – Disposal of empty bags	Professionals	Tier 1/no PPE	4.7E-03
Scenario [12] – Disposal of product after floor application	Professionals	Tier 1/no PPE	2.09E+01
		Tier 2a/gloves	1.07E+00
<b>Disinfection of floors of outdoor animal enclosures (Use #6)</b>			
Scenario [13a] – manual application onto <b>minimal</b> floor surfaces- outdoor – <b>Poultry</b>	Professionals	Tier 1/no PPE	2.11E+01
		Tier 2a/gloves	1.21E+00
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor – <b>Poultry</b>	Professionals	Tier 1/no PPE	1.77E+02
		Tier 2b/gloves + RPE (APF 40)	8.83E+00
Scenario [14] – semi automated loading into the tank of a tractor - outdoor	Professionals	Tier 1/no PPE	5.15E+00
Scenario [15a] – semi-automated application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Professionals	Tier 1/no PPE	9.03E-01
Scenario [15b] – semi-automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Professionals	Tier 1/no PPE	7.23E+00
		Tier 2a/gloves	4.44E-01
Scenario [16] – Disposal of empty bags	Professionals	Tier 1/no PPE	4.7E-03
Scenario [17] – Disposal of product after disinfection- outdoor	Professionals	Tier 1/no PPE	2.13E+01
		Tier 2a/gloves	1.43E+00

<b>Disinfection of animal accommodations walls using a brush (Use #5)</b>			
Scenario [18]- Automated transfer to a medium volume tank	Professionals	Tier 1/no PPE	7.28E-01
Scenario [19]- manual loading from medium volume tank to a bucket	Professionals	Tier 1/no PPE	2.23E+01
		Tier 2a/gloves + impermeable coverall	2.27E-01
Scenario [20]- manual loading from small bag to a bucket	Professionals	Tier 1/no PPE	1.33E+01
		Tier 2a/gloves	1.43E+00
Scenario [21]- application on walls by brush	Professionals	Tier 1/no PPE	7.60E+00
		Tier 2a/gloves	2.80E+00
Scenario [24] – dermal contact with wet treated surfaces - adults	Professionals and general public	Tier 1/no PPE	4.89E+01
Scenario [23] – Disposal of empty bags	Professionals	Tier 1/no PPE	4.7E-03
Scenario [25] – dermal contact with dried treated surfaces - adults	Professionals and general public	Tier 1/no PPE	1.17E+00
Scenario [26] – dermal and oral contact with wet treated surfaces - toddler	General public	Tier 1/no PPE	8.25E+01
Scenario [27] – dermal and oral contact with dried treated surfaces - toddler	General public	Tier 1/no PPE	2.57E+00

### Local effect – calcium dihydroxide

<b>Scenarios and values to be used in risk assessment</b>			
<b>Scenario number</b>	<b>Exposed group</b>	<b>Tier/PPE</b>	<b>Estimated total uptake (mg/kg bw/d)</b>
<b>Disinfection of sewage sludge and manures (Uses # 1 &amp; 2)</b>			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	2.32E+01
		Tier 2/ RPE (APF 40)	5.80E-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	Professionals	Tier 1/no PPE	3.77E+01
		Tier 2/ RPE (APF 40)	3.77E+00
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.5
		Tier 2/ RPE (APF 40)	0.063
<b>Disinfection of floor surfaces of animal accommodations , transportation animal bedding materials (Uses # 3&amp;4)</b>			
Scenario [7] – manual loading for floor application	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2/ RPE (APF 40)	2.75E+00
Scenario [8a] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2a/ RPE (APF 40)	2.75E+00
Scenario [8b] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	9.70E+01
		Tier 2b/ RPE (APF 40)	2.43E+00
Scenario [8c] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Professionals	Tier 1/no PPE	1.40E+02
		Tier 2b/ RPE (APF 40)	3.50E+00
Scenario [8d] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Professionals	Tier 1/no PPE	9.70E+01
		Tier 2b/ RPE (APF 40)	2.43E+00
	Professionals	Tier 3/no PPE	9.58

Scenario [8] – manual loading + application onto floor surfaces- indoor – <b>Field study</b>		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 <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	1.10E+02
		Tier 2b/ RPE (APF 40)	2.75E+00
Scenario [10b] – Semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	4.50E+01
		Tier 2b/ RPE (APF 40)	1.13E+00
Scenario [10c] – Semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Professionals	Tier 1/no PPE	3.60E+02
		Tier 2b/ RPE (APF 40)	9.00E+00
Scenario [10d] – Semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	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 – <b>Field study</b>	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 – <b>Field study</b>	Professionals	Tier 1/no PPE	2.79E+00
		Tier 1b/RPE (APF 10)	2.79E-01
<b>Disinfection of floors of outdoor animal enclosures (Use #6)</b>			
Scenario [13a] – manual application onto <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Professionals	Tier 1/no RPE	4.50E+01
		Tier 2/ RPE (APF40)	1.13E+00
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Professionals	Tier 1/no RPE	4.50E+01
		Tier 2/ RPE (APF40)	1.13E+00
Scenario [13] – manual loading + application onto floor surfaces- outdoor – <b>Field study</b>	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 <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Professionals	Tier 1/no RPE	1.10E+01
		Tier 2/ RPE (APF40)	2.75E-01
Scenario [15b] – semi-automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	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- <b>Field study</b>	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- <b>Field study</b>	Professionals	Tier 1/no PPE	2.79E+00
		Tier 1b/RPE (APF 10)	2.79E-01
<b>Disinfection of animal accommodations walls using a brush (Use #5)</b>			
Scenario [18]- Automated transfer to a medium volume tank	Professionals	Tier 1/no PPE	4.90E+00
		Tier 2/ RPE (APF40)	1.23E-01
Scenario [19]- manual loading from medium volume tank to a bucket	Professionals	Tier 1/no PPE	3.10E-01
		Tier 2/ RPE (APF4)	7.76E-02
Scenario [20]- manual loading from small bag to a bucket	Professionals	Tier 1/no PPE	1.60E+03
		Tier 2/ RPE (APF40)	3.99E+01
Scenario [21]- application on walls by brush	Professionals	Tier 1/no PPE	5.38E-01
		Tier 2/ RPE (APF4)	1.34E-01
Scenario [23] – Disposal of empty bags	Professionals	Tier 1/no PPE	2.5E+00
		Tier 2/RPE (APF 40)	6.3E-02

### Systemic exposure – magnesium

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group	Tier/PPE	Estimated total uptake (mg/kg bw/d)
<b>Disinfection of sewage sludge and manures (Uses # 1 &amp; 2)</b>			
Scenario [1] – manual loading	Professionals	Tier 1/no PPE	2.08E-01
Scenario [2] – semi-automated loading	Professionals	Tier 1/no PPE	2.14E-01
Scenario [3] – automated loading	Professionals	Tier 1/no PPE	3.13E-02
Scenario [4] – cleaning of the treatment unit	Professionals	Tier 1/no PPE	5.84E-01
		Tier 2a/gloves	2.45E-01
Scenario [5] – Disposal of empty bags	Professionals	Tier 1/no PPE	1.74E-04
<b>Disinfection of floor surfaces of animal accommodations, transportation and animal bedding materials (Uses # 3&amp;4)</b>			
Scenario [7] – manual loading into the wheelbarrow	Professionals	Tier 1/no PPE	2.06E-01
Scenario [8a] – manual application – indoor – <b>Minimal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	8.26E-01
		Tier 2a/gloves	5.56E-02
Scenario [8b] – manual application – indoor – <b>Maximal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	6.94E+00
		Tier 2a/gloves	4.54E-01
Scenario [8c] – manual application – indoor – <b>Minimal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	3.50E-01
		Tier 2a/gloves	2.55E-02
Scenario [8d] – manual application – indoor – <b>Maximal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	2.43E+00
		Tier 2a/gloves	1.58E-01
Scenario [9] – semi automated loading into the tank of tractor	Professionals	Tier 1/no PPE	2.02E-01
Scenario [10a] – semi-automated application – indoor – <b>Minimal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	3.85E-02
Scenario [10b] – semi-automated application – indoor – <b>Maximal</b> floor surfaces - <b>Poultry</b>	Professionals	Tier 1/no PPE	2.91E-01

Scenario [10c] – semi-automated application – indoor – <b>Minimal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	1.91E-02
Scenario [10d] – semi-automated application- indoor – <b>Maximal</b> floor surfaces - <b>Cattle</b>	Professionals	Tier 1/no PPE	1.02E-01
Scenario [11] – Disposal of empty bags	Professionals	Tier 1/no PPE	1.74E-04
Scenario [12] – Disposal of product after floor application	Professionals	Tier 1/no PPE	8.12E-01
		Tier 2a/ gloves	4.14E-02
<b>Disinfection of floors of outdoor animal enclosures (Use #6)</b>			
Scenario [13a] – manual application onto <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	8.18E-01
		Tier 2a/gloves	4.69E-02
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Professionals	Tier 1/no PPE	6.88E+00
		Tier 2a/gloves	3.94E-01
Scenario [14] – semi automated loading- outdoor	Professionals	Tier 1/no PPE	2.00E-01
Scenario [15a] – semi-automated application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Professionals	Tier 1/no PPE	3.51E-02
Scenario [15b] – semi-automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Professionals	Tier 1/no PPE	2.81E-01
Scenario [16] – Disposal of empty bags	Professionals	Tier 1/no PPE	1.74E-04
Scenario [17] – Disposal of product after disinfection- outdoor –	Professionals	Tier 1/no PPE	8.26E-01
		Tier 2a/gloves	5.56E-02
<b>Disinfection of animal accommodations walls using a brush (Use #5)</b>			
Scenario [18]- Automated transfer to a medium volume tank	Professionals	Tier 1/no PPE	2.82E-02
Scenario [19]- manual loading from medium volume tank to a bucket	Professionals	Tier 1/no PPE	8.64E-01
		Tier 2a/gloves + impermeable coverall	8.79E-03
Scenario [20]- manual loading from small bag to a bucket	Professionals	Tier 1/no PPE	5.17E-01
		Tier 2a/gloves	5.57E-02
Scenario [21]- application on walls by brush	Professionals	Tier 1/no PPE	2.93E-01



Scenario [24] – dermal contact with wet treated surfaces - adults	Professionals and general public	Tier 1/no PPE	1.89E+00
Scenario [23] – Disposal of empty bags	Professionals	Tier 1/no PPE	1.74E-04
Scenario [25] – dermal contact with dried treated surfaces - adults	Professionals and general public	Tier 1/no PPE	4.53E-02
Scenario [26] – dermal and oral contact with wet treated surfaces - toddler	General public	Tier 1/no PPE	3.18E+00
Scenario [27] – dermal and oral contact with dried treated surfaces - toddler	General public	Tier 1/no PPE	9.92E-02

### 2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation – **calcium hydroxide (Ca(OH)<sub>2</sub>)**

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

<sup>1</sup> default for dynamic intraspecies differences

Reference values to be used in Risk Characterisation – **calcium (Ca<sup>2+</sup>)**

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

Reference values to be used in Risk Characterisation – **magnesium (Mg<sup>2+</sup>)**

Reference	Study	NOAEL (LOAEL)	AF <sup>1</sup>	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  $\text{Ca}^{2+}$  and  $\text{Mg}^{2+}$ ) 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  $\text{Ca}^{2+}$**  and **250 mg/d (= 4.2 mg/kg bw/d) for  $\text{Mg}^{2+}$** .

During the meeting WG I 2022, it has been demonstrated that even considering a recommended daily intake of 950 mg  $\text{Ca}^{2+}$ /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<sup>2+</sup>)**

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [1] – manual loading	Tier 1/no PPE	42	5.36E+00	12.77%	YES
Scenario [2] – semi-automated loading	Tier 1/no PPE	42	5.52E+00	13.1%	YES
Scenario [3] – automated loading	Tier 1/no PPE	42	8.06E-01	1.92%	YES
Scenario [4]-cleaning	Tier 1/no PPE	42	1.50E+01	35.83%	YES
	Tier 2a/gloves	42	6.32E+00	15.04%	YES
	Tier 2b/ gloves + coated coverall	42	2.14E+00	5.10%	YES
Scenario [5]- Disposal of empty bags	Tier 1/no PPE	42	4.7E-03	0.011%	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	2.02E+01	48.05%	YES
	Tier 2/ gloves + coated coverall		2.6E+00	6.19%	YES
Scenario 2-4+5	Tier 1/no PPE	42	2.02E+01	48.05%	YES
	Tier 2/ gloves + coated coverall		2.8E+00	6.626%	YES

**Systemic effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [1] – manual loading	Tier 1/no PPE	4.2	2.08E-01	4.96%	YES
Scenario [2] – semi-automated loading FORKLIFT- INDOOR	Tier 1/no PPE	4.2	2.14E-01	5.10%	YES
Scenario [3] – automated loading	Tier 1/no PPE	4.2	3.13E-02	0.75%	YES
Scenario [4]- cleaning	Tier 1/no PPE	4.2	5.84E-01	13.91%	YES
	Tier 2a/gloves	4.2	2.45E-01	5.94%	YES
Scenario [5]- Disposal of empty bags	Tier 1/no PPE	4.2	1.74E-04	0.004%	YES

**Combined Exposure – [Loading phase+ cleaning phase+disposal of empty bags] (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario 1-4+5	Tier 1/no PPE	4.2	5.71E+00	136.06%	<b>NO</b>
	Tier 2/gloves		5.0E-01	11.9%	YES
Scenario 2-4+5	Tier 1/no PPE	4.2	7.83E-01	18.65%	YES
	Tier 2/gloves		2.55E-01	6.07%	YES

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

<b>Task/ Scenario</b>	<b>Tier</b>	<b>AEC mg/m3</b>	<b>Estimated uptake mg/m3</b>	<b>Estimated uptake/ AEC (%)</b>
Scenario [1] – manual loading	Tier 1/no RPE	0.3	2.32E+01	<b>7733.3%</b>
	Tier 2/ RPE (APF40)	0.3	5.80E-01	<b>193.3%</b>
Scenario [2] – semi-automated loading FORKLIFT - indoor	Tier 1/no RPE	0.3	1.70E+01	<b>5666.7%</b>
	Tier 2/ RPE (APF40)	0.3	4.25E-01	<b>141.7%</b>
Scenario [2] - semi-automated loading TELEHANDLER - indoor	Tier 1/no PPE	0.3	1.10E+00	<b>367</b>
	Tier 2b/ RPE (APF40)	0.3	0.03E+00	10
Scenario [3] – automated loading	Tier 1/no RPE	0.3	3.90E+00	<b>1300.0%</b>
	Tier 2/ RPE (APF40)	0.3	9.75E-02	32.5%
Scenario [4] - cleaning	Tier 1/no RPE	0.3	2.32E+01	<b>7733%</b>
	Tier 2/ RPE (APF40)	0.3	5.80E-01	<b>193.3%</b>
Scenario [5] – Disposal of empty bags	Tier 1/no RPE	0.3	2.5	<b>833</b>
	Tier 2/ RPE (APF40)	0.3	0.063	21

○ **Qualitative local risk assessment**

The product EULA HYDRA-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:	

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	- Wear: - Substance/ task appropriate gloves - Protection coverall - Face shield - Substance/ task appropriate respirator	
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## **Disinfection of sewage sludges 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 dihydroxide 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/m<sup>3</sup> 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<sup>3</sup> 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, animal transportation and bedding materials (Uses # 3 & 4)**

**Systemic effects (Ca<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [7] – manual loading for floor application	Tier 1/no PPE	42	5.31E+00	12.64%	YES
Scenario [8a] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	2.13E+01	50.69%	YES
	Tier 2/gloves	42	1.43E+00	3.41%	YES
Scenario [8b] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	1.79E+02	425.93%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)	42	8.87E+00	21.12%	YES
Scenario [8c] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	9.02E+00	21.47%	YES
	Tier 2/gloves	42	6.56E-01	1.56%	YES
Scenario [8d] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	6.26E+01	149.03%	<b>NO</b>
	Tier 2/gloves	42	4.07E+00	9.70%	YES
Scenario [9] – semi-automated loading- indoor	Tier 1/no PPE	42	5.22E+00	12.42%	YES
Scenario [10a] – Semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	9.92E-01	2.36%	YES
Scenario [10b] – Semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	7.48E+00	17.82%	YES
	Tier 2/gloves	42	7.00E-01	1.67%	YES
Scenario [10c] – Semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	4.92E-01	1.17%	YES
Scenario [10d] – Semi-automated application	Tier 1/no PPE	42	2.62E+00	6.23%	YES

onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>					
Scenario [11] – Disposal of empty bags	Tier 1/no PPE	42	4.7E-03	0.011%	YES
Scenario [12] – Disposal of the product after application	Tier 1/no PPE	42	2.09E+01	49.81%	YES
	Tier 2a/no PPE		1.07E+00	2.54%	YES

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

#### Combined effects (Ca<sup>2+</sup>)

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 <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	2.66E+01	63.35%	YES
	Tier 2/gloves		1.88E+00	4.47%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	1.84E+02	438.62%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		9.33E+00	22.21%	YES
Manual loading – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	1.43E+01	34.16%	YES
	Tier 2/gloves		1.12E+00	2.66%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	6.79E+01	161.72%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		3.57E+00	8.5%	YES
Semi-automated loading – semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	6.21E+00	14.78%	YES
	Tier 2/gloves		4.9E-01	1.16%	YES
Semi-automated loading – semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	42	1.27E+01	30.2%	YES
	Tier 2/gloves		1.04E+00	2.5%	YES
Semi-automated loading – semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	5.71E+00	13.59%	YES
	Tier 2/gloves		4.99E-01	1.18%	YES
Semi-automated loading – semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	42	7.84E+00	18.7%	YES
	Tier 2/gloves		5.88E-01	1.4%	YES

**Systemic effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (YES/NO)</b>
Scenario [7] – manual loading for floor application	Tier 1/no PPE	4.2	2.06E-01	4.91%	YES
Scenario [8a] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	8.26E-01	19.68%	YES
	Tier 2/gloves		5.56E-02	1.32%	YES
Scenario [8b] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	6.94E+00	165.33%	<b>NO</b>
	Tier 2/gloves		4.54E-01	10.80%	YES
Scenario [8c] – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	3.50E-01	8.33%	YES
Scenario [8d] – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	2.43E+00	57.85%	YES
	Tier 2/gloves		1.58E-01	3.76%	YES
Scenario [9] – semi-automated loading-indoor	Tier 1/no PPE	4.2	2.02E-01	4.82%	YES
Scenario [10a] – Semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	3.85E-02	0.92%	YES
Scenario [10b] – Semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	2.91E-01	6.92%	YES
Scenario [10c] – Semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	1.91E-02	0.46%	YES
Scenario [10d] – Semi-automated application onto <b>maximal</b> floor	Tier 1/no PPE	4.2	1.02E-01	2.42%	YES

surfaces- indoor - <b>Cattle</b>					
Scenario [11]- Disposal of empty bags	Tier 1/no PPE	4.2	1.74E-04	0.004%	YES
Scenario [12] - Disposal of product after application	Tier 1/no PPE	4.2	8.12E-01	19.34%	YES
	Tier 2a/gloves		4.14E-02	0.99%	YES

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

**Combined effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Manual loading – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tiers 1/no PPE	4.2	1.03E+00	24.59%	YES
	Tier 2/gloves		7.3E-02	1.7%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	7.15E+00	170.26%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		4.71E-01	11.22%	YES
Manual loading – manual application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	5.57E-01	13.26%	YES
	Tier 2/gloves		4.33E-02	1.03%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	2.64E+00	62.78%	YES
	Tier 2/gloves		1.76E-01	4.18%	YES
Semi-automated loading – semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	2.41E-01	5.74%	YES
Semi-automated loading – semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Poultry</b>	Tier 1/no PPE	4.2	4.93E-01	11.74%	YES
Semi-automated loading – semi-automated application onto <b>minimal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	2.22E-01	5.28%	YES
Semi-automated loading – semi-automated application onto <b>maximal</b> floor surfaces- indoor - <b>Cattle</b>	Tier 1/no PPE	4.2	3.04E-01	7.24%	YES

○ **Semi-quantitative local risk assessment**

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



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



- **Qualitative local risk assessment**

The product EULA HYDRA-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, animal transportation and bedding materials**

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, processes, uses,	Potential exposure route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
Very High	Eye Dam.1, H318	-	3	Professionals	-Loading from the bags to the wheelbarrow/tractor -Application on the floor surfaces -Disposal of the lime product after application	Dermal Sources for contamination being from: - opening and handling bags - cleaning - hand to eye transfer	few minutes per day or less	Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM:  - Wear: - Substance/ task appropriate gloves - Protective coverall - Face shield - Substance/	Acceptable following the relevant RMM and PPE
Low	Skin Irrit.2, H315	-				Dermal Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day		

Low	STOT SE 3, H335					Inhalation Sources for contamination being from: - opening and handling bags - cleaning	More than few minutes but equal to or less than few hours per day	task appropriate respirator	
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## Disinfection of indoor floor surfaces of animal accommodations, animal transportation and bedding materials (Uses #3 and 4) - 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  $\leq 1\mu\text{m}$ ) whereas the AEC value set for  $\text{CaOH}_2$  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 HYDRA 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<sup>9</sup> and NF EN 143<sup>10</sup>*, 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.

<sup>9</sup> NF EN 159: Respiratory protective devices – Recommendations for selection, use, care and maintenance – Guidance document.

<sup>10</sup> 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<sup>3</sup> (short, medium and long-term) is based on an epidemiological study in humans (██████████ 2004<sup>11</sup>).

In this study, 12 volunteers were exposed during 20 min to 0, 1, 2 and 5 mg/m<sup>3</sup> CaO dust. The parameters studied included nasal resistance, nasal secretion, mucociliary transport time and chemesthetic 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 chemesthetic 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<sup>3</sup> 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<sup>3</sup>.

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<sup>3</sup>.

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.

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<sup>11</sup> ██████████ 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 outdoor animal enclosures (Use # 6)

### Systemic effects (Ca<sup>2+</sup>)

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 <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	42	2.11E+01	50.15%	YES
	Tier 2/gloves		1.21E+00	2.87%	YES
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	42	1.77E+02	422.28%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		8.83E+00	21.03%	YES
Scenario [14] – semi-automated loading- outdoor- <b>Poultry</b>	Tier 1/no PPE	42	5.15E+00	12.25%	YES
Scenario [15a] – semi-automated application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no PPE	42	9.03E-01	2.15%	YES
Scenario [15b] – semi-automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no PPE	42	7.23E+00	17.21%	YES
	Tier 2/gloves		4.44E-01	1.06%	YES
Scenario [16] – Disposal of empty bags	Tier 1/no PPE	42	4.7E-03	0.011	YES
Scenario [17] – Disposal of the product after the application	Tier 1/no PPE	42	2.13E+01	48.41%	YES
	Tier 2/gloves		1.43E+00	3.25%	YES

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

#### Combined effects (Ca<sup>2+</sup>)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptabl e (yes/no)
Manual loading – manual application onto <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Tiers 1/no PPE	42	2.72E+01	64.73%	YES
	Tier 2/gloves		2.1E+00	5.1%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	42	1.89E+02	450.85%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		9.53E+00	22.69%	YES
Manual loading-manual application - <b>Field study</b>	Tier 3/no PPE	42	2.09E+01	49.84%	YES
	Tier 3a/gloves		1.08E+00	2.57%	YES
Manual disposal of lime after application – <b>Field study</b>	Tier 3/no PPE	42	2.09E+01	49.81%	YES
	Tier 3a/gloves		1.07E+00	2.54%	YES
Semi-automated loading-semi-automated application onto <b>minimal</b> floor surfaces-outdoor- <b>Poultry</b>	Tiers 1/no PPE	42	6.05E+00	14.41%	YES
	Tier 2a/gloves		3.28E-01	0.78%	YES
Semi-automated loading-semi-automated application onto <b>maximal</b> floor surfaces-outdoor- <b>Poultry</b>	Tiers 1/no PPE	42	1.24E+01	29.46%	YES
	Tier 2/gloves		7.16E-01	1.71%	YES
Semi-automated loading-semi-automated application - <b>Field study</b>	Tier 3/no PPE	42	9.16E-01	2.18%	YES



**Systemic effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [13a] – manual application onto <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	4.2	8.18E-01	19.47%	YES
	Tier 2/gloves		4.69E-02	1.12%	YES
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	4.2	6.88E+00	163.92%	<b>NO</b>
	Tier 2/gloves		3.94E-01	9.38%	YES
Scenario [14] – semi-automated loading- outdoor- <b>Poultry</b>	Tier 1/no PPE	4.2	2.00E-01	4.76%	YES
Scenario [15a] – semi-automated application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no PPE		3.51E-02	0.84%	YES
Scenario [15b] – semi-automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no PPE	4.2	2.81E-01	6.68%	YES
Scenario [16] – Disposal of empty bags	Tier 1/no PPE	4.2	1.74E-04	0.004%	YES
Scenario [17] – disposal	Tier 1/no PPE	4.2	8.26E-01	19.7%	YES
	Tier 2/gloves		5.56E-02	1.3%	YES

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

**Combined effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>AEL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ AEL (%)</b>	<b>&lt; 13% UL* (yes/no)</b>
Manual loading – manual application onto <b>minimal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	4.2	1.05E+00	25.13%	<b>NO</b>
	Tier 2/gloves		8.29E-02	2.0%	YES
Manual loading – manual application onto <b>maximal</b> floor surfaces- outdoor - <b>Poultry</b>	Tier 1/no PPE	4.2	7.35E+00	175.01%	<b>NO</b>
	Tier 2/gloves + RPE (APF 40)		3.70E-01	8.81%	YES
Semi-automated loading-semi-automated application onto <b>minimal</b> floor surfaces-outdoor- <b>Poultry</b>	Tier 1/no PPE	4.2	2.35E-01	5.59%	YES
Semi-automated loading-semi-automated application onto <b>maximal</b> floor surfaces-outdoor- <b>Poultry</b>	Tier 1/no PPE	4.2	4.80E-01	11.4%	YES

○ **Semi-quantitative local risk assessment**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>AEC (mg/m3)</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated concentration (mg/m3)</b>	<b>Estimated concentration / AEC (%)</b>
Scenario [13a] – manual application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no RPE	0.3	4.50E+01	15000.0%	<b>NO</b>
	Tier 2/ RPE (APF40)		1.13E+00	375.0%	<b>NO</b>
Scenario [13b] – manual application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no RPE	0.3	4.50E+01	15000.0%	<b>NO</b>
	Tier 2/ RPE (APF40)		1.13E+00	375.0%	<b>NO</b>
Manual application onto floor surfaces outdoor- <b>Field study</b>	Tier 3/no PPE	0.3	1.18E+01	3940.0%	<b>NO</b>
	Tier 3b/ RPE (APF 40)		2.96E-01	98.5%	YES
Scenario [14] – semi- automated loading- outdoor- poultry	Tier 1/no RPE	0.3	8.80E+00	2933.3%	<b>NO</b>
	Tier 2/ RPE (APF40)		2.20E-01	73.3%	YES
Scenario [15a] – semi- automated application onto <b>minimal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no RPE	0.3	1.10E+01	3666.7%	<b>NO</b>
	Tier 2/ RPE (APF40)		2.75E-01	91.7%	YES
Scenario [15b] – semi- automated application onto <b>maximal</b> floor surfaces- outdoor- <b>Poultry</b>	Tier 1/no RPE	0.3	1.10E+01	3666.7%	<b>NO</b>
	Tier 2/ RPE (APF40)		2.75E-01	91.7%	YES
Semi- automated application - outdoor – <b>Field study</b>	Tier 3/no PPE	0.3	5.59E+00	1863.3%	<b>NO</b>
	Tier 3b/ RPE (APF 20)		2.80E-01	93.2%	YES

Scenario [16] - Disposal of empty bags	Tier 1/no PPE	0.3	2.5E+00	<b>833%</b>	<b>NO</b>
	Tier 2/RPE (APF 40)		6.3E-02	21%	YES
Scenario [17] - Disposal of lime- outdoor - <b>Field study</b>	Tier 3/no PPE	0.3	2.79E+00	930.0%	<b>NO</b>
	Tier 3b/ RPE (APF 10)		2.79E-01	93.00%	YES



○ **Qualitative local risk assessment**

The product EULA HYDRA-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 of duration 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, technician 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 #6) -**

### **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 #2).

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.

## Disinfection of animal accommodations walls using a brush (Use #5)

### Systemic effects (Ca<sup>2+</sup>)

Task/ Scenario	Tier	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario [18]- Automated transfer to a medium volume tank	Tier 1/no PPE	42	7.28E-01	1.73%	YES
Scenario [19]- manual loading from medium volume tank to a bucket	Tier 1/no PPE	42	2.23E+01	53.09%	YES
	Tier 2/gloves + impermeable coverall		2.27E-01	0.54%	YES
Scenario [20]- manual loading from small bag to a bucket	Tier 1/no PPE	42	1.33E+01	31.7%	YES
	Tier 2/gloves		1.43E+00	3.4%	YES
Scenario [21]- application on walls by brush	Tier 1/no PPE	42	7.60E+00	18.09%	YES
	Tier 2/gloves		2.80E+00	6.66%	YES
Scenario [23] - Disposal of empty bags	Tier 1/no PPE	42	4.7E-03	0.011	YES
Scenario [24] - dermal contact with wet treated surfaces - adults	Tier 1/no PPE	42	4.89E+01	116.50%	<b>NO</b>
Scenario [25] - dermal contact with dried treated surfaces - adults	Tier 1/no PPE	42	1.17E+00	2.8%	YES

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

**Combined effects (Ca<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptabl e (yes/no)</b>
Automated transfer – manual loading to bucket- application	Tiers 1/no PPE	42	3.06E+01	72.8%	<b>NO</b>
	Tier 2/gloves + coverall		3.07E+00	3%	YES
Manual loading – manual application	Tier 1/no PPE	42	2.4E+01	57.1%	YES
	Tier 2/gloves		3.93E+00	9.3%	YES



**Systemic effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [18]- Automated transfer to a medium volume tank	Tier 1/no PPE	4.2	2.82E-02	0.67%	YES
Scenario [19]- manual loading from medium volume tank to a bucket	Tier 1/no PPE	4.2	8.64E-01	20.58%	YES
	Tier 2/gloves + impermeable coverall		8.79E-03	0.21%	YES
Scenario [20]- manual loading from small bag to a bucket	Tier 1/no PPE	4.2	5.17E-01	12.3%	YES
	Tier 2/gloves		5.57E-02	1.3%	YES
Scenario [21]- application on walls by brush	Tier 1/no PPE	4.2	2.93E-01	6.97%	YES
Scenario [23] - Disposal of empty bags	Tier 1/no PPE	4.2	1.74E-04	0.004%	YES
Scenario [24] - dermal contact with wet treated surfaces - adults	Tier 1/no PPE	4.2	1.89E+00	44.9%	YES
Scenario [25] - dermal contact with dried treated surfaces - adults	Tier 1/no PPE	4.2	4.53E-02	1.1%	YES

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

**Combined effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptabl e (yes/no)</b>
Automated transfer – manual loading to bucket- application	Tiers 1/no PPE	4.2	1.18E+00	28.1%	YES
	Tier 2/gloves + coverall		1.18E-01	2.8%	YES
Manual loading – manual application	Tier 1/no PPE	4.2	7.88E-01	18.75%	YES
	Tier 2/gloves		1.56E-01	3.7%	YES

○ **Semi-quantitative local risk assessment**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>AEC (mg/m3)</b>	<b>Estimated concentration (mg/m3)</b>	<b>Estimated concentration / AEC (%)</b>
Scenario [18]- Automated transfer to a medium volume tank	Tier 1/no PPE	0.3	4.90E+00	<b>1633.3%</b>
	Tier 2/ RPE (APF40)		1.23E-01	40.8%
Scenario [19]- manual loading from medium volume tank to a bucket	Tier 1/no PPE	0.3	3,10E-01	<b>103.40%</b>
	Tier 2/ RPE (APF4)		7.76E-02	25.90%
Scenario [20]- manual loading from small bag to a bucket	Tier 1/no PPE	0.3	1.60E+03	<b>531911.1%</b>
	Tier 2/ RPE (APF40)		3.99E+01	<b>13297.8%</b>
Scenario [21]- application on walls by brush	Tier 1/no PPE	0.3	5.38E-01	<b>179.30%</b>
	Tier 2/ RPE (APF4)		1.34E-01	44.80%%
Scenario [23] – Disposal of empty bags	Tier 1/no PPE	0.3	2.5E+00	<b>833%</b>
	Tier 2/RPE (APF 40)		6.3E-02	21%

○ **Qualitative local risk assessment**

The product EULA HYDRA-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 animal accommodations walls with a brush

Hazard			Exposure				Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)	Risk	
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
Very High	Eye Dam.1, H318	-	3	Professionals	-Loading from the bags to the bucket/medium volume tank -Application on walls with milk of lime	Dermal Sources for contamination being from: - opening and handling bags - application - hand to eye transfer	few minutes per day or less	- 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 - application	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	RMM: -Minimisation of splash and spills	
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### **Conclusion for Use #5: Disinfection of animal accommodations; limewashing of walls- PT 3**

Taking into consideration the results on quantitative and qualitative risk assessments, the risk for human health is considered acceptable for the loading and the disposal of empty bags considering the following PPE:

- ✓ gloves
- ✓ protective coverall;
- ✓ 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).

Unacceptable risk has been observed during the manual loading of the powder from a small bag (25 kg) to a final bucket (used to prepare the water suspended lime).

The eCA proposal to use a dosage device to perform the loading and minimizing the inhalation exposure during the task has not been accepted by the Working Group members (WG I 2022) based on the lack of quantitative data to support the proposal.

Therefore, small bags of 25 kg are not authorized for this use.

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

- ✓ gloves;
- ✓ protective coverall,
- ✓ a respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter)

Moreover, the following RMM are needed:

- ✓ Considering the use of big bags (a half to one tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin);
- ✓ Minimisation of splash and spills during application of water suspended lime;
- ✓ Do not let bystander (including co-workers and children) touch the treated surfaces until complete drying.
- ✓ Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (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.

**Risk for non-professional users**

No exposure is foreseen.

**Risk for the general public****Systemic effects (Ca<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [26] – dermal and oral contact with <b>wet</b> treated surfaces - toddler	Tier 1/no PPE	42	8.25E+01	196.39%	<b>NO</b>
Scenario [27] – dermal and oral contact with <b>dried</b> treated surfaces - toddler	Tier 1/no PPE	42	2.57E+00	6.13%	YES

**Systemic effects (Mg<sup>2+</sup>)**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>UL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ UL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [20] – dermal and oral contact with <b>wet</b> treated surfaces - toddler	Tier 1/no PPE	4.2	3.18E+00	75.70%	YES
Scenario [21] – dermal and oral contact with <b>dried</b> treated surfaces - toddler	Tier 1/no PPE	4.2	9.92E-02	2.36%	YES

A following RMM are needed to prevent indirect exposure of children:

- ✓ Do not touch treated surfaces until complete drying;
- ✓ Do not let children enter the treated areas.

## **Overall conclusion**

### **Disinfection of sewage sludge and manures**

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

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

Moreover, it is also likely that the addition of calcium hydroxide to sewage 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 unit treatment 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 unit treatment 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<sup>3</sup> 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, animal transportation, bedding materials 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;
- protection 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;
- For the disposal of small empty bags, moisten the bag and fold it carefully in order to avoid any spills.
- Considering the use of big bags (a half to one 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.

### **Disinfection of animal accommodation walls by brush**

The risk for human health is considered acceptable for the loading 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).

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

- gloves;
- protective coverall;
- respiratory protective equipment at least APF 4 (airtight face piece covering eyes, nose, mouth and chin according to NF EN 149 with a P1 filter).

Moreover, the following RMM are needed:

- Considering the use of big bags (a half to one tone), the loading of the product and the disposal of empty bags must be performed fully automatically using a telehandler (including a closed cabin);
- Minimisation of splash and spills during application of water suspended lime.
- Do not touch the treated surfaces until complete drying.

- Do not let bystander (including co-workers and children) and pets enter the treatment area during all the treatment duration (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.

***Risk for consumers via residues in food***

Considering that the active substance is composed from  $\text{Ca}^{2+}$ , which is an essential element of the body expected to be regulated by the animal metabolism, the general public dietary exposure related to the intended uses is not considered to be relevant.

**Conclusion**

Regarding intended uses on sewage sludge (TP2 use#1) and manure (TP3 use#2), no dietary exposure is expected.

Regarding intended uses on floors and walls surface indoor in livestock accommodations or transportations (TP3 use#3 and use#5) and uses on floors of outdoor animal enclosures (TP3 use#6), no dietary exposure is expected considering the instructions of use (*the product should not be applied in the presence of animals*).

Regarding intended uses on bedding materials (TP3 use#4), the animals may be in direct contact with the active substance. Therefore, an indirect exposure via food of animal origin might be expected for these uses. Nevertheless, regarding the natural exposure and the toxicological properties of the compound under consideration,  $\text{Ca}^{2+}$ , RMS considered that the dietary risk from consumer related to the intended uses is negligible.

***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 HYDRA-LIME 23 is a PT2 and PT3 product containing calcium dihydroxide, Hydrated lime (CAS 1305-62-0) that is applied for:

- disinfection of sewage sludge (PT02),
- disinfection of manure (PT03),
- disinfection of indoor floor of animal accommodations (PT03),
- disinfection of animal bedding materials (PT03),
- disinfection of indoor walls of animal accommodations (PT03),
- disinfection of indoor floor of animal transportation (PT03),
- disinfection of outdoor floors of animal enclosures (PT03).

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 HYDA-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 dihydroxide, Hydrated lime CAS 1305-62-0, Product Type 2: Disinfectants and algacides 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)<sub>2</sub>).

#### **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 HYDRA-LIME 23 are not available. Therefore, all data pertaining to the active substance are derived from the Calcium dihydroxide, Hydrated lime CAR (2016).

##### ***Further Ecotoxicological studies***

No data required.

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

No data available.

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

No data available.

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

No data available.

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

Further information on the secondary ecological effect is not required.

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

Indirect routes: to soil and groundwater from uses in manure, floor of animal accommodations, animal bedding materials, walls of animal accommodations, and sewage sludge.

Direct routes:

- ✓ to soil and groundwater from use in animal outdoor enclosures,
- ✓ to STP from use in animal transportation.

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

No data available.

***Leaching behaviour (ADS)***

No data available.

***Testing for distribution and dissipation in soil (ADS)***

Standard aerobic degradation studies in soil are not considered necessary for hydrated lime. This is because upon addition to soil hydrated lime would simply dissociate to its respective ion constituents where they would form part of existing chemical cycles in the natural environment (Doc IIA of calcium dihydroxide, Hydrated lime UK, 2016).

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

Hydrated lime would simply dissociate to its respective ion constituents ( $\text{Ca}^{2+}$  and  $\text{OH}^-$ ) 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  $\text{Ca}^{2+}$  and  $\text{OH}^-$  ions in nature.

**Dissipation**

Hydrated lime would simply dissociate to its respective ion constituents ( $\text{Ca}^{2+}$  and  $\text{OH}^-$ ) 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  $\text{Ca}^{2+}$  and  $\text{OH}^-$  ions in nature.

***Testing for distribution and dissipation in air (ADS)***

Since hydrated lime is expected to have a vapour pressure well below  $10^{-5}$  Pa, exposure via air is not expected.

**Summary table of half-lives identified relevant metabolites and transformation products in air**

No data available.

**Dissipation**

No data available.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not relevant for the use of EULA HYDRA-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 HYDRA-LIME 23.

### **PNECs**

The following table contains a summary of PNECs of the active substance Calcium dihydroxide for the respective compartments (Calcium dihydroxide CAR, Hydrated lime 2016). Since hydrated lime was the only form tested in the fate and effects studies, toxicity has been expressed in the form of the hydrated lime equivalents.

<b>Summary of PNECs of the active substance Calcium dihydroxide</b>				
<b>Compartment</b>	<b>Species</b>	<b>Endpoint</b>	<b>Safety factor</b>	<b>PNEC (Hydrated lime equivalents)</b>
Surface water	<i>Daphnia magna</i>	48h EC <sub>50</sub> = 49.1	100	0.491 mg/L
Sediment	-	-	-	-
Microorganisms (STP)	<i>Activated sludge</i>	3h EC <sub>50</sub> = 300.4 mg/L	100	3.004 mg/L
Soil	<i>Spinacia oleracea</i>	21d NOEC <sub>plant</sub> = 1080 mg.kg <sup>-1</sup> dw*	10	108 mg.kg <sup>-1</sup> dw*
Bird	-	-	-	-
Mammal	-	-	-	-

\*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<sup>2+</sup>, Mg<sup>2+</sup> and OH<sup>-</sup>) 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
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Assessed scenarios	<u>Scenario 1</u> : 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	<u>Scenario 2.1</u> : Application to manure, <u>Scenario 2.2</u> : Application on animal bedding materials, <u>Scenario 2.3</u> : Application on indoor walls of animal accommodations, <u>Scenario 2.4</u> : Application on indoor floor of animal accommodations, <u>Scenario 3</u> : Application on indoor floor of animal transportation, <u>Scenario 4</u> : Application on floors of outdoor animal enclosures.
ESD(s) used	<u>Scenario 2.1</u> : ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 ✓ ESDTP18, Emission scenario document for Insecticides for stables and manure storage systems, 2006 <u>Scenario 2.2, 2.3, 2.4 and 3</u> : ✓ ESDTP3, Veterinary hygiene biocidal products, 2011 <u>Scenario 4</u> : 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, 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 Hydrated Lime PT2, with the following application rate in comparison with the product EULA HYDRA-LIME 23:

<b>Application rate of active substance in sewage sludge</b>			
	<b>Representative product of the CAR Hydrated Lime, 2016</b>	<b>EULA HYDRA-LIME 23 product</b>	<b>Remarks</b>
Fraction of a.s in the product (-)	1	1	-
Maximal application rate of the product (in % of dry solid weight of sludge)	50	200 (i.e. 2 kg product/kg dry solid weight of sludge)	-
Application rate of the a.s (in % of dry solid weight of sludge)	50	200	= Fraction of a.s in the product x Maximal application rate of the product

It has been demonstrated that the use of the representative product of the CAR generates applications of lime in agricultural soil lower than 16t/ha/year. The same reasoning can be used for the product EULA HYDRA-LIME 23 (see table below).

<b>Application rate of active substance in agricultural fields</b>		
	<b>Representative product of the CAR Hydrated lime, 2016</b>	<b>EULA HYDRA-LIME 23 product</b>
<b>Input</b>		
Application rate of the a.s for the use described in the CAR	50% of dry solid weight of sludge	200% of dry solid weight of sludge
Maximum application rate of sludge in agricultural land per year	5000 kg dry solid sludge/ha/year	
<b>Output</b>		
Amount of lime added to the sludge during the treatment	2500 kg	10000 kg
Total dry weight of treated sludge after the treatment	7500 kg	15000 kg
Application of a.s per ha per year due to the final 5000 kg of actual sludge landed in agricultural field	$5000/7500 * 2500 = 1.7$ t/ha/year	$5000/15000*10000 = 3.3$ t/ha/year

As the use of EULA HYDRA-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 HYDRA-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 (TP3): disinfection of animal accommodation

For the four following uses:

- 2.1: disinfection of manure,
- 2.2: disinfection of animal bedding materials,
- 2.3: disinfection of indoor walls of animal accommodations and
- 2.4: disinfection of indoor floor of animal accommodations,

the product is mixed to manure for its disinfection or released into manure after application on surfaces. The mix hydrated lime/manure is removed when accommodations are cleaned and sent to manure storage for use in fields. The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. 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 directly exposed to the active substance.

All parameters (area of accommodations, number of animals...) considered are from ESDTP3, 2011 and ESDTP18 for stables and manure storage systems, 2006. For an easier reading of the PAR, only worst-case situations are presented:

- ✓ For cattle: veal calves emissions,
- ✓ For poultry: turkeys emissions.

##### *Scenario 2.1: disinfection of manure*

The 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:

<b>1) Concentration of a.s in manure after the application of product</b>				
	<b>Symbol</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
		<b>EULA HYDRA-LIME 23 product Scenario 2.1</b>		
Fraction of a.s in the product	Fbioc	1	[-]	-
Maximum application rate of product in manure	-	100	[kg/m <sup>3</sup> of manure]	-
<b>Concentration of a.s in manure after the last application of product</b>	-	<b>100</b>	[kg/m <sup>3</sup> 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.

<b>2) Application rate of manure in arable and grassland</b>					
<b>Parameters</b>	<b>Symbol from ESDTP3/18</b>	<b>Value</b>		<b>Unit</b>	<b>Remarks</b>
<b>Input</b>					
		<b>Scenario 2.1 - Manure</b>			
		<b>Veal calves</b>	<b>Turkey</b>		
Amount of nitrogen produced per animal per day	Qnitrog <sub>i1</sub>	0.02382	0.00482	[kg/day/animal]	ESDTP3, 2011
Amount of manure produced per animal per day	-	0.007	0.00036	[m <sup>3</sup> /animal/d]	ESDTP18, 2006 Table in Appendix 5 with conversion of L to m <sup>3</sup>
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
<b>Intermediate Calculations</b>					

Concentration of nitrogen in the manure	-	3.40	13.39	[kg/m <sup>3</sup> ]	Concentration of nitrogen in the manure = Amount of nitrogen produced per animal per day / Amount of manure produced per animal per day
<b>Output</b>					
<b>Maximum application rate of manure on grassland</b>	-	<b>49.96</b>	<b>12.69</b>	[m <sup>3</sup> /year/ha soil]	<u>Maximum application rate of manure on grassland or arable land</u> =
<b>Maximum application rate of manure on arable land</b>	-	<b>49.96</b>	<b>12.69</b>	[m <sup>3</sup> /year/ha soil]	Maximum emission standard for nitrogen on grassland or arable land / Concentration of nitrogen in the manure

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

<b>3) Application rate of active substance in arable land and grassland</b>				
<b>Input</b>				
<b>Parameters</b>	<b>Value</b>		<b>Unit</b>	<b>Remarks</b>
	<b>Scenario 2.1 - Manure</b>			
	<b>Veal calves</b>	<b>Turkey</b>		
Concentration of a.s in manure	100	100	[kg/m <sup>3</sup> of wet manure]	-
Maximum application rate of manure on grassland and arable land	49.96	12.69	[m <sup>3</sup> /year/ha soil]	-
<b>Output</b>				
<b>3) Maximum application rate of active substance on grassland or arable land per year per hectare</b>	<b>5.00</b>	<b>1.27</b>	[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 HYDRA-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 HYDRA-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 animal bedding materials (straw, sawdust, woodchip...)*

The dry product is applied on animal bedding material (straw, sawdust, woodchip) once (for cattle) or twice a week (for poultry) and will be mixed in manure after application.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) claimed by the applicant are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:

“Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or 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%).

In the ESDTP3, no individual value for the bedding material surface is available. It is therefore calculated by adding the “floor surface” value to “other areas inside” value, Therefore, for treatment in:

- Veal caves accommodations, the surface of bedding material is  $160+20 = 180 \text{ m}^2$ .
- Turkeys accommodations, the surface of bedding material is  $3330+60 = 3390 \text{ m}^2$ .

Concerning the application rate:

- For veal calves, 1.5 kg of product/animal are considered. Therefore,  $80 \times 1.5 = 120$  kg of product (or 120 kg of active substance) are needed to treat the bedding material of 80 animals distributed over  $180\text{m}^2$ .
- For turkeys, the value given by the applicant is 0.2 kg product/ $\text{m}^2$  at a maximum.

Calculations are done according to scenario “Disinfection of animal housing” from ESDTP3 (2011). It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

Concentration of a.s in manure after the last application					
Parameter	Symbol	Value		Unit	S/D/O
<b>Input</b>					
Type of House	cat-subcat <sub>(i1)</sub>	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype <sub>(i2)</sub>	Disinfectant <sub>t</sub>	Disinfectant	[-]	D

<b>Concentration of a.s in manure after the last application</b>					
<b>Parameter</b>	<b>Symbol</b>	<b>Value</b>		<b>Unit</b>	<b>S/D/O</b>
Emission to STP	Elocal <sub>wastewater</sub>	Not relevant	Not relevant	[-]	O
Amount of product prescribed to be used per m <sup>2</sup>	Qprod m <sup>2</sup>	Not relevant	0.2	[kg/m <sup>2</sup> ]	S
Amount of product prescribed to be used per animal	Qprod ani	1.5	Not relevant	[kg/animal]	S
Fraction of active substance in the product	Fbioc	1	1	[-]	S
Area of the housing for application (bedding material surfaces only)	AREA <sub>i1</sub>	not relevant	3390	[m <sup>2</sup> ]	D
Amount of active ingredient to be used for one application	Qai-prescri <sub>1,i2,i3</sub>	120	678	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	52*	104*	[-]	D
Biocide application interval	Tbioc-int	7*	3*	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	Nanimal <sub>i1</sub>	80	10000	[-]	D
Amount of nitrogen per animal	Qnitrog <sub>i1</sub>	0.02382	0.00482	[kg/d]	D
<b>IF NITROGEN IMMISSION STANDARDS ARE APPLIED</b>					
Nitrogen immission standard for one year - grassland	QN <sub>grassland</sub>	170	170	[kg.ha <sup>-1</sup> ]	D
Nitrogen immission standard for one year - arable land	QN <sub>arable_land</sub>	170	170	[kg.ha <sup>-1</sup> ]	D
<b>Intermediate Calculations</b>					
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 <sub>grassland and arable land</sub>	1*	1*	[-]	O
Amount of active ingredient in manure - grassland / arable land	Qai-grass/arab <sub>i1,i2,i3,i4</sub>	60	339	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	Qnitrog-grass <sub>i1,i4</sub>	101	2555	[kg]	O
Amount of nitrogen produced during the	Qnitrog-arab <sub>i1,i4</sub>	404	10218	[kg]	O

Concentration of a.s in manure after the last application					
Parameter	Symbol	Value		Unit	S/D/O
relevant period for every relevant (sub)category of animal/housing i1 and application to arable land					
<b>Outputs</b>					
<b>Soil exposure via manure spreading</b>					
Annual application rate per hectare (arable land)	-	25.2	5.64	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	101**	22.6**	[kg/yr/ha]	O

\*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations ( $Napp\text{-}manure_{gr}$  and  $Napp\text{-}manure_{ar} = 1$ ). Therefore, the number of disinfectant applications in one year ( $Napp\text{-}bioc$ ) and the biocide application interval ( $Tbioc\text{-}int$ ) 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 HYDRA-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 HYDRA-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 2.3: disinfection of indoor walls of animal accommodations*

The dry product is mixed with water and applied on walls of indoor animal accommodations, annually or before a production cycle, at a frequency that depends on sanitary breaks of animal cycles.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year ( $Napp\text{-}bioc$ ) and the biocide application interval ( $Tbioc\text{-}int$ ) claimed by the applicant are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:

“Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or 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%).

In the ESDTP3, no individual value for the walls surface is available. It is therefore calculated from the "Wall+roof" value, considering that the individual roof value could be equal to the "Floor" value.

Therefore, for treatment in:

- Veal caves accommodations, the surface of walls is  $330-160 = 170 \text{ m}^2$ .
- Turkeys accommodations, the surface of walls is  $4650-3330 = 1320 \text{ m}^2$ .

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
<b>Input</b>					
Type of House	cat-subcat <sub>(i1)</sub>	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype <sub>(i2)</sub>	Disinfectant	Disinfectant	[-]	D
Emission to STP	Elocal <sub>wastewater</sub>	Not relevant	Not relevant	[-]	O
Amount of product prescribed to be used per m <sup>2</sup>	Qprod	0.8	0.8	[kg/m <sup>2</sup> ]	S
Fraction of active substance in the product	Fbioc	1	1	[-]	S
Area of the housing for application (walls only)	AREA <sub>i1</sub>	170	1320	[m <sup>2</sup> ]	D
Amount of active ingredient to be used for one application	Qai-prescri <sub>1,i2,i3</sub>	136	1060	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	1*	1*	[-]	D
Biocide application interval	Tbioc-int	365*	365*	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	Nanimal <sub>i1</sub>	80	10000	[-]	D
Amount of nitrogen per animal	Qnitrog <sub>i1</sub>	0.02382	0.00482	[kg/d]	D
<b>IF NITROGEN IMMISSION STANDARDS ARE APPLIED</b>					
Nitrogen immission standard for one year - grassland	Q <sub>N,grassland</sub>	170	170	[kg.ha <sup>-1</sup> ]	D
Nitrogen immission standard for one year - arable land	Q <sub>N,arable_land</sub>	170	170	[kg.ha <sup>-1</sup> ]	D

Concentration of a.s in manure after the last application					
Parameter	Symbol	Value		Unit	S/D/O
<b>Intermediate Calculations</b>					
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 <sub>i1,i2,i 3,i4</sub>	68	528	[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 <sub>i1,i4</sub>	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 <sub>i1,i4</sub>	404	10218	[kg]	O
<b>Outputs</b>					
<b>Soil exposure via manure spreading</b>					
Annual application rate per hectare (arable land)	-	28.6	8.78	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	114**	35.1**	[kg/yr/ha]	O

\*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations ( $Napp\text{-}manure_{gr}$  and  $Napp\text{-}manure_{ar} = 1$ ). Therefore, the number of disinfectant applications in one year ( $Napp\text{-}bioc$ ) and the biocide application interval ( $Tbioc\text{-}int$ ) 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 HYDRA-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 HYDRA-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 2.4: disinfection of indoor floor of animal accommodations*

The dry product is applied on concrete or mud floor before a production cycle, at a frequency that depends on sanitary breaks of animal cycles.

Lime is highly reactive to the organic matter. Due to the strong degradation kinetics for lime (some hours), it can be assumed that residues resulting from former applications during the manure storage period are negligible. Moreover, as mentioned in the CAR, much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). As a worst-case assumption, the last application of lime mixed with manure is considered to



calculate the emissions into the environment. Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emissions.

The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:

"Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant or 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
<b>Input</b>					
Type of House	cat-subcat <sub>(i1)</sub>	Veal calves	Turkey in free range – litter floor	[-]	D
Type of biocide	bioctype <sub>(i2)</sub>	Disinfectant	Disinfectant	[-]	D
Emission to STP	Elocal <sub>wastewater</sub>	Not relevant	Not relevant	[-]	O
Amount of product prescribed to be used per m <sup>2</sup>	Qprod	1	1	[kg/m <sup>2</sup> ]	S – covering the efficient dose of 0.8 kg/m <sup>2</sup>
Fraction of active substance in the product	Fbioc	1	1	[-]	S
Area of the housing for application (floor only)	AREA <sub>i1</sub>	160*	3330*	[m <sup>2</sup> ]	D
Amount of active ingredient to be used for one application-	Qai-prescri <sub>1,i2,i3</sub>	160	3330	[kg]	O
Number of disinfectant applications in one year	Napp-bioc	4**	2**	[-]	D
Biocide application interval	Tbioc-int	91**	182**	[d]	D/O
Number of manure applications - grassland	Nlapp-grass	4	4	[-]	D
Number of manure applications - arable land	Nlapp-arab	1	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	53	[d]	D
Manure application time interval for arable land	Tar-int	212	212	[d]	D
Number of animals	Nanimal <sub>i1</sub>	80	10000	[-]	D
Amount of nitrogen per animal	Qnitrog <sub>i1</sub>	0.02382	0.00482	[kg/d]	D

<b>Concentration of a.s in manure after the last application</b>					
<b>Parameter</b>	<b>Symbol</b>	<b>Value</b>		<b>Unit</b>	<b>S/D/O</b>
<b>IF NITROGEN IMMISSION STANDARDS ARE APPLIED</b>					
Nitrogen immission standard for one year - grassland	$Q_{N,grassland}$	170	170	[kg.ha <sup>-1</sup> ]	D
Nitrogen immission standard for one year - arable land	$Q_{N,arable\_land}$	170	170	[kg.ha <sup>-1</sup> ]	D
<b>Intermediate Calculations</b>					
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	$Q_{ai-grass/arab_{i1,i2,i3,i4}}$	80	1670	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	$Q_{nitrog-grass_{i1,i4}}$	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	$Q_{nitrog-arab_{i1,i4}}$	404	10218	[kg]	O
<b>Outputs</b>					
<b>Soil exposure via manure spreading</b>					
Annual application rate per hectare (arable land)	-	33.7	27.7	[kg/yr/ha]	O
Annual application rate per hectare (grassland)	-	135***	111***	[kg/yr/ha]	O

\* The risk assessment was carried out taking into account the area to be treated claimed by the applicant (floor 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 ( $T_{bioc-int}$ ) 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 HYDRA-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 HYDRA-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  $E_{local\ wastewater}$  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  $E_{local\ wastewater}$  is done according to the ESDTP3, 2011, and presented in the table below:

<b>Emission calculations</b>				
<b>Input</b>	<b>Symbol</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Area of trucks (mammal transports)	AREAmam	4546	[m <sup>2</sup> ]	ESDTP03, 2011
Area of trucks (poultry transports)	AREApoul	1120	[m <sup>2</sup> ]	ESDTP03, 2011
Area of containers (poultry transports)	AREAcont	3355	[m <sup>2</sup> ]	ESDTP03, 2011
Content of active ingredient in formulation	Fbioc	1	[-]	ESDTP03, 2011
Amount of product prescribed to be used per m <sup>2</sup>	Qprodi2,i3	800	[g/m <sup>2</sup> ]	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
<b>Output</b>				
<b>Emission from one application to a standard STP or an on-site waste water treatment plant (mammal)</b>	<b>Elocal wastewateri2i3i4 mammal</b>	<b>3273</b>	[kg/d]	

<b>Emission from one application to a standard STP or an on-site waste water treatment plant (poultry)</b>	<b>Elocal wastewateri2i3i4 poultry</b>	<b>3222</b>	[kg/d]	
<b>PEC<sub>STP</sub> calculation</b>				
<b>Input</b>				
Fraction of release to water from the STP	F <sub>water</sub>	1*	[-]	
Effluent discharge rate of STP	EFFLUENT <sub>stp</sub>	2000000	[L/d]	Vol IV Part B+C; 2017
<b>Output</b>				
<b>PEC<sub>STP</sub> resulting of one application to a standard STP or an on-site waste water treatment plant (mammal)</b>	<b>PEC<sub>STP</sub> mammal</b>	<b>1.64</b>	[g/L]	
<b>PEC<sub>STP</sub> resulting of one application to a standard STP or an on-site waste water treatment plant (poultry)</b>	<b>PEC<sub>STP</sub> poultry</b>	<b>1.61</b>	[g/L]	

\*As the K<sub>oc</sub> is set to 0 kg/L and no information is available about biodegradation in STP, a fraction of release to water from the STP (F<sub>water</sub>) of 100% is considered.

As both PEC<sub>STP</sub> are higher than the doses assessed in the CAR (and more than 500 times higher than the PNEC<sub>STP</sub> 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 RMM is 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/m<sup>2</sup> or 0.8 kg a.s/m<sup>2</sup> 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<sup>12</sup>, 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***

<b>Identification of relevant receiving compartments based on the exposure pathway</b>								
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 bedding material	Scenario 2.2	No	No	No	No	Yes	Yes
	Disinfection of indoor walls of animal accommodations	Scenario 2.3	No	No	No	No	Yes	Yes
	Disinfection of indoor floor surfaces of animal accommodations	Scenario 2.4	No	No	No	No	Yes	Yes
	Disinfection of animal transportation area	Scenario 3	Yes	Yes	Yes	No	Yes	Yes
	Disinfection of floors of outdoor animal enclosures	Scenario 4	No	No	No	No	Yes	Yes

<b>Input parameters (only set values) for calculating the fate and distribution in the environment</b>			
Input	Value	Unit	Remarks
Molecular weight	74.09	g/mol	(IIB, 2016)
Vapour pressure	<1.0E-05	Pa	Not conducted as melting point above 300°C. It can be assumed the vapour pressure is <10 <sup>-5</sup> Pa. (CAR 2016)
Water solubility (at 0°C)	1.85	g/l	(CAR, 2016)
Log Octanol/water partition coefficient	<<3	Log 10	(CAR, 2016)

<sup>12</sup> 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 <sup>3</sup> /mol	Not applicable (CAR, 2016)
Biodegradability	-		Not applicable (CAR, 2016)
DT <sub>50</sub> for biodegradation in surface water	-	d or hr (at 12°C)	When dissolved in water, Hydrated lime dissociates into Ca <sup>2+</sup> and OH <sup>-</sup> , which are chemically and biologically not further degradable (CAR, 2016)
DT <sub>50</sub> for hydrolysis in surface water	-	d or hr (at 12°C /pH)	When dissolved in water, Hydrated lime dissociates into Ca <sup>2+</sup> and OH <sup>-</sup> , which are chemically and biologically not further degradable (CAR, 2016)
DT <sub>50</sub> for photolysis in surface water	-	d or hr	Not applicable, see Hydrolysis (CAR, 2016)
DT <sub>50</sub> for degradation in soil (T <sub>0</sub> to T=6h after application of lime in soil)	0.752h	hr	(CAR, 2016)
DT <sub>50</sub> for degradation in soil (T=6h to T=+∞ after application of lime in soil)	372	hr	(CAR, 2016)

### Calculated PEC values

For uses assessed in scenarios:

- ✓ 1 (treatment of sewage sludge),
- ✓ 2.1 (treatment of manure),
- ✓ 2.2 (treatment of bedding material),
- ✓ 2.3 (treatment of walls of indoor animal accommodations),
- ✓ 2.4 (treatment of animal indoor floor accommodations),
- ✓ 4 (treatment of animal outdoor enclosures):

As all the uses generate lower emissions than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of EULA HYDRA-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<sub>STP</sub> is calculated (see [Emission estimation](#) section):

- ✓ For mammals: PEC<sub>STP</sub> = 1.64 g/L
- ✓ For poultry: PEC<sub>STP</sub> = 1.61 g/L

## **Groundwater**

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

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,  $\text{Ca}^{2+}$  ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwater.

## **Primary and secondary poisoning**

### Primary poisoning

It is not believed that powders are in a form that could be sufficiently appetent to bird or mammal so they would be at risk.

Moreover, for scenarios 1 and 2, as the product is mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

### Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents ( $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ , and  $\text{OH}^-$ ) in the environment.

### **2.2.8.3** Risk characterisation

## **Atmosphere**

For hydrated lime, exposure via air (and subsequent phototransformation in air) would be negligible based on its structure and its expected low vapour pressure ( $\ll 1.0\text{E-}05$  Pa).

Due to the negligible exposure, no formal risk assessment of air compartment is considered necessary.

## **Aquatic compartment (surface water, sediment and sewage treatment plant)**

For uses assessed in scenarios:

- ✓ 1 (treatment of sewage sludge),

- ✓ 2.1 (treatment of manure),
- ✓ 2.2 treatment of bedding material),
- ✓ 2.3 (treatment of walls of indoor animal accommodations),
- ✓ 2.4 (treatment of animal indoor floor accommodations),
- ✓ 4 (treatment of animal outdoor enclosures):

According to WG ENV I 2020 conclusions, a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage systems is not relevant for lime products. Therefore, no risk assessment is carried out for the aquatic compartment (surface water, sediment) in case of the run-off emission path. Moreover, the following RMM will be included to prevent any releases to the STP: "Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant or 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 <sub>STP</sub> (mg/L)	PNEC <sub>STP</sub> (mg/L)	PEC/PNEC
Scenario 3 – indoor floor of animal transportation - Mammals	1640	3.004	<b>545.9</b>
Scenario 3 – indoor floor of animal transportation - Poultry	1610	3.004	<b>536</b>

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 HYDRA-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)	
<b>PT2</b>		
1 – Disinfection of sewage sludge	3.3	
<b>PT3</b>	Veal calves	Turkeys
2.1 – Disinfection of manure	5.00	1.27
2.2 - Disinfection of bedding material	0.10	0.02
2.3 - Disinfection of indoor walls of animal accommodations	0.11	0.04
2.4 - Disinfection of indoor floor surfaces of animal accommodations	0.14	0.11



3 - Disinfection of animal transportation area	n.r.	n.r.
4 - Disinfection of floor of outdoor animal enclosures	n.r.	16

n.r.: not relevant

Therefore, the use of EULA HYDRA-LIME 23 leads to acceptable risks to the terrestrial compartment even in considering an aggregated assessment of all the uses.

### **Groundwater**

Hydrated lime dissociates into  $\text{Ca}^{2+}$  and  $\text{OH}^-$  when in contact with water.

The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment,  $\text{Ca}^{2+}$  ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwater.

### **Primary and secondary poisoning**

#### Primary poisoning

It is not believed that powders are in a form that could be sufficiently appetent to birds or mammals so they would be at risk.

For scenario 1 and 2, as the product is mixed with sewage sludge or manure, it is not believed that it could be sufficiently appetent to bird or mammals so they would be at risk.

#### Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents ( $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ , and  $\text{OH}^-$ ) in the environment.

### **Aggregated exposure (combined for relevant emissions sources)**

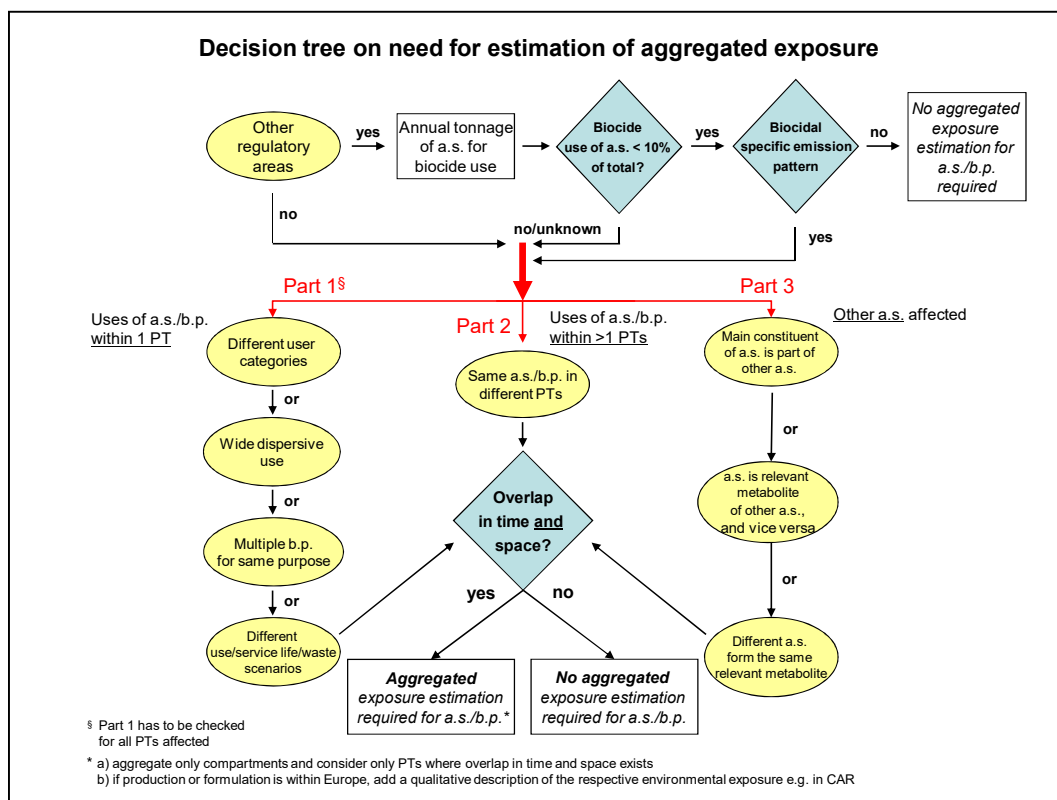


Figure 1: Decision tree on the need for estimation of aggregated exposure

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.

### Overall conclusion on the risk assessment for the environment of the product

Acceptable risks are foreseen 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 animal bedding material,
- ✓ disinfection of indoor walls of animal accommodations,

- ✓ 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<sup>13</sup>

#### 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	<b>Annex II/III requirement:</b> Appearance (at 20°C and 101.3 kPa) <b>IUCLID Section No. 3.1</b>	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
Author: [REDACTED]	Year: 1985	<b>Annex II/III requirement:</b> Appearance (at 20°C and 101.3 kPa) <b>IUCLID Section No. 3.1</b>	IUCLID Document name: Appearance (at 20°C and 101.3 kPa) - active substance reference	Title: Lehrbuch der anorganischen Chemie  No report number provided	Type of publication: publication		no	No
No author provided	No year provided	<b>Annex II/III requirement:</b> Acidity, alkalinity <b>IUCLID Section No. 3.2</b>	IUCLID Document name: Acidity, alkalinity - active substance 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	<b>Annex II/III requirement:</b>	IUCLID Document name:	Title: Burnt Lime active substance	Type of publication: study			No

<sup>13</sup> When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

		Storage stability tests <b>IUCLID Section No. 3.4.1</b>	Storage stability tests- active substance reference	dossier: Doc. No.: 245-001; CB3.7/01 No report number provided	report			
No author provided	No year provided	<b>Annex II/III requirement:</b> Light <b>IUCLID Section No. 3.4.2.1</b>	IUCLID Document name: Reactivity towards container material - 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
Author: [REDACTED]	Year: 2017	<b>Annex II/III requirement:</b> Technical characteristics of the biocidal product <b>IUCLID Section No. 3.5</b>	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	yes
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Technical characteristics of the biocidal product <b>IUCLID Section No. 3.5</b>	IUCLID Document name: Wet sieve_Biocalco M50 - Eurofins 2019	Title: Report of Carmeuse biocide lime products analysis No report number provided	Type of publication: study report		yes	yes
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Technical characteristics of the biocidal product	IUCLID Document name: Wet sieve_Biocalco M50 - Eurofins 2019	Title: Wet Sieving of Biocalco M50 No report number provided	Type of publication: study report	Company Owner: Eurofins Agrosience Services EcoChem GmbH Eutinger Straße 24 D – 75223 Niefern-Öschelbronn Germany Carmeuse Europe Boulevard de Lauzelle 65	yes	yes

		<b>IUCLID Section No. 3.5</b>				B-1348 Louvain-la-Neuve Belgium		
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Technical characteristics of the biocidal product  <b>IUCLID Section No. 3.5</b>	IUCLID Document name: Wet sieve_Lhoist_2019	Title: Laser diffraction data_wet sieve - Lhoist  No report number provided	Type of publication: other company data			yes
Author: [REDACTED]	Year: 2012	<b>Annex II/III requirement:</b> Corrosive to metals  <b>IUCLID Section No. 4.16</b>	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	<b>Annex II/III requirement:</b> Corrosive to metals  <b>IUCLID Section No. 4.16</b>	IUCLID Document name: Corrosive to metals_BAM 1999	Title: Beurteilung der korrosion von kalkmilch hinsichtlich ihrer einstuftung 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 Standardization)	Year: 2013	<b>Annex II/III requirement:</b> METHODS OF DETECTION AND	IUCLID Document name: Analytical methods for determination in	Title: ISO 17091:2013 Workplace air — Determination of lithium hydroxide,	Type of publication: publication			No

		IDENTIFICATION  <b>IUCLID Section No. 5</b>	air	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	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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: Forschungsgemeinschaft Kalk, 1/03/ C 023 Jan 2003  Company Owner: NA	not specified	No
Author: [REDACTED]	Year: 2004	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols,	IUCLID Document name: 6.7-2 from AS A5 10.02 Capizzi-Banas et al Liming as an advanced treatment for	Title: Liming as an advanced treatment for sludge sanitisation: helminth eggs elimination - Ascaris as a model  Report no. NA	Type of publication: publication	Source: Water Research 38: 3251-3258: Doc. No. 392-024  Company Owner: NA	not specified	No

		laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	sludge sanitisation. 2004 (Phase 3 - PT 2)					
Author: [REDACTED]	Year: 1984	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	IUCLID Document name: 6.7-3 From AS A5 10.03 Pfuderer G Hygienic aspects related to the treatment and use of sewage sludge. 1985 (Phase 2 - PT 2)	Title: Hygienic 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	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used	IUCLID Document name: 6.7-6 - Evaluation of Liming in liquid and solid manure (Phase 2 - PT 2 and 3), Daughies, 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




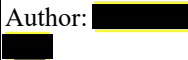
		including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>						
Author: [REDACTED]	Year: 2018	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance	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 conditions (Phase 2 Step 2)	Type of publication: study report	Source: NA  Company Owner: EuLA, Brussels, Belgium	not specified	yes

		standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>		Report no. J000714-1				
Author: [REDACTED] [REDACTED]	Year: 2018	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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] [REDACTED]	Year: 2018	<b>Annex II/III requirement:</b> 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: 6.7-10 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 Step 2) Porous surfaces	Type of publication: study report	Source: NA  Company Owner: EuLA Brussels Belgium	not specified	yes

		relevant <b>IUCLID Section No. 6.7</b>		Report no. J000714-2				
Author: [REDACTED]	Year: 2018	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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	<b>Annex II/III requirement:</b> 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: 6.7-12 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  Report no. J000714-2	Type of publication: study report	Source: NA  Company Owner: EuLA Brussels Belgium	not specified	yes

		<b>IUCLID Section No. 6.7</b>						
Author: Prof. Dr. [REDACTED]	Year: 2008	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	IUCLID Document name: 6.7-13 - Evaluation of Liming in liquid manure - 90 day - Phase 2 (PT 3), Daughshies, 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	No
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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

Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	IUCLID Document name: 6.7-15 Calcium dihydroxide_Simulated 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	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	IUCLID Document name: 6.7-15 Calcium dihydroxide Modified NF T 72-281, Bacteria, Yeast Fungi, Veterinary High Level Soil, 1143/0419, Carre, Final, 2019	Title: Test Report No RE-1143/0419 Determination of microbicide activity of EuLA hydra-lime 23 according to a methodology issued to NF T 72-281  Report no. RE 1143/0419	Type of publication: study report	Source: NA  Company Owner: EuLA, 1000 Brussels, Belgium	not specified	yes
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b>	IUCLID Document name:	Title: Test Report No RE-1303/0919/A	Type of publication: study	Source: NA	not specified	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  <b>IUCLID Section No. 6.7</b>	6.7-15A Calcium dihydroxide Modified NF T 72-281, Fungi, Aspergillus brasiliensis, Veterinary Low Level Soil, RE-1303/0919/A, Carre, Final, 2019	Determination of microbicide activity of EuLA Hydra-lime 23 according to a methodology issued to NF T 72-281 (Fungicidal Only)  Report no. RE-1303/0919/A	report	Company Owner: EuLA, 1000 Brussels, Belgium		
Author: 	Year: 2019	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	IUCLID Document name: 6.7-15B Calcium dihydroxide Modified NF T 72-281, Virus - Porcine Parvovirus, Veterinary High Level Soil, RE-1298/0819, Carre, Final, 2019	Title: Test Report No RE-1298/0819 Determination of microbicide activity of EuLA Hydra-lime 23 according to a methodology issued to NF T 72-281 and prEN 17122 (Virucidal Efficacy)  Report no. RE-1298/0819	Type of publication: study report	Source: NA  Company Owner: EuLA, 1000 Brussels, Belgium	not specified	yes
Author: 	Year: 2019	<b>Annex II/III requirement:</b> Efficacy data to support these	IUCLID Document name: 6.7-16 Calcium oxide - Phase 3:	Title: EFFECTIVENESS STUDY OF A BIOCIDES	Type of publication: study report	Company Owner: Lhoist o behalf of EuLA	no	yes

		claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	Field Trial - PT 3 Poultry - RITTMO 18-445R	PRODUCT FOR TREATMENT OF POULTRY (FARM TRIAL)  No report number provided				
Author: [REDACTED]	Year: 2019	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	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	<b>Annex II/III requirement:</b> Efficacy data to support these claims, including any available	IUCLID Document name: 6.7-18 Calcium oxide - Phase 3: Field Trial - PT 3 Pigs - RITTMO	Title: EFFICACY STUDY OF A BIOCIDAL PRODUCT Treatment of swine husbandry building	Type of publication: study report	Company Owner: Lhoist on behalf of EuLA	no	yes

		standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant  <b>IUCLID Section No. 6.7</b>	19-413R	No report number provided				
██████████	Year: 2020			Test report WA no.: 161-1/20	Type of publication: study report	ARGE Kalk GbR	no	yes
██████████	Year: 2020			Test report WA no.: 161-2-k2/20	Type of publication: study report	ARGE Kalk GbR	no	yes
██████████	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

#### Disinfection of sewage sludges and manures





ART modélisation-  
MANURES SLUDGES



RISKOFDERM  
MANURES SLUDGES

### Disinfection of floor surfaces and bedding materials



RISKOFDERM  
indoor floor surface



ART modélisation-  
Floor application.zip

### Disinfection of walls



RISKOFDERM  
automated transfer



Exposure  
calculations.xlsx

## 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)<sup>14</sup>

### 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 peer reviewed and agreed by the WG members (WG I 2022)**

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

According to the information provided by the applicant, the biocidal product is always removed after the treatment of the floor surfaces of animal accommodations, transportation, bedding materials and outdoor enclosures. Animals are not present during the treatment (which includes the application, the contact time of 48h and the removal of the product by sweeping).

Animals are not expected to be directly in contact with residues as the floor has to be covered with fresh straw before the re-entry. Moreover, after a contact time of 48h, no lime residues is expected on floor surfaces but only reaction products (with no irritant properties expected) that are swept at the end of the treatment. Considering that, no local RA is performed.

Regarding systemic RA, it is not considered relevant taking into account that animal exposure via feed is excluded by the addition of a specific RMM to remove feed during the treatment. Furthermore, the Ca<sup>2+</sup> and Mg<sup>2+</sup> intake from the product is considered negligible compared to those from the normal feeding of livestock.

#### **Disinfection of animal accommodation walls by brush**

Animals are not present during the treatment of walls that includes the application, the contact time and the drying period. In order to avoid exposure to the wet treated surfaces, a RMM is proposed to not let animals re-enter the accommodations before complete drying of surfaces.

Regarding the exposure to dried surfaces, no local risk assessment has been performed based on the fact that the irritant properties of the water suspended lime applied on the walls are no longer expected after drying. Indeed, after application of the water suspended lime, water evaporates and hydrated lime reacts with CO<sub>2</sub> from the air to form CaCO<sub>3</sub> that does not present any irritant properties.

<sup>14</sup> If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

Considering a systemic risk assessment due to exposure to  $\text{Ca}^{2+}$  and  $\text{Mg}^{2+}$ , it is not considered relevant taking into account that intake from the product from a licking behaviour is considered negligible compared to those from the normal feeding of livestock.

The following RMMs are proposed:

- Animals should not be present during all the treatment duration;
- Do not let animal re-enter the accommodations before complete drying of surfaces.