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

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

(submitted by the evaluating Competent Authority)

Calcium dihydroxide family

Product type(s): 3

[Calcium dihydroxide]

Case Number in R4BP: [BC-RQ038593-12]

Evaluating Competent Authority: Ireland

Date: 12/09/2023

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CONCLUSION

The Calcium hydroxide family products are dustable powders for PT 3 use in the disinfection of indoor floor surfaces of animal accommodations by professional users. The products in the family are blends of the active substance calcium dihydroxide (hydrated lime, Cas no. 1305-62-0) and the inert filler calcium carbonate (Cas No. 471-34-1), therefore, the relevant sections described in the Hydrated Lime CAR (UK, 2016) are also relevant for the biocidal products. This assessment also makes reference to the Commission Implementing Regulation (EU) 2016/1935 published in Nov, 2016 to approve calcium dihydroxide (hydrated lime) as an existing active substance for use in biocidal products of product – types 2 and 3.

Physico chemical properties and analytical methods

Although no further studies were submitted for assessment of the physical, chemical or technical properties for the calcium hydroxide biocidal family, the IE CA considered the waivers that were produced in the Hydrated Lime CAR (UK, 2016) and which have undergone peer review. These waivers have been considered in the scope of this assessment and have been deemed acceptable.
With regard to the physical hazards, no further studies were submitted for this assessment however the IE CA have considered the waivers produced in the CAR (2016) and the products do not exhibit any other physico-chemical hazards.
A comprehensive assessment of the methods of detection and identification of the active substance were considered during the CAR (UK, 2016) for calcium dihydroxide, the IE CA are in agreement that the analytical methods for the active are applicable to the products and are suitable.

Efficacy

The IE CA considers that all products within the family have been supported by the efficacy data. An evaluation of the data demonstrated the products are efficacious against the target organisms for the proposed use using a 2 hours contact time and under veterinary high soil (dirty) conditions. In consequence, the products can be authorised.

Human Health

The product is classified as causing serious eye damage and as an irritant to skin and the respiratory tract. Notwithstanding this the human health evaluation has found the use scenarios to be safe if appropriate risk mitigation and engineering controls are in-place. The uses do not represent an unacceptable risk systemically or locally and consequently the products can be authorised.

Environmental Exposure

The application of slurry containing spent $Ca(OH)_2$ residues from the use of $Ca(OH)_2$ as a disinfectant in cattle housing results in soil exposure. However, the maximum application rate associated with the application of manure containing lime residues (Tier 2 0.27 tonnes /ha) is less than the maximum lime application rate applied in agriculture to control pH in Ireland (7.5 tonnes/ha).

Surface water exposure could result from runoff. During the E-consultation on the procedure of the environmental exposure assessment of products with the active substance hydrated lime, burnt lime and dolomitic burnt lime the EU Working Group agreed that a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage system is not relevant for lime products. When dissociation occurs, hydrated lime dissociates into Ca^{2+} and OH^{-}. The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. In terms of the surface water compartment Ca^{2+} ions are expected to be major constituents in many surface water bodies. Similar conclusions apply to the groundwater compartment. Ca^{2+} ions are expected to be major constituents in many groundwater zones. Overall, no further detailed assessment is considered necessary in this case. This is consistent with the approached adopted for the EU assessment of the active substance. In addition, the parametric drinking water limit of 0.1 µg/L for organic pesticides, usually used as a decision-making criterion regarding groundwater exposure is not applicable to inorganic compounds such as $Ca(OH)_2$. Parametric drinking water quality standards have not been set in Council Directive 98/83/EC for calcium ions and hydroxide/ carbonate ions.

Ecotoxicology

During the discussion of the lime product families at the WG-I-2020 meeting it was agreed that the emission and effect of lime to STP can be assessed qualitatively when it is used as disinfectant in animal housing. It was also agreed that a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage system is not relevant for lime products and so a qualitative assessment was carried out. Overall, no unacceptable risks to the STP or the aquatic compartment were identified.

It was agreed that a qualitative assessment of the terrestrial compartment could be performed because the dissociation products of the lime variants (Ca^{2+}, Mg^{2+} and OH^{-}) form parts of existing chemical cycles in the natural environment. The maximum application rate associated with the application of manure containing lime residues (Tier 2 0.27 tonnes /ha) is less than the maximum lime application rate applied in agriculture to control pH in Ireland (7.5 tonnes/ha).

With the exception of daily applications in housing associated with dairy cows (specifically farms with a 250 kg N/ha derogation) there is no concern to the environment from the proposed uses. However, the products can be used on these farms (dairy cows, 250 kg N/ha) if the biocide is applied every 2 d instead of every day. In addition to ensure that no unacceptable long-term pH changes in soil occur from spreading of manures or sewage sludges containing lime residues from the calcium dihydroxide products, the soil pH should be monitored as part of routine agricultural practice.

Overall, the risks are considered acceptable for the environment when the following risk mitigation measures (RMM) are implemented:

- Do not apply the products if releases from animal housings, manure/slurry storage areas can be directed to a sewage treatment plant.

- On farms that have a nitrogen derogation (250 kg N/ha/yr) the application interval between product applications in dairy housing is restricted to 2 day

Recommendation

- To avoid potential over liming, soil pH should be considered prior to spreading manures or slurry containing lime residues from calcium dihydroxide products. In addition soil pH should be monitored as part of routine agricultural practice to ensure the soil pH remains within acceptable norms.

The above RMMs and recommendation should be placed on the product label and SPC.

ASSESSMENT REPORT

Summary of the product assessment

Administrative information

Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Calcium dihydroxide family	IRELAND

Authorisation holder

Name and address of the authorisation holder	**Name**	Clogrennane Lime Ltd
	Address	Clogrennane R93 EV26 Carlow Ireland
Authorisation number	IE/BPA 70613	
Date of the authorisation	12/09/2023	
Expiry date of the authorisation	12/09/2033	

Manufacturer(s) of the products of the family

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

Name of manufacturer	Bennettsbridge Limestone
Address of manufacturer	Kilree, Sheastown, Bennettsbridge, Co Kilkenny, Ireland
Location of manufacturing sites	Kilree, Sheastown, Bennettsbridge, Co Kilkenny, Ireland

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Name of manufacturer	Kilwaughter Minerals Ltd
Address of manufacturer	9 Starbog Road, Larne, Co Antrim, BT40 2TJ
Location of manufacturing sites	9 Starbog Road, Larne, Co Antrim, BT40 2TJ

Name of manufacturer	McGrath Limestone (Cong) Ltd
Address of manufacturer	Cregaree Quarries, Cong, Mayo, Ireland, F31 W425
Location of manufacturing sites	Cregaree Quarries, Cong, Mayo, Ireland, F31 W425

Name of manufacturer	Nutribio
Address of manufacturer	Nutribio Ltd. Tivoli Industrial Estate Cork Ireland
Location of manufacturing sites	Nutribio Ltd. Tivoli Industrial Estate Cork Ireland

Manufacturer(s) of the active substance(s)

Active substance	Calcium dihydroxide
Name of manufacturer	Clogrennane Lime Ltd
Address of manufacturer	Clogrennane R93 EV26 Carlow Ireland
Location of manufacturing sites	Clogrennane R93 EV26 Carlow Ireland

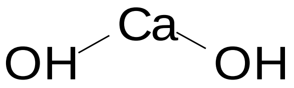
Product (family) composition and formulation

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 ☐

Identity of the active substance

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

Candidate(s) for substitution

Not applicable

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Calcium dihydroxide	Calcium dihydroxide	Active substance	1305-62-0	215-137-3	15	65
Calcium carbonate	Calcium carbonate	Non-active substance	471-34-1	207-439-9	35	85

Information on technical equivalence

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

Information on the substance(s) of concern

Calcium carbonate is a naturally occurring inorganic substance and is not classified. The substance is the starting material for manufacture of the active substance. It does not fulfil the criteria to be defined as a substance of concern.

Type of formulation

DP: Dustable powder

Hazard and precautionary statements

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

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

Authorised use(s)

Use description

Table 1. Use # 1 – Disinfection of indoor floor surfaces of animal accomodations

Product Type	PT 3 Veterinary hygiene
Where relevant, an exact description of the authorised use	The product is spread directly onto the floors of animal accommodations (cattle)
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor
Application method(s)	Direct application
Application rate(s) and frequency	Disinfection of indoor floor surfaces of animal accommodations. The product is spread onto the floors of

<table>
<tr><td></td><td>animal accommodations using manual or automated techniques. Manual spreading using a shovel or semi-automated using a low-impact spreader.
On concrete floors
1. Wash the installation with running water
2. Sprinkle the appropriate amount of product from the table below to cover the damp ground.
<table>
<tr><th>Calcium dihydroxide content in product (%)</th><th>Amount of product (kg /m^2)</th></tr>
<tr><td>15</td><td>1</td></tr>
<tr><td>20</td><td>0.75</td></tr>
<tr><td>30</td><td>0.5</td></tr>
<tr><td>40</td><td>0.375</td></tr>
<tr><td>50</td><td>0.3</td></tr>
<tr><td>65</td><td>0.23</td></tr>
</table>
3. Leave to act for at least 2 h</td></tr>
<tr><td>Category(ies) of users</td><td>Professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>Bulk Big bags or sacks: 400 - 1000 kg
Paper sacks: 5- 25 kg</td></tr>
</table>

Use-specific instructions for use

Contact time: 2 hours
No more than one application should be applied per day.
A minimum interval of 2 days between applications must be observed on farms that have a nitrogen derogation (250 kg N/ha/yr).

To ensure that no unacceptable long-term pH changes in soil occur from spreading of manures or sewage sludges containing lime residues from calcium dihydroxide products, the soil pH should be monitored as part of routine agricultural practice.

Use-specific risk mitigation measures

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

Individual protection measures
Respiratory protection: Provide sufficient air exchange and/or exhaust in work rooms. Respirator with a particle filter (EN 143) See also the exposure scenario.
Hand protection: Protective gloves: Nitrile rubber.

Eye/face protection: Tightly fitting safety goggles. Do not wear contact lenses.
Skin protection: Long sleeved clothing, close fittings at openings. Footwear protecting against chemicals.

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

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

First aid measures: If systems persist or in case of doubt seek medical advice
Inhalation: If inhaled move to fresh air. Call a doctor.

Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation develops, get medical attention.

Eye contact: Rinse immediately with plenty of water, also under eyelids for at least 15 minutes.
Remove contact lenses. Get medical attention.

Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.

Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

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

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

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

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

Lime products are not degradable. If stored in damp conditions the products may react, but there is no loss of the active substance

General directions for use

Instructions for use

The product is used as provided.
Application can be manual or semi-automated.
The specific directions for the use should be followed.

Risk mitigation measures

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

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

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

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

- On farms that have a nitrogen derogation (250 kg N/ha/yr) the application interval between product applications in dairy housing is restricted to 2 days

Recommendation

- To avoid potential over liming, soil pH should be considered prior to spreading manures or slurry containing lime residues from calcium dihydroxide products. In addition soil pH should be monitored as part of routine agricultural practice to ensure the soil pH remains within acceptable norms.

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

First aid measures: If systems persist or in case of doubt seek medical advice

Inhalation: If inhaled move to fresh air. Call a doctor.

Skin contact: Before washing, use a dry brush to remove dust from skin. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation develops, get medical attention.

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Remove contact lenses. Get medical attention.

Ingestion: Rinse mouth with water. Do not induce vomiting. Drink water. Call doctor immediately.

Direct effects: Eye damage/irritation and skin irritation. May cause irritation of the respiratory tract.
Treat symptomatically.

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

Instructions for safe disposal of the product and its packaging

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

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

Keep in a dry place.
Avoid: Exposure to air or moisture over prolonged periods. Keep away from acids, significant quantities of paper, straw, and nitro compounds.
Keep out of the reach of children.
Do not use aluminium for storage if there is a risk of contact with water

Other information

DP: Dustable powder

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	400 – 1000 kg	Paper	N/A	Professional	Yes
Sack	5 - 25 kg	Paper	N/A	Professional	Yes

**powder tanker up to 30T are not including in this table even though 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 the applicant has no data on individual circumstances applicable at the site of use..*

Documentation

Data submitted in relation to product application

See Annex 3.1

Access to documentation

The applicant is a member of EuLA, the legal entity supporting the active substance. A letter of access to the active substance dossier has been supplied.

Assessment of the biocidal product (family)

Intended use(s) as applied for by the applicant

Table 2. Use # 1 – Disinfection of indoor floor surfaces of animal accommodations (cattle)

<table>
<tr><td>Product Type</td><td>3</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>The product is spread directly onto the floors of animal accommodations (cattle)</td></tr>
<tr><td>Target organism (including development stage)</td><td>Bacteria, yeast</td></tr>
<tr><td>Field of use</td><td>Indoor</td></tr>
<tr><td>Application method(s)</td><td>Direct application</td></tr>
<tr><td>Application rate(s) and frequency</td><td>Disinfection of indoor floor surfaces of animal accommodations. 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.
On concrete floors
1. Wash the installation with running water
2. Sprinkle the appropriate amount of product from the table below to cover the damp ground.
<table>
<tr><th>Calcium dihydroxide content in product (%)</th><th>Amount of product (kg /m²)</th></tr>
<tr><td>15</td><td>1</td></tr>
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3. Leave to act for at least 2 h</td></tr>
<tr><td>Category(ies) of users</td><td>Professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>Bulk Big bags or sacks: 400 - 1000 kg
Paper sacks: 5 - 25 kg</td></tr>
</table>

Physical, chemical and technical properties

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. The main physico-chemical endpoints have been addressed in the active substance dossier and to which the applicant has access.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual	N/A	Solid	Appendix 1, Chapter 1, CAR, UK, 2016
Colour at 20 °C and 101.3 kPa	Visual	N/A	Off-white (Depends on impurities)	Appendix 1, Chapter 1, CAR, UK, 2016
Odour at 20 °C and 101.3 kPa	Visual	N/A	Odourless, bitter taste	Appendix 1, Chapter 1, CAR, UK, 2016
Acidity / alkalinity	CIPAC MT 31	Ca. 98% w/w	0.24 – 0.26 % m/m as NaOH	AS dossier B3.5/01
Relative density / bulk density	CIPAC MT 186 OECD 106 EC Method A3	2,080 – 2,300 kg/m^3 (literature) ≥ 97.0% (Precal 50N: 97.0% w/w) (Precal 50S: 98.2% w/w)	Relative density: 2.26 Pour density: 0.39 g/mL Tap density: 0.51 g/mL Relative density: 2.22 Pour density: 0.45 g/mL Tap density: 0.57 g/mL	Appendix 1, Chapter 1, CAR, UK, 2016 and AS dossier: A3.1.3/02 A3.1.3/03
Storage stability test – **accelerated storage**	Waiver	N/A	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.	Section 3.4.1, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Storage stability test – **long term storage at ambient temperature**	Waiver	N/A	Lime products are not degradable. If stored in damp conditions the	Section 3.4.1, CAR, UK, 2016 Note: This waiver was

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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.	produced in the CAR and has gone through peer review, this is deemed acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	N/A	The products are mixtures of naturally occurring substances. They are not subject to instability in the presence of light or under different temperature conditions.	Section 3.4.2.1, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver	N/A	Lime products are not degradable. If stored in damp conditions the products may react, but there is no loss of the active substance.	Section 3.4.2.1, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver	N/A	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	Section 3.4.2.1, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			used as container material for this product. Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime-based products (e.g. milk of lime) For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk transportation of wet lime products.	
Particle size distribution, content of dust/fines, attrition, friability	Waiver	N/A	The active substance is made from a naturally occurring substance; limestone. The particle size will be dependent upon the source of the limestone and will not be consistent. ASTM C110 - 15 are the standard test methods for physical testing	Section 3.5, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of quicklime, hydrated lime and limestone. The standard sieve sizes are > 1 mm, 0.1 - 0.99 mm and < 0.099mm. 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.	
Flowability/Pourability/Dustability	Waiver	N/A	The products are made from a naturally occurring substance; limestone. The particle size will be dependent upon the source of the limestone and will not be consistent. See particle size information above.	Section 3.5, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Physical compatibility	Waiver	N/A	According to long-time experience, Hydrated lime (and consequently the Hydrated lime products) can be stored without any problems in paper and plastic	Section 3.6, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			materials/ bags and in silos.	
Chemical compatibility	Waiver	N/A	Keep away from acids and nitro compounds. Aluminium should not be used for transport and storage.	Section 3.6, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Surface tension	Waiver	N/A	The study does not need to be conducted because based on structure, surface activity is not expected or cannot be predicted The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts for which surface activity is not expected.	Section 3.8, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Viscosity	Waiver	N/A	Not aplicable to solids	Section 3.9 CAR, UK, 2016

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Note: This is deemed acceptable.

1) Handbook of Chemistry and Physics, 70th Edition **1989 – 1990**, CRC Press Inc. Boca Raton, Florida. Doc.No. 192-002; A3.1.1/01.

(2) CD Römpp Chemie Lexikon – Version 1.0, Stuttgart/New York: Georg Thieme Verlag **1995**. Doc.No. 192-003; A3.1.3/01.

(3) Hollemann, Wiberg, "Lehrbuch der anorganischen Chemie", 91. – 100. Auflage, de Gruyter, Berlin, New York 1985. Doc.No. 192-001; A3.1.1/02.

(4) Dirk Lohmann: „Untersuchungen zur Vermeidung zu hoher pH-Werte in weichen Trinkwässern bei der Inbetriebnahme von Rohrleitungen mit einer Zementmörtelauskleidung", Dissertation, Duisburg. http://www.ub.uni-duisburg.de/ETD-db/theses/available/duett-05212001-095224/unrestricted/inhalt.htm. Doc.No. 192-005; A3.4.2/01.

(5) J. W. Kauffman, R. H. Hauge, J. L. Margrave: *„Infrared Matrix Isolation Studies of the Interactions of Mg, Ca, Sr and Ba Atoms and Small Clusters with Water", High Temperature Science* **1984**, *18*, pp. 97-118. Doc.No. 192-004; A3.4.2/02.

(6) R.T. Haslam, G. Calingaert, C.M. Taylor:" The Hydrates of Lime", J. Am. Chem. Soc., **1924**, 46 (2), pp. 308-311. Doc. No. 192-010; A3.5/01.

(7) A. Seidell, **1919**, "Solubilities of inorganic and organic substances – a compilation of quatitantive solubility data from the periodical literature"; Stanhope Press. Doc. No. 192-011; A3.5/02.

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

This assessment has been carried out on the following family of products containing a blend of the active substance, calcium dihydroxide, of between 15 – 65% and the inert filler, calcium carbonate, of between 35 -85%.

The products considered in the scope of this assessment are White Agri Rhino Hydrated Lime, Bennettsbridge Limestone Hydrated Cubicle Lime 15%, Bennettsbridge Limestone Hydrated Cubicle Lime 20%, Bennettsbridge Limestone Hydrated Cubicle Lime 30%, Bennettsbridge Limestone Hydrated Cubicle Lime 50%.

Calcium carbonate is the starting material for manufacture of the active substance. A read across to the active substance data set in the CAR, (UK,2016) is therefore deemed acceptable.

The products are off-white solids of naturally occurring origin.

A number of waivers were produced in the CAR (UK, 2016) and have undergone peer review. These waivers have been considered in the scope of this assessment and have been deemed acceptable.

Physical hazards and respective characteristics

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Explosives	Waiver	N/A	Not explosive, As stated in the CAR, according to the TNsG on data requirements 'The test can be exempted when [...] absence of certain reactive groups in the structural formula or its “oxygen balance” establishes beyond reasonable doubt that the substance is incapable of decomposing, forming gases or releasing heat very rapidly'. These criteria apply fully to calcium dihydroxide.	Section 4.1, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Flammable solids	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded.	Section 4.2, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Self-reactive substances and mixtures	Waiver	N/A	Neither the active substance or calcium carbonate will react exothermically with water-, they are simple organic salts so will not emit flammable gas. In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. The active substance and hence the products are not self-reactive	Section 4.8, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Pyrophoric liquids	Waiver	N/A	The biocidal products are solids, hence this endpoint is not relevant.	Section 4.8, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Pyrophoric solids	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. The active substance and hence the products are not pyrophoric	Section 4.8, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Self-heating substances and mixtures	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. The active substance and	Section 4.8, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			hence the products are not pyrophoric	peer review, this is deemed acceptable.
Substances and mixtures which in contact with water emit flammable gases	Waiver	N/A	In contact with water, the active substance and hence the products will not emit flammable gases	Section 4.12, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Oxidising solids	Waiver	N/A	'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 calcium dihydroxide because calcium and oxygen are in their respective preferred oxidation state.	Section 4.4, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Organic peroxides	Waiver	N/A	Substance does not fall under the definition of organic peroxide.	Section 4.15, CAR, UK, 2016 Note: This waiver was produced in the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				CAR and has gone through peer review, this is deemed acceptable.
Corrosive to metals	Waiver	N/A	Experience indicates that paper bags lined with plastic (to prevent contact with moisture), plastic bags, steel, stainless steel and Aluminium do not react significantly with dry lime and so can be used as container material for this product. Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime based products (e.g. milk of lime) For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk	Section 4.16, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
			transportation of wet lime products.	
Auto-ignition temperatures of products (liquids and gases)	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded.	Section 4.17, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Relative self-ignition temperature for solids	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded.	Section 4.17, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.
Dust explosion hazard	Waiver	N/A	In $Ca(OH)_2$, Calcium and Oxygen are in their respective preferred oxidation state and is not explosive as the substance is not combustible or flammable. In addition, the absence of a dust explosion hazard is supported by the use of inert limestone dust to prevent dust explosions in coal mining.	Section 4.17, CAR, UK, 2016 Note: This waiver was produced in the CAR and has gone through peer review, this is deemed acceptable.

Conclusion on the physical hazards and respective characteristics of the product

This assessment has been carried out on the following family of products containing a blend of the active substance calcium dihydroxide of between 15 – 65% and the inert filler calcium carbonate of between 35 -85%.

The products considered in the scope of this assessment are White Agri Rhino Hydrated Lime, Bennettsbridge Limestone Hydrated Cubicle Lime 15%, Bennettsbridge Limestone Hydrated Cubicle Lime 20%, Bennettsbridge Limestone Hydrated Cubicle Lime 30%, Bennettsbridge Limestone Hydrated Cubicle Lime 50%.

Calcium carbonate is the starting material for manufacture of the active substance calcium dihydroxide and a read across to the active substance data set in the CAR, (UK,2016) is therefore deemed acceptable.
A number of waivers were produced in the CAR (UK, 2016) and have undergone peer review. These waivers have been considered in the scope of this assessment and have been deemed acceptable.
The products are stable to light and temperature. If allowed to become damp, the active substance may react but there is no loss of the active material.
The products are all solid inhalable powders, off-white and naturally occurring origin.

The products are powders and were considered as dust explosion hazards however with calcium dihdroxide and calcium carbonate, the calcium and oxygen are in their respective preferred oxidation state and are not explosive as neither substance is combustible or flammable. The products do not exhibit any other physico-chemical hazards. 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.

Methods for detection and identification

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products.
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) *Impurities* *(SiO_2, combined oxides, Iron, moisture, CO_2, S, P, Mn, free Si, C and $CaCO_3$)*	Gravimetric, Volumetric, EDTA, Pyrophosphate, Insoluble matter	N/A	N/A	N/A	See Table below			N/A	ASTM C25-99 (1999)

Active substance (Na, Mg, Al, Si, P, S, Cl, K, Ca, Ti, Mn, Fe, Sr, Ba and Pb,)	X-ray spectrometric analysis	5							ASTM C1271-99 (1999)
	Ca as % CaO				53,347 53,683 54,304 55,599 55,837		0,28 % 0,30 % 0,23 % 0,20 % 0,26 %		
	Mg as % MgO				0,176 0,216 0,637 0,919 1,406		8,52 % 2,78 % 1,10 % 1,09 % 3,49 %		
	Si as % SiO_2				0,054 0,156 0,627 0,875 1,866		22,22 % 5,77 % 1,75 % 2,97 % 3,32 %		
	Fe as % Fe_2O_3				0,0244 0,0359 0,1357 0,1917 0,8792		5,33 % 5,01 % 1,69 % 1,10 % 1,56 %		
	Al as % Al_2O_3				0,0463 0,0736 0,1142 0,1159 0,4404		3,24 % 5,43 % 2,63 % 3,11 % 3,70 %		
	Mn as % Mn				0,0024 0,0035 0,017		12,50 % 8,57 % 21,18 %		

					0,0248 *0,09*		1,21 % 0,44 %		
Active substance *(calcium, magnesium, oxide and hydroxide.* *Impurities minerals of silicon (silicates), aluminium, iron (pyrite), manganese, carbon (carbonates), sulphur (sulphates, pyrite) and water.)*	ICP AA	Duplicate							ASTM CC 1301 – 95 (1995) (Reapproved 2001)
Active substance	Titration		N/A	Reproducibility: 12.64%			*2.30*		EN12945
Active substance	AA (Mg)			Reproducibility: 0.25%			*0.21*		DIN EN 12946 DIN EN 12947 DIN EN 12048 DIN EN 14397-2

ASTM C25 – 99:

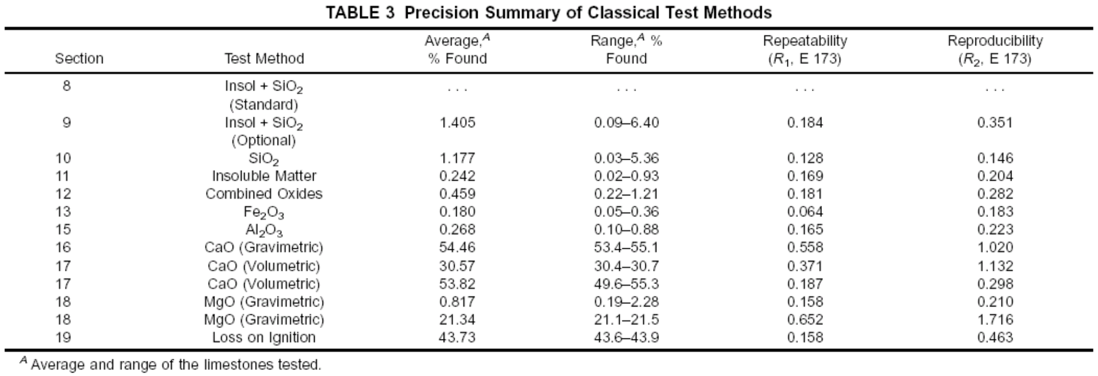

TABLE 3 Precision Summary of Classical Test Methods

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

[A] Average and range of the limestones tested.

Analytical methods for monitoring

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

Analytical methods for soil

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

The main influences of Lime variants on soil are the change of the pH-value and the change of Ca^{2+} and Mg^{2+} contents. The applicant has provided details of the following standards to measure these changes;

NF ISO 10390: “French standard: Soil quality – determination of pH”. Doc. No. 492-020.

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

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

Analytical methods for air

This International Standard specifies a method for the determination of the time-weighted average mass concentration of lithium hydroxide (LiOH), sodium hydroxide (NaOH), potassium hydroxide (KOH), and calcium dihydroxide [Ca(OH)2] in workplace air by collection of the particulate hydroxides on a filter and analysis of the corresponding cations using ion chromatography.

For aerosol sampling, the method is applicable to the personal sampling of the inhalable fraction of airborne particles, as defined in ISO 7708, and to static (area) sampling.

The method is applicable to the determination of masses of 0,005 mg to at least 2,5 mg of lithium per sample and 0,01 mg to at least 5 mg of sodium, potassium, and calcium per sample.

The concentration range of particulate LiOH, NaOH, KOH, and Ca(OH)2 in air for which the measuring procedure is applicable is determined by the sampling method selected by the user. For a 1 m3 air sample, the working range is approximately 0,002 mg m−3 to at least 20 mg m−3 for all four hydroxides. For a 30 l air sample, the lower limit of the working range is approximately 0,1 mg m−3 for all four hydroxides.

The procedure does not allow differentiation between the hydroxides and their corresponding salts if both are present in the air. If the cations are present alone in the form of hydroxides, the method is specific for these basic compounds. In other circumstances, the results obtained represent the highest concentration of the hydroxides that could be present in the sampled air.

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

Analytical methods for water

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

Analytical methods for animal and human body fluids and tisues

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

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

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

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

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

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

Conclusion on the methods for detection and identification of the product

A comprehensive assessment of the methods of detection and identification of the active substance were considered during the CAR (UK, 2016) for calcium dihydroxide. As the products considered in this assessment are a family of products containing a blend of the active substance calcium dihydroxide of between 15 – 65% and the inert filler calcium carbonate of between 35 - 85%, a read across to the active substance data set in the CAR, (UK,2016) is therefore deemed acceptable.

The following analytical methods covering the monitoring of the active substance, determination of the active in animal and human body fluids and tissues, soil, water and air were included.
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.

Efficacy against target organisms

Function and field of use

Disinfectant products for use in Product Type 3. The products are for veterinary applications such as livestock housing (PT3).

Their use is for the disinfection of hard non-porous inanimate surfaces. They are not intended to be used for direct contact with food or feeding stuffs. The products are intended for direct application onto the substrate. The products are for professional use only and are bactericidal and yeasticidal.

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

Disinfectant products intended to control bacteria and yeasts, on surfaces in veterinary applications such as livestock housing.

Effects on target organisms, including unacceptable suffering

The pH and exothermic reaction of the products in contact with moisture disrupt the cell wall of the target organisms.

Mode of action, including time delay

Two effects of hydrated lime are known:

> 1) Increased alkalinity - Addition of sufficient quantities of Lime to organic waste brings about a rapid and sustained increase in pH, to a level > 12. The high concentration of free OH^- ions results in the denaturation of protein structures of microorganisms such as cell walls, capsid structures, enzymes and organelles.
>
> 2) Increase in free / non-ionised ammonia (NH_3) - Proteolytic activity in biodegrading organic matter results in high concentrations of nitrogenous compounds. The high pH associated with lime activity is sufficient to convert any ammonium ions (NH^{4+}) into free / non-ionised ammonia gas (NH_3). Ammonia gas diffuses into bacterial cells, altering chemical equilibrium between intra-and extra-cellular environments, and impeding essential enzymatic function to bring about cell death. 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 hours for the most resistant bacteria and up to 3 months for the most pH resistant parasites.

Efficacy data

A full package of efficacy against various organisms is presented to show that the products are efficacious against the mandatory species for the proposed application in PT 3.
Furthermore, as was noted in the outcome of the e-consultation on the validity of EN tests requiring the substance to be dissolved in water, these tests, for example suspension tests, are not valid for lime products due to the low solubility. It was suggested that tests were the products are mixed with the substrate (e.g. mixed with manure or sewage sludge) or spread onto the surface are more appropriate. Therefore, although certain tests below are not directly applicable to the use proposed they do show the efficacy of the products against various target organisms in accepted valid tests, which cannot be proved using the EN tests indicated in the ECHA Guidance document.

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 Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 65%	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 14349: 2012 Bactericidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications. Note that the additional test organism *S. uberis* was also incorporated into the protocol	A bactericidal surface test for non-porous surfaces found in veterinary applications The product was applied at a rate of 100% product (65% active substance) allowed to remain in contact for 30 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	**FAIL** with notes: >4 Log reduction The product “65% Calcium hydroxide” was found to be Bactericidal against *E. hirae* only on non porous hard surfaces (without mechanical action) when applied at 100% for 30 minutes exposure time under veterinary high soil conditions at 10°C.	6.7-01 Study No. BT-ARW-03-02 EN 14349: 2012 BluTest Laboratories Woodall(2019)

						>3<4 log reduction results were recorded for *S. aureus* and *S. uberis.* *Ps. aeruginosa* and *P.vulgaris* results were invalid.	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 65%	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 16437: 2014 Bactericidal Activity Phase 2 Step 2 Porous surface test for veterinary applications. Note that the additional test organism *S. uberis* was also incorporated into the protocol	A bactericidal surface test for porous surfaces found in veterinary applications The product was applied at a rate of 100% product (65% active substance) allowed to remain in contact for 60 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	**FAIL** with notes: <4 Log reduction The product “65% Calcium hydroxide” was found NOT to be Bactericidal against *E. hirae*, *S. aureus, Ps. aeruginosa* and *P.vulgaris* on porous hard surfaces (without mechanical action) when applied at 100% for 60 minutes exposure time under veterinary high soil conditions at 10°C. The product was found to be effective (>4log reduction) against *S. uberis* under the above conditions.	6.7-02 Study No. BT-ARW-03-02-A1 EN 16437: 2014 BluTest Laboratories Woodall(2019)

Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 65%	*Candida albicans* ATCC 10231 *Aspergillus* *brasiliensis* ATCC 16404	EN 16438: 2014 Fungicidal and/or Yeasticidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A fungicidal and yeasticidal surface test for non-porous surfaces found in veterinary applications The product was applied at a rate of 100% product (65% active substance) allowed to remain in contact for 60 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	**PASS – Yeasticidal** >3log reduction The product "65% Calcium hydroxide" was found to be effective against *C.albicans* at a concentration of 100% and a contact time of 60 minutes under Veterinary High Soil conditions and a test temperature of 10°C on non-porous surfaces. The product was found not to be fungicidal against *A. brasiliensis* under the above conditions	6.7-03 Study No. BT-ARW-03-02 EN 16438: 2014 BluTest Laboratories Woodall(2019)
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 10%	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	EN 14349: 2012 Bactericidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A bactericidal surface test for non porous surfaces found in veterinary applications The product was applied at a rate of 100% product (10% active substance) allowed to remain in	**FAIL**: <4 Log reduction, all organisms	6.7-04 Study No. BT-ARW-03-03 EN 14349: 2012

			Proteus vulgaris ATCC 13315 *Streptococcus uberis* DSM 20569	Note that the additional test organism *S. uberis* was also incorporated into the protocol	contact for 30 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	The product “10% Calcium hydroxide” was found NOT to be Bactericidal against *E. hirae* , *S. aureus, Ps. aeruginosa, S. uberis* and *P.vulgaris* on non-porous hard surfaces (without mechanical action) when applied at 100% for 30 minutes exposure time under veterinary high soil conditions at 10°C.	BluTest Laboratories Woodall(2019)
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 10%	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315 *Streptococcus uberis* DSM 20569	EN 16437: 2014 Bactericidal Activity Phase 2 Step 2 Porous surface test for veterinary applications. Note that the additional test organism *S. uberis* was also incorporated into the protocol	A bactericidal surface test for porous surfaces found in veterinary applications The product was applied at a rate of 100% product (10% active substance) allowed to remain in contact for 60 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	**FAIL**: <4 Log reduction The product “10% Calcium hydroxide” was found NOT to be Bactericidal against *E. hirae* , *S. aureus, Ps. aeruginosa, S. uberis* and *P.vulgaris* on porous hard surfaces (without mechanical action) when applied at 100% for 60 minutes	6.7-05 Study No. BT-ARW-03-03-A1 EN 16437: 2014 BluTest Laboratories Woodall(2019)

						exposure time under veterinary high soil conditions at 10°C.	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 10%	*Candida albicans* ATCC 10231 *Aspergillus* *brasiliensis* ATCC 16404	EN 16438: 2014 Fungicidal and/or Yeasticidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A fungicidal and yeasticidal surface test for non porous surfaces found in veterinary applications The product was applied at a rate of 100% product (10% active substance) allowed to remain in contact for 60 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	**FAIL:** <3 Log reduction The product "10% Calcium hydroxide" was found to NOT be effective against *C. albicans* or *A. brasiliensis* at a concentration of 100% and a contact time of 60 minutes under Veterinary High Soil conditions and a test temperature of 10°C on non-porous surfaces.	6.7-06 Study No. BT-ARW-03-03 EN 16438: 2014 BluTest Laboratories Woodall(2019)
Disinfectant Disinfection of Surfaces, Materials, Equipment and	PT3 The disinfection of surfaces as found in	Calcium hydroxide 65% Product	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538	EN 1656: 2010 Bactericidal Activity Phase 2 Step 1	A bactericidal suspension test for products used in veterinary applications	**PASS – Bactericidal** >5 log reduction, all organisms	6.7-07 Study No. 0557A/18

Vehicles in the Veterinary Area	Veterinary Applications	Applied at a rate of 60% (Active Substance concentration of 39%)	*Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	Suspension test for veterinary applications.	The product was applied at a rate of 60% product (39% active substance) allowed to remain in contact for 30 minutes, in the presence of 3g/L BSA simulating veterinary clean (low soil) conditions, Test temperature was 10°C	The product "65% Calcium hydroxide" was found to be effective against all bacteria tested at a concentration of 60% and a contact time of 30 minutes under Veterinary Low Soil (clean) conditions and a test temperature of 10°C.	MLUA – 01337A-18 EN 1656: 2010 MLUA Krowas (2018)
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide 65% Product Applied at a rate of 60% (Active Substance concentration of 39%)	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349: 2012 Bactericidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A bactericidal surface test for non porous surfaces found in veterinary applications The product was applied at a rate of 60% product (39% active substance) allowed to remain in contact for 60 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	FAIL: With Notes A >5 Log reduction was recorded against three of the four test organisms' with a >3 log reduction recorded against the fourth organism. The product "65% Calcium hydroxide" was found to be Bactericidal against *S. aureus, Ps. aeruginosa,* and *P.vulgaris* only on non -porous hard surfaces (without mechanical action)	6.7-08 Study No. 0557A/18 MLUA – 01337A-18 EN 14349: 2012 MLUA Krowas (2018)

						when applied at 60% (39% active substance) for 60 minutes exposure time under veterinary high soil conditions at 10°C. The product recorded a >3log but <4log reduction against *E.hirae* under the above conditions and concentration	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (>80% pure) Product Applied at a rate of 800g product/m^2 together with 2000ml/m^2 water (>640g AS/m^2)	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349: 2012 Bactericidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A bactericidal surface test for non porous surfaces found in veterinary applications The (>80% pure) product was applied at a rate of 800g product/ m^2 together with 2000ml/m^2 water and allowed to remain in contact for 30 minutes, in the presence of 3g/L BSA simulating veterinary clean(low soil) conditions, Test temperature was 10°C	**PASS – Bactericidal** >4 log reduction, all organisms The product ">80% Calcium hydroxide" was found to be effective against all bacteria tested when it was applied at a rate of 800g product/ m^2 together with 2000ml/m^2 of and a contact time of 30 minutes under Veterinary Low Soil (clean) conditions and a test temperature of 10°C.	6.7-09 Study No. J000714-1 EN 14349 (clean): 2012 MSL Burney/Crane (2018)

Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (>80% pure) Product Applied at a rate of 800g product/m^2 together with 2000ml/m^2 water (>640g AS/m^2)	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 14349: 2012 Bactericidal Activity Phase 2 Step 2 Non porous surface test for veterinary applications.	A bactericidal surface test for non porous surfaces found in veterinary applications The (>80% pure) was applied at a rate of 800g product/ m^2 together with 2000ml/m^2 water and allowed to remain in contact for 30 minutes, in the presence of 10g/L BSA + 10g/L Yeast Extract - simulating veterinary dirty (high soil) conditions, Test temperature was 10°C	FAIL: With Notes A >5 Log reduction was recorded against three of the four test organisms' with a >3 log reduction recorded against the fourth organism. The product ">80% pure Calcium hydroxide" was found to be Bactericidal against, *Ps. aeruginosa, E.hirae* and *P.vulgaris* only on non porous hard surfaces (without mechanical action) when applied at a rate of 800g product/m^2 together with 2000ml/m^2 water (>640g AS/m^2) for 60 minutes exposure time under veterinary high soil conditions at 10°C. The product recorded a	6.7-10 Study No. J000714-1 EN 14349 (dirty): 2012 MSL Burney/Crane (2018)

						>3log but <4log reduction against *S. aureus* under the above conditions and concentration.	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (>80% pure) Product Applied at a rate of 800g product/m^2 together with 2000ml/m^2 water (>640g AS/m^2)	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Proteus vulgaris* ATCC 13315	EN 16437: 2014 Bactericidal Activity Phase 2 Step 2 Porous surface test for veterinary applications.	A bactericidal surface test for porous surfaces found in veterinary applications The (>80% pure) was applied at a rate of 800g product/ m^2 together with 2000ml/m^2 water and allowed to remain in contact for 60 minutes, in the presence of 3g/L BSA simulating veterinary clean (low soil) conditions, Test temperature was 10°C	FAIL: With Notes A >4 Log reduction was recorded against two of the four test organisms, *Pseudomonas aeruginosa* and *Proteus vulgaris* with a >3 log reduction recorded against a third organism, *Staphylococcus aureus,* but <2 log reduction against *Enterococcus hirae* The product ">80% pure Calcium hydroxide" was found to be Bactericidal against *Ps. Aeruginosa,* and *P.vulgaris* only on porous hard surfaces (without mechanical action) when applied at a rate of 800g product/m^2 together with 2000ml/m^2 water (>640g AS/m^2)	6.7-11 Study No. J000714-2 EN 16437 (clean): 2014 MSL Burney/Crane (2018)

						for 60 minutes exposure time under veterinary high soil conditions at 10°C. The product recorded a >3log but <4log reduction against *S. aureus* under the above conditions and concentration.	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide >80%)	Staphylococcal bacteria Streptococcal bacterial	Field Trial to investigate the effects of treating cubicles and its impact on the incidence of cow udder contamination	Cubicles were treated with (a) Hydrated Lime (>80%), (b) a 50:50 mix of hydrated lime with ground lime and (c) ground lime only. A number of cows were split into equal cohorts. Trial length was up to 72 days. Treatment was on a daily basis	The trial demonstrated that the daily treatment of cow cubicles with hydrated lime (Calcium hydroxide significantly reduced the incidence of cow udder contamination.	6.7-12 Moore Park Report Field Trial Gleeson D.(2010)
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide 65%) Applied at a rate of 1000g/ m^2 Together with 0.5L/ m^2 water	*Pseudomonas aeruginosa* DSM 939 *Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799	Simulated Use Test according to a methodology based on NF T 72-281 Bactericidal efficacy of lime (Calcium hydroxide)	A simulated use test utilising principles found in NF T 72-287 applied in a manner to give multiple surface replicates (5cm x 5cm mosaic tile carriers). All organisms exposed for 2 hours to a combination of 1000g/m^2 treatment of "65% Calcium hydroxide" and 0.5L/m^2	**PASS Bactericidal** The product "65% Calcium hydroxide" was found to be Bactericidal, bringing about a greater than 4 log reduction in surface populations of all four organisms tested at a concentration of 1000g/m2 when	6.7-13 Study No. RE-1347/1019 IRM Carre (2020)

			Enterococcus hirae CIP 58.55		in total(2 x 0.25 L/m^2) water. Interfering substance was included representing high level soiling for the veterinary area (10g/L BSA + 10g/L Yeast Extract). Evaluation was by counting survivors and comparing to the control carriers. The temperature throughout the test was maintained at 15-22°C	applied in combination with a total of 0.50L/m^2 water under veterinary high level soil conditions at a test temperature of 15-22 °C	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide 65%) Applied at a rate of 1000g/ m^2 Together with 0.5L/ m^2 water	*Candida albicans* ATCC 10231	Simulated Use Test according to a methodology based on NF T 72-281 Yeasticidal efficacy of lime (Calcium hydroxide)	A simulated use test utilising principles found in NF T 72-287 applied in a manner to give multiple surface replicates (5cm x 5cm mosaic tile carriers). *C.albicans* exposed for 2 hours to a combination of 1000g/m^2 treatment of “65% Calcium hydroxide” and 0.5L/m^2 in total(2 x 0.25 L/m^2) water. Interfering substance was included representing	**PASS – Yeasticidal** The product “65% Calcium hydroxide” was found to be Yeasticidal, bringing about a greater than 4 log reduction in surface populations of *C.albicans* tested at a concentration of 1000g/m2 when applied in combination with a total of 0.50L/m^2 water under veterinary high level soil conditions at a test	6.7-14 Simulated Use Test based on NF T 72-281 Study No. RE-1347/1019 IRM

					high level soiling for the veterinary area (10g/L BSA + 10g/L Yeast Extract. Evaluation was by counting survivors and comparing to the control carriers. The temperature throughout the test was maintained at 15-22°C	temperature of 15-22 °C	Carre (2020)
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide 10%) Applied at a rate of 1000g/ m^2 Together with 0.5L/ m^2 water	*Pseudomonas aeruginosa* DSM 939 *Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Enterococcus hirae* CIP 58.55	Simulated Use Test according to a methodology based on NF T 72-281 Bactericidal efficacy of lime (Calcium hydroxide)	A simulated use test utilising principles found in NF T 72-287 applied in a manner to give multiple surface replicates (5cm x 5cm mosaic tile carriers). All organisms exposed for 2 hours to a combination of 1000g/m^2 treatment of “10% Calcium hydroxide” and 0.5L/m^2 in total(2 x 0.25 L/m^2) water. Interfering substance was included representing high level soiling for the veterinary area (10g/L BSA + 10g/L Yeast Extract). Evaluation was by counting survivors and	**PASS Bactericidal** The product “10% Calcium hydroxide” was found to be Bactericidal, bringing about a greater than 4 log reduction in surface populations of all four organisms tested at a concentration of 1000g/m2 when applied in combination with a total of 0.50L/m^2 water under veterinary high level soil conditions at a test temperature of 15-22 °C **FAIL Yeasticidal** The product was found not to be yeasticidal against *C.albicans*	6.7-15 Simulated Use Test based on NF T 72-281 Study No. RE-1375/1019 IRM Carre (2020)

					comparing to the control carriers. The temperature throughout the test was maintained at 15-22°C	under the above conditions	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide 15%)	*Streptococcus uberis* DSM 20569	Simulated Use Test according to a methodology based on NF T 72-281 Microbiocidal (*Bactericidal S. uberis* only,) efficacy of lime (Calcium dihydroxide (15%))	A simulated use test utilising principles found in NF T 72-287 applied in a manner to give multiple surface replicates (5cm x 5cm mosaic tile carriers). One organism (*S. uberis)* was exposed for 2 hours to a combination of 1000g/m^2 treatment of Ca hydroxide 15% and wetted with water (applied in two steps of 0.25L/ m^2). Interfering substance was included representing high level soiling for the veterinary area (10g/L BSA + 10g/L Yeast Extract. Evaluation was by counting survivors and comparing to the control carriers.	**PASS Bactericidal against the specific named organism *S. uberis*** The product "Calcium Hydroxide 15%" was found to be Bactericidal against the specific named organism *S. uberis,* bringing about a greater than 4 log reduction in surface populations within 2 hours. The treatment was a combination of 1000g/m^2 treatment of Calcium hydroxide 15% wetted with water (applied in two steps of 0.25L/ m^2), carried out under veterinary high soiling	6.7-16 Simulated Use Test based on NF T 72-281 IRM Study No. RE 1539/1220 (Carre, 2021)

					The temperature throughout the test was maintained at 15-22°C	conditions, at a test temperature maintained at 15-22 °C	
Disinfectant Disinfection of Surfaces, Materials, Equipment and Vehicles in the Veterinary Area	PT3 The disinfection of surfaces as found in Veterinary Applications	Calcium hydroxide (Calcium hydroxide 15%) Applied at a rate of 1000g/ m^2 Together with 0.5L/ m^2 water	*Candida albicans* ATCC 10231	Simulated Use Test according to a methodology based on NF T 72-281 Yeasticidal efficacy of lime (Calcium hydroxide)	A simulated use test utilising principles found in NF T 72-287 applied in a manner to give multiple surface replicates (5cm x 5cm mosaic tile carriers). *C. albicans* exposed for 2 hours to a combination of 1000g/m^2 treatment of "15% Calcium hydroxide" and 0.5L/m^2 in total(2 x 0.25 L/m^2) water. Interfering substance was included representing high level soiling for the veterinary area (10g/L BSA + 10g/L Yeast Extract. Evaluation was by counting survivors and comparing to the control carriers.	**PASS – Yeasticidal** The product "15% Calcium hydroxide" was found to be Yeasticidal, bringing about a greater than 4 log reduction in surface populations of *C. albicans* tested at a concentration of 1000g/m2 when applied in combination with a total of 0.50L/m^2 water under veterinary high level soil conditions at a test temperature of 15-22 °C	6.7-17 Simulated Use Test based on NF T 72-281 Study No. RE-1422/0920 IRM Carre (2020)

					The temperature throughout the test was maintained at 15-22°C		

According to the Biocidal Products Regulation (BPR) for a hard surface disinfectant such as Lime to be used in environments such as animal housing, a quantitative suspension test (Phase 2 Step 1) and a quantitative surface test (Phase 2, Step 2) – both simulating practical conditions appropriate to its intended use (temperature, soiling, porous, non-porous, contact time etc.) are required. However, due to the low solubility nature of the product some efficacy laboratory tests (standard EN tests) may not be appropriate for demonstrating the efficacy of lime products as the EN tests require dilution. In a recent E-consultation it was agreed that the standard EN protocols using water as a carrier substance were not suitable for efficacy testing of lime-based products. The IE CA regards simulated use tests based on modification of Phase 2, Step 2 EN protocols using hard surfaces, as a more suitable method for evaluating the efficacy of lime-based products.

Several EN suspension and surface tests have been included by the applicant as part of the body of evidence for the product. However, these tests are not valid for an insoluble active substance such as Calcium hydroxide which is applied as a dry powder or thick slurry.

A modified Phase 2, step 2 EN 14349 surface test was submitted (6.7-1) for the evaluation of bactericidal activity of the product containing 65% Calcium hydroxide under dirty conditions with a contact time of 30 mins at 10°C. In this test the product failed to meet the 4 log reduction requirements of EN 14349 against four of the five organisms. However, the IE CA believes that due to the products insolubility, EN 14349 is not a suitable method for the demonstration of efficacy of dry powder product such as this.

A modified EN 16437 quantitative surface test was submitted (6.7-2) for the evaluation of bactericidal activity (including Streptococcus uberis DSM 20569) of the product containing 65% Calcium hydroxide under dirty conditions with a contact time of 60 mins at 10°C. In this test the product failed to meet the requirements of EN 16437 against four of the five organisms tested. The product was applied dry and therefore the IE CA believes that EN 16437 may not be a suitable method due to the products insolubility and the constraints of the test methodology.

A modified EN 16438 quantitative surface test (6.7-3) was submitted for the evaluation of fungicidal or yeasticidal activity of the product containing 65% Calcium hydroxide under dirty conditions with a contact time of 60 mins at 10°C on non-porous surfaces. In this test the product met the requirements of EN 16438 (>3 log reduction) against Candida Albicans and therefore demonstrated yeasticidal activity under these conditions. The product failed to meet the required log reduction against Aspergillus brasiliensis and therefore did not demonstrate fungicidal activity. However, this is not relevant to the application as the applicant is not claiming for fungicidal activity and it is not a basic requirement for PT 3 hard surface disinfectants under the BPR.

A modified Phase 2, step 2 EN 14349 surface test was submitted (6.7-4) for the evaluation of bactericidal activity of the product containing 10% Calcium hydroxide under dirty conditions with a contact time of 30 mins at 10°C. In this test the product failed to meet the requirements of EN 14349 (4 log reduction) against all five of the tested organisms. There were validation failures for three of the organisms which again may indicate that this method is not suitable for directly applied dry products. However, this test is not relevant to the current application as there is no 10% Calcium Hydroxide product within the product family.

A modified EN 16437 quantitative surface test was submitted (6.7-5) for the evaluation of bactericidal activity (including Streptococcus uberis DSM 20569) of the product containing

10% Calcium hydroxide under dirty conditions with a contact time of 60 mins at 10°C. In this test the product failed to meet the requirements of EN 16437 against four of the five organisms tested. The product was applied dry and therefore the IE CA believes that EN 16437 may not be a suitable method due to the products insolubility and the constraints of the test methodology. In addition, this test is not relevant to the current application as there is no 10% Calcium Hydroxide product within the product family.

A modified EN 16438 quantitative surface test (6.7-6) was submitted for the evaluation of fungicidal or yeasticidal activity of the product containing 10% Calcium hydroxide under dirty conditions with a contact time of 60 mins at 10°C on non-porous surfaces. In this test the product failed to provide a sufficient level of efficacy against either Candida albicans or Aspergillus brasiliensis therefore recording a fail for both fungicidal and yeasticidal activity under the conditions of the test. As with other studies evaluated for this product, the IE CA believes that the application of dry product onto a carrier with no further addition of moisture within the test may indicate that the test method is unsuitable for this product.

A quantitative Phase 2, Step 1 suspension test (6.7-7) was submitted for the evaluation of bactericidal activity of the product containing 60% Calcium hydroxide under clean conditions at 10°C. Although the E-consultation on the validity of EN tests for Lime products concluded a suspension test was neither suitable or necessary for this application, the product met the requirements of EN 1656 (5 log reduction) and demonstrated bactericidal activity for all tested organisms under low level soil conditions. The IE CA notes that this product would typically be used in an area of high-level soiling and therefore this test result does not fit the in-use conditions of the product.

A Phase 2, Step 2 EN 14349 surface test was submitted (6.7-8) for the evaluation of bactericidal activity of the product containing 65% Calcium hydroxide under dirty conditions with a contact time of 60 mins at 10°C. The product failed to meet the 4 log reduction requirements of EN 14349 against three of the four organisms tested and therefore failed to achieve a Pass. However, the IE CA believes that EN 14349 is not a suitable method for the demonstration of efficacy of dry powder product due to its insolubility.

A modified phase 2, step 2 EN 14349 surface test was submitted (6.7-9) for the evaluation of bactericidal activity of the product containing Calcium hydroxide (80% pure product) under clean conditions with a contact time of 30 mins at 10°C. In this test the product met the requirements of EN 14349 against all four standard organisms within a 30-minute contact time under clean conditions. The IE CA notes that this product would typically be used in an area of high-level soiling. The product demonstrated sufficient activity to record a Pass; however, the IE CA does not consider this test relevant to the current application as there is no 80% Calcium Hydroxide product within the product family.

A modified Phase 2, step 2 EN 14349 surface test was submitted (6.7-10) for the evaluation of bactericidal activity of the product containing Calcium hydroxide (80% pure product) under dirty conditions with a contact time of 30 mins at 10°C. The product failed to meet the 4 log reduction requirements of EN 14349 against three of the four organisms and therefore failed to achieve a Pass. The IE CA believes that EN 14349 is not a suitable method for the demonstration of efficacy of dry powder product such as this due to its insolubility. In addition, the IE CA does not consider this test relevant to the current application as there is no 80% Calcium Hydroxide product within the product family.

A modified EN 16437 quantitative surface test was submitted (6.7-11) for the evaluation of bactericidal activity of the product containing Calcium hydroxide (80% pure product) under clean conditions with a contact time of 60 mins at 10°C. In this test the product failed to meet the requirements of EN 16437 against two of the four organisms tested. The product was applied dry and therefore the IE CA believes that EN 16437 may not be a suitable method due to the products insolubility and the constraints of the test methodology. This test is irrelevant to the current application as there is no 80% Calcium Hydroxide product within the product family.

A report on the effect of using hydrated lime as a bedding material on the microbial count (Staphylococcal and Streptococcal bacteria) on teats prior to calving and the infection levels post calving (Gleeson, D. 2013) was submitted (6.7-12) as supporting evidence of the efficacy of Calcium hydroxide. Sixty cows were split into three equal cohorts and exposed to one of three treatments; a) Hydrated lime only; b) 50:50 hydrated lime and ground lime, and c) ground lime only. Cow teats were swabbed daily, and results noted. The results demonstrate that daily treatment of a cubicle floor with hydrated lime reduced the percentage of cows presenting with both Staphylococcal bacteria and or Streptococcal bacteria when compared with the control group. The IE CA considers this study as supporting the biocidal activity of Calcium hydroxide.

The applicant submitted 5 simulated use (SU) tests (6.7-13 – 6.7-17) of products containing 10%, 15% and 65% Calcium hydroxide. These tests were performed according to a highly modified version of AFNOR NF-T72-281. These tests were surface tests carried out in a larger scale environment under simulated use conditions. The SU tests allowed for a larger surface than the recommended Phase 2, step 2 tests for PT3 use. An experimental chamber of approximately 150 cubic metres was used for the test and it allowed for the spreading of the dry material onto a large target surface with the subsequent addition of a small volume of (sprinkled) water. All SU tests were carried out under veterinary 'high soiling conditions' (10g/L of yeast extract and 10g/L of bovine albumin), at 15-22°C with a contact time of 2 hours.

- Bactericidal and yeasticidal activity were demonstrated by SU tests 6.7-13 and 6.7-14 which evaluated efficacy against target organisms Pseudomonas aeruginosa DSM 939, Escherichia coli DSM 682, Staphylococcus aureus DSM 799, Enterococcus hirae CIP 58.55 and Candida albicans ATCC 10231 using the 65% Calcium hydroxide product.
- Bactericidal activity was demonstrated by SU test 6.7-15 which evaluated efficacy against Pseudomonas aeruginosa DSM 939, Escherichia coli DSM 682, Staphylococcus aureus DSM 799, Enterococcus hirae CIP 58.55 and Candida albicans ATCC 10231 using the 10% Calcium hydroxide product. This test did not demonstrate yeasticidal activity.
- Bactericidal activity for specific disinfection against S. uberis was demonstrated by SU test 6.7-16 which evaluated efficacy against Streptococcus uberis DSM 20569 using the 15% Calcium hydroxide product.
- Yeasticidal activity was demonstrated by SU test 6.7-17 which evaluated efficacy against Candida albicans ATCC 10231 using the 15% Calcium hydroxide product.

It should be noted that the SU test method was based on a highly modified AFNOR NF T 72-281 methodology. These modified tests allowed for surface tests to be carried out in a larger scale environment. Products were tested under simulated use conditions i.e. mimicking the EN surface tests for PT3 use. The applicant states that there is no historic precedence for this modification and therefore has used a nominal >4 log reduction for bacteria and a >3 log reduction for yeast as this is the required log reduction in the standard EN Veterinary surface test method (EN14349/EN16437/EN16438). The IE CA deems this an acceptable log reduction to demonstrate bactericidal and yeasticidal activity.

The IE CA notes that in the SU tests the applicant has tested the product(s) against a range of organisms representative of those found in the standard EN tests for PT 3 use. However, they have substituted the required Proteus hauseri (formally known as Proteus vulgaris) with E. Coli, claiming that based on previous experience with this modified method, P. Hauseri was not compatible with this method. Although this is not ideal and P. Hauseri is one of the four recommended bacteria in the EN surface test methods for PT3, the IE CA considers it an acceptable substitute. Both organisms are gram negative, indole positive, rod shaped bacteria which can be found in soil, water and faecal matter. S. Uberis was also included as a target organism as the applicant wishes to claim specific disinfection activity against this organism.

As directed by the BPR, specific conditions relating to the field of use for the products have been included in the simulated use tests such as high level of soiling, contact time and application rate.

The SU tests were performed at a temperature of 15-22°C. Typically products for PT3 use are tested at 10°C or below since the temperature in animal housings can be low as per the BPR guidance. However, the applicant has provided the following justification to account for the higher temperature. The environmental control system of the experimental chamber does not allow for the whole volume to be chilled down and kept at 10°C or lower. The chamber was maintained at a nominal, typical ambient temperature throughout the day and allowed to cool overnight, resulting in an experimental temperature range of 15-22°C. The facility in which the test was performed is state-of-the-art with respect to the experimental room. In addition, there are no known accredited facilities that could carry out the simulated use test as required and at a maintained temperature of 10°C.

Furthermore, EN standard studies have been provided that demonstrate calcium hydroxide is efficacious, at the mandated PT 3 temperature.

- Krowas et al 2018 (IUCLID Reference: 6.7-07) shows that a 65% calcium hydroxide product fulfils the mandatory efficacy requirements in a Phase 2 Step 1 test (EN 1656) at 10°C.
- Krowas et al 2018 (IUCLID Reference: 6.7-08) shows that a 65% calcium hydroxide product, fulfills the mandatory efficacy requirements in a Phase 2 Step 2 (non porous surface) test (EN 14349) at 10°C.
- MSL (IUCLID Reference: 6.7-10) showed calcium hydroxide to be effective in in a Phase 2 Step 2 (non porous surface) test (EN 14349) at 10°C against three of the four organisms tests. A similar study (IUCLID Reference: 6.7-09) showed calcium hydroxide to be effective in the same test but under clean conditions against all four organisms.

The IE CA believes this is an acceptable justification for the deviation from the BPR guidance in regard to the higher test temperature.

The IE CA notes that the applicant has not submitted a simulated use test to show bactericidal activity using the 15% Calcium hydroxide product. However, they have submitted a simulated use test which tested against Pseudomonas aeruginosa DSM 939, Escherichia coli DSM 682, Staphylococcus aureus DSM 799, Enterococcus hirae CIP 58.55 using the 10% Calcium hydroxide product which achieved a pass thereby demonstrating bactericidal activity. Consequently, the IE CA deems this to be acceptable as it can be expected that if the product demonstrated bactericidal activity using the 10% product then the 15% product would achieve similar results.

References

Gleeson, D. 2013. The effect of using hydrated lime as a bedding material on the microbial count on teats prior to calving and the infection levels post calving. Irish Journal of agriculture and food research. 52: 159-171.

Conclusion on the efficacy of the product
Following a comprehensive review of the data provided, the IE CA considers the products to be bactericidal with specific disinfection activity against S. Uberis and yeasticidal as they have demonstrated a sufficient level of efficacy against the target organisms. All products within the family have been supported and have been shown to be efficacious in the disinfection of veterinary hard surfaces using a 2 hours contact time and under veterinary high soil (dirty) conditions.

Occurrence of resistance and resistance management

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

Also, the other effects described:

- Increase in free / non-ionised ammonia (NH_3)
- Increased temperature
- Decreased water availability and increased osmotic pressure

are also non-specific effects and development of resistance against these can be excluded.

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

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

Known limitations

There are no known limitations for the biocidal products

Evaluation of the label claims

The proposed label claims are in line with the existing efficacy data and supports the claims against bacteria and yeasts.

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

Not applicable

Risk assessment for human health

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. The products have therefore been assessed for human health effects in the evaluation for inclusion of the active substance in the Union List. The summary of the human health effects is copied from the CAR for the active substance;

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

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

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

It should be noted that due to the irritant properties of hydrated lime, the risk characterisation for systemic effects, if any, will differ (e.g. absorption values and conclusions/predictions on some endpoints) depending on whether exposure levels occur below or above the irritation threshold(s) of hydrated lime. Whilst the available data (see subsequent sections) allow the identification of an irritation threshold of around 1 mg m^{-3} for the inhalation route, there is insufficient evidence for the identification of irritation thresholds for the dermal and oral routes of exposure. For these routes, as risks for local effects cannot be assessed, the implementation of appropriate risk mitigation measures should ensure that exposure is prevented.

Critical endpoints

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

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

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

With regard to local irritative effects, no threshold/NOAEC/AEC has been identified for the occurrence of such effects on the skin and eye. Therefore, for these routes of exposure, as risks cannot be assessed, exposure needs to be prevented by the implementation of risk mitigation measures. For the inhalation route of exposure, the external hydrated lime exposure concentrations will be compared with the relevant AEC value. In the active substance evaluation an AEC value for inhalation of 0.3 mg m^{-3} was proposed and derived by dividing the NOAEC of 1 mg m^{-3} by an overall AF of 3.2 (default for dynamic intraspecies differences).
However, based on the adopted Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for Calcium oxide (CaO) and Calcium hydroxide (Ca(OH)2) the European Commission has established an IOELV of 1 mg/m³ respirable fraction (8h-TWA) for both calcium dihydroxide and calcium oxide. (Commission Directive (EU) 2017/164 of 31 January 2017). This is considered to be protective against adverse effects in case of long-term exposure to calcium dihydroxide and calcium oxide. The IOELV takes precedence over calculated or National limits. The IOELV will be applied for all non-biocidal uses which may also occur in the same facilities. The AEL prescribed in the CAR is therefore precautionary in comparison with the IOELV in place for all other uses.

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

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

__Assessment of effects on Human Health__

Skin corrosion and irritation

Data waiving	
Information requirement	Skin irritation
Justification	No new data on skin irritation/corrosion is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. The available data indicate that hydrated lime causes significant skin irritation and that classification with Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is appropriate. Although severe and irreversible scabbing was observed in animals, this is insufficient for corrosivity classification. In addition, in the human cases of alkali burns, the level of skin damage was consistent with irritation rather than corrosion. These findings, however, together with the strong alkaline properties of hydrated lime should be taken into account in the risk assessment

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	No new data on eye irritation is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. The available data indicate that hydrated lime is severely irritating to the eye and that classification with Eye Dam.1 H318 is appropriate.

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No new data on irrition in the respiratory tract is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. There is no specific investigation of the ability of hydrated lime to cause irritation to the respiratory tract in animals. However, two

	studies in humans involving exposures to hydrated lime or burnt lime have shown that hydrated lime causes sensory irritation of the nose, eye and throat. Effects considered adverse have been reported starting from a concentration of 2 mg m^{-3} for 20 min, and a NOAEC of 1 mg m^{-3} for a 20-min exposure has been identified. There is no information on the respiratory effects of hydrated lime at exposure concentrations higher than 5 mg m^{-3}; however, based on its severe skin and eye irritant properties and its strong alkaline properties, it is most likely that frank tissue damage would occur at higher concentrations. These data indicate that classification of hydrated lime with STOT SE 3 H335 (in accordance with Regulation EC/1272/2008) is appropriate

Skin sensitization

Data waiving	
Information requirement	Skin sensitisation
Justification	No new data on skin sensitisation is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. There are no studies, which have specifically investigated the skin sensitisation potential of hydrated lime. The UK CA agree at active substance evaluation that the irritant properties of the substance prevent a meaningful assessment of its skin sensitising properties at irritant concentrations; however, there remains an uncertainty as to whether at non-irritant concentrations hydrated lime may possess skin sensitisation potential. Although non-irritant concentrations of hydrated lime result in physiological concentrations of Ca^{2+} and OH^-, the activity of hydrated lime at these physiological concentrations on the skin surface (i.e. outside the body) may differ from that inside the body where sophisticated buffer/homeostatic mechanisms or binding processes operate. Therefore, the UK CA disagreed that since Ca^{2+} and OH^- are abundant essential elements of the body, they do not possess skin sensitising potential outside the body. There are no reports of cases of skin sensitisation from workers exposed to hydrated lime. Overall, it is unclear whether hydrated lime at non-irritant concentrations may possess skin sensitisation potential. However, given the lack of reports of cases of skin sensitisation from workers exposed to hydrated lime, and as the recommended risk mitigation measures resulting from failure to identify a threshold for the irritant properties of the substance will prevent skin exposure, testing for skin sensitisation is unnecessary.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Respiratory sensitisation
Justification	No new data on respiratory sensitisation is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. In worker health surveys and epidemiological studies of workers exposed to hydrated lime there has been no mention of effects related to respiratory sensitisation. No classification is proposed.

Acute toxicity

Data waiving	
Information requirement	Acute toxicity - oral
Justification	No new data on acute toxicity is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. In a recent oral gavage study in the rat conducted according to current guidelines and GLP the LD_{50} value was greater than the limit dose of 2000 mg kg^{-1} (Arcelin, 2007). No significant systemic effects were observed up to an oral dose of 2000 mg kg^{-1} . Classification for acute toxicity by the oral route is not required.

Acute toxicity by inhalation

Data waiving	
Information requirement	Acute toxicity - inhalation
Justification	No new data on acute toxicity is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. There are no data on which to base classification of hydrated lime for acute toxicity by the inhalation route. A study in human volunteers investigating only the local effects of burnt lime on the respiratory tract showed that sensory irritation of the nose and throat occurred at 2 and 5 mg m^{-3} CaO for 20 min, but not at 1 mg m^{-3} for 20 min. Classification for acute toxicity by the inhalation route is not required.

Acute toxicity by dermal route

Data waiving	
Information requirement	Acute toxicity - dermal
Justification	No new data on acute toxicity is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products. Hydrated lime was applied for 24 hours as supplied at the limit dose of 2500 mg kg^{-1} under semi-occlusive conditions (Kietzmann, 1994). In this study, the LD_{50} value was greater than 2500 mg kg^{-1} No significant systemic effects were observed up to a dermal dose of 2500 mg kg^{-1} . Classification for acute toxicity by the dermal route is not required.

Information on dermal absorption

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

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

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for the active substance and is not classified. It is an inherent impurity in the active substance at up to 20%.

The active substance, including calcium carbonate and other impurities, has been evaluated for toxicity, therefore there are no additional non-active substances of concern that need to be additionally addressed.

Available toxicological data relating to a mixture

Not applicable, there are no mixtures in the product.

Endocrine Disruption (ED)

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

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

The summary from the CAR for the assessed lime equivalents including calcium oxide and calcium dihydroxide, specifies;

Overall, the lead health effects of hydrated lime are the systemic repeated dose effects caused by excess calcium (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) in the body and the local irritative effects on the external surfaces of the body (skin, eye, respiratory tract and gastrointestinal tract) caused by the hydroxide ion.

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

Exposure assessment

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

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

List of scenarios

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

Industrial exposure

There are no industrial use scenarios for this product.

Professional exposure

Scenario [1]: Loading – Manual opening of bags

Description of Scenario [1]		
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicted for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. The worker cuts open the bag (25 – 50 kg) with a knife. The bag may be on the floor or by the hopper opening. Workers will wear coverall, boots and gloves.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product (AS)	50 kg
	Inhalation rate[2]	1.25 m^3/hour
	Frequency[6]	3 x day
	Duration[4]	1 min/bag
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[6]	10 mg/m^3
	Hand surface area[5]	820 cm^2
Tier 2	Inhalation exposure[3]	1.1 mg/m^3
	Dermal exposure – Hand only, inside glove[7]	3.05 mg/min
	Natural Ventilation[4]	30% protection
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

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

[4.] ECHA Recom6_methods_models 2016 No. 10

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

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

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

Calculations for Scenario 1

Tier 2 Inhalation exposure:

$1.1\ \mathrm{mg/m^3} \times 0.1 \times 0.7 = 0.077\ \mathrm{mg/m^3}$

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

Description of Scenario [2]		
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicted for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. To empty the bags the operator opened the hatch and placed the bag on top. The operator then cut open the upper part of the bag. The hatch was then closed (the lime then disperses in the hopper). The hatch was reopened, and the empty bag removed and shaken to empty out the remaining lime. The empty bag was thrown to the ground. The operation was repeated until the silo is full or until the required quantity of lime had been added. Workers will wear coverall, boots and gloves.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Amount of product (AS)	2 x 25 kg bag/min
	Total number of bags/day (average)[6]	60
	Inhalation rate[2]	1.25 m^3/hour
	Frequency[6]	3 x day
	Duration[4]	10 mins
	Dermal exposure – Hand only[3]	305 mg/min
	Inhalation exposure[3]	7.2 mg/m^3
	Hand surface area[5]	820 cm^2
Tier 2	Inhalation exposure[6]	2.58 mg/m^3
	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

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

[4] ECHA Recom6_methods_models 2016 No. 10

[5] Biocides Human Health Exposure Methodology v 1 2015

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

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

Calculations for Scenario 2

Tier 2 Inhalation exposure:

$2.58 \text{ mg/m}^3 \times 0.1 = 0.258 \text{ mg/m}^3$

Scenario [3]: Application – Manual spreading of dry product - indoors

Description of Scenario [3]

The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate.

The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into wheelbarrows or onto floors. The lime will then be spread using a spade or shovel over the area to be treated.
The floors will be damp after cleaning between each use. Accomodations will be cleaned after every change of stock; after animals are sent for slaughter, when the animals are moved out during summer, after the breeding period is completed.
Matting or other floor coverings that retain moisture may be present.

Manual spreading will take place in smaller animal houses (henhouses, stables, lambing/calving sheds) and in transportation.
Natural ventilation.
Workers will wear coveralls, boots and gloves.

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

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

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

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate	500 g/m^2
	Floor area[7]	160 m^2
	Inhalation rate[2]	1.25 m^3/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – Hand only[6]	305 mg/min
	Inhalation exposure[3]	12 mg/m^3
	Hand surface area[5]	820 cm^2
Tier 2[2]	Dermal exposure – Hand only, inside glove[3]	3.05 mg/min
	Inhalation exposure[8]	2.58 mg/m^3
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

[3]. van Hemmen (1992) Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85. Indicative value for mixing and loading of solid pesticides (wettable powders). The indicative 90th percentile of the inhalation exposure is 15 mg formulation per hour, which is considered applicable for about 25 kg active substance applied per day.

[4]. ECHA Recom6_methods_models 2016 No. 10

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

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

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

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

Calculations for Scenario 3

Tier 2 Inhalation exposure:

$2.58 \text{ mg/m}^3 \times 0.1 = 0.258 \text{ mg/m}^3$

Scenario [4]: Application – Automated spreading of dry product - indoors

Description of Scenario [4]
The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. The product can be provided in 25-50 kg bags that workers will manually open (Scenario 1) and pour directly from the bags into the hopper of a towed spreader (Scenario 2). The spreader will be towed behind a small tractor or quad bike. The floors will be damp after cleaning between each use. Accommodations will be cleaned after every change of stock; after animals are sent for slaughter, when the animals are moved out during summer, after the breeding period is completed. Matting or other floor coverings that retain moisture may be present. Automated spreading will take place in large animal houses and sheds. Natural ventilation or Local Exhaust Ventilation in enclosed pultry sheds. Workers will wear coveralls, boots and gloves. Application rates and default values for floor areas of accommodation to be treated are derived from PT 3 ESD, 2011 Appendices. (See Appendix 3.2). The only models available for determination of exposure from spreading of powders in agricultural areas are for use of plant protection products. The EUROPOEM model (v1.2) has been used to determine exposure to the operator using the vehicle mounted/draw boom sprayer scenario. As the model assumes outdoor application, no further Protection Factor for ventilation is applied. A workplace monitoring study for exposure during automated spreading for soil treatment has been performed (Teerlinck and Detry, 2010). The rates and area of application greatly exceed those that would be treated for the biocidal uses. However, the study shows that exposure concentrations for inhalation are below the IOELV.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Application rate	500 g/m^2
	Application area[6]	3390 m^2
	Inhalation rate[2]	1.25 m^3/hour
	Frequency	1 x day
	Duration[4]	1 hour
	Dermal exposure – hand only[3]	0.03 mg/min
	Dermal exposure – body[3]	0.00117 mg/min
	Inhalation exposure[3]	0.01 g/h 0.125 mg/m^3
	Hand surface area[5]	820 cm^2

	Natural ventilation [5]	30 % protection
Tier 2	Inhalation exposure[7]	<1.0 mg/m^3
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

[3] EUROPOEM operator exposure model v 1.2

[4] Biocides Guidance Database; Human Exposure, worst case for ready to use products for spraying.

[5] Biocides Human Health Exposure Methodology v 1 2015

[6] PT 3 ESD, 2012 Annexes: Default values for accommodation and transport areas. Turkeys, free range with litter floor

[7] Teerlinck M and Detry D (2010) Workplace Dust Monitoring. Carmeuse Research & Technology, Bd de Lauzelle 65, B-1348 Louvain-La-Neuve Report No. 5RM/50/60280555/00/EN/001.

Calculations for Scenario 4

No further calculations.

Scenario [5]: Cleaning and Maintenance – Manual cleaning of mixing or spreading equipment

Description of Scenario [5]
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicted for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. Cleaning and maintenance are classed as occasional tasks. Maintaining the compound units and silo mechanisms in the state of operation by doing, at fixed times, visual inspections and repairs, as well as by removing occasional damage Observations are performed daily Checking the technical condition of equipment, blockage of electrical vibrators, lubricating lubrication points is performed every 3 months. Hopper cleaning with mechanical tool or pressure washer is performed 2 to 3 times a year. Disassembling and cleaning of equipment and mechanisms, verification of qualification of components for repair or replacement, repair or replacement of parts, assembly of mechanisms and operation test, painting, commissioning, and putting into use, only takes place every 3 years. The following tasks were referenced in the exposure measurement study - Changing the skip for treated sludge or transfer to the handling gear for the latter to a storage area - Refilling tanks of the handling gear - Scraping deposits (leaks/spillages) of sludge off the ground The assessment in the CAR considered the following maintenance tasks: Workers will wear coverall, boots and gloves. None of the available exposure models considers cleaning and maintenance of equipment as a separate measurement for inhalation exposure. TNsG on Human health Assessment (2002); Dust and soil adhesion model 3 has dermal exposure measurements for a separate task of bag collection and crushing. The values is for dust on gloves only.

	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Inhalation rate[2]	1.25 m^3/hour
	Frequency[6]	Daily
	Duration[4]	10 mins
	Dermal exposure – hand[3]	228 mg/min

	Inhalation exposure[6]	2.58 mg/m^3
	Hand surface area[5]	820 cm^2
Tier 2	PPE – gloves[5]	90% Protection
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

[3] TNsG for Human Health Assessment (2002) Dust and soil adhesion Model 3, 75th Percentile.

[4] ECHA Recom6_methods_models 2016 No. 10

[5] Biocides Human Health Exposure Methodology v 1 2015

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

Calculations for Scenario 5

Tier 2 Inhalation exposure:

2.58 mg/m^3 x 0.1 = 0.258 mg/m^3

Scenario 6]: Disposal – Disposal of empty bags

Description of Scenario [6]		
This scenario is covered by the active substance evaluation. The product will be used in the same way as indicted for the worse case representative product. A summary is presented for reference, however exposure parameters have been updated in line with the current guidance on Human Exposure to Biocidal Products and the Technical Agreements The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. Workers will wear coverall, boots and gloves. None of the available exposure models considers disposal of bags as a separate measurement for inhalation exposure. But the task was included in the Operator Exposure measurement study. TNsG on Human health Assessment (2002); Dust and soil adhesion model 3 has dermal exposure measurements for a separate task of bag collection and crushing. The values is for dust on gloves only.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Inhalation rate[2]	1.25 m^3/hour
	Frequency[6]	Daily
	Duration[4]	10 mins
	Dermal exposure – hand[3]	228 mg/min
	Inhalation exposure[6]	2.58 mg/m^3
	Hand surface area[5]	820 cm^2
Tier 2	PPE – gloves[5]	90% Protection
	RPE[5] – Filtering half masks (FFP3)	PF = 10

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

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

[3] TNsG for Human Health Assessment (2002) Dust and soil adhesion Model 3, 75th Percentile.

[4] ECHA Recom6_methods_models 2016 No. 10

[5] Biocides Human Health Exposure Methodology v 1 2015

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

Calculations for Scenario 6

Tier 2 Inhalation exposure:

2.58 mg/m^3 x 0.1 = 0.258 mg/m^3

Scenario [7]: Disposal – Manual disposal, using spade/shovel, to manure waste

Description of Scenario [7]		
The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. The exhausted lime will be mixed in with used bedding and manure. Frequency of cleaning is dependent upon the accommodation/transportation usage. Due to the nature of the wastes dermal exposure will be negligible. Exposure to lime dusts is unlikely as the lime has reacted with moisture. Furthermore, Risk Mitigation Measures are in place to prevent workers being exposed to poultry dusts. Inhalation exposure to residual lime dust is considered to be negligible in comparison with exposure to dusts from bedding materials. Manual disposal will mainly take place in transportation, smaller animal housing or cleaning out of pens. Workers will wear coverall, boots and gloves.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Frequency	Daily
Tier 2	PPE – gloves[5]	90% Protection

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

Calculations for Scenario 7

No additional calculation performed.

Scenario [8]: Disposal – Automated disposal, using tractor, to manure waste

<table>
<tr><th colspan="3">Description of Scenario [8]</th></tr>
<tr><td colspan="3">The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate.

The exhausted lime will be mixed in with used bedding and manure. Frequency of cleaning is dependent upon the accommodation/transportation usage. Due to the nature of the wastes dermal exposure will be negligible.
Exposure to lime dusts is unlikely as the lime has reacted with moisture. Furthermore, Risk Mitigation Measures are in place to prevent workers being exposed to poultry dusts. Inhalation exposure to residual lime dust is considered to be negligible in comparison with exposure to dusts from bedding materials.

Automated disposal will mainly take place large animal housing.

Workers will wear coverall, boots and gloves.</td></tr>
<tr><td></td><td>Parameters</td><td>Value</td></tr>
<tr><td rowspan="2">Tier 1</td><td>Body weight[1]</td><td>60 kg</td></tr>
<tr><td>Frequency</td><td>Daily</td></tr>
<tr><td>Tier 2</td><td>PPE – gloves[5]</td><td>90% Protection</td></tr>
</table>

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

Calculations for Scenario 8

No additional calculation performed.

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

Summary table: estimated exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated dermal exposure (mg/min)**	**Total Exposure for semi-quantitative assessment (mg/m^3)**
Scenario 1	1 2	10 0.077	305 3.05	10 0.077
Scenario 2	1 2	2.58 0.11	305 3.05	2.58 0.258
Scenario 3	1 2	2.58 0.258	305 3.05	2.58 0.258
Scenario 4	1 2	0.125 <1.0	0.03 0.03	0.125 <1.0
Scenario 5	1 2	2.58 0.258	228 228	2.58 0.107
Scenario 6	1 2	2.58 0.258	228 228	2.58 0.258
Scenario 7	1	Negligible	Negligible	Negligible
Scenario 8	1	Negligible	Negligible	Negligible

Further information and considerations on scenario [1 to 8]
The products are skin irritants and cause serious damage to the eyes. Consequently, wearing of full protective clothing (boots, coverall, protective gloves and goggles) is mandatory.
RPE of at least Filtering half masks (FFP3) should be worn when dust levels are above the AEL of 0.3 mg/m³ respirable fraction and no forced ventilation measures are in place.

Combined scenarios

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

Scenario 1: Opening of bags

Scenario 2: Tipping of bags into hoppers
Scenarios 3 to 4: Application of the products
Scenario 5: Cleaning and maintenance
Scenarios 6 to 8: Disposal tasks
Scenario 9: Bystander exposure

However the critical factor is inhalation exposure. This measurement is not time dependent or additive. As indicated in the Operator exposure model referenced in the CAR for the active substance; INTERPRETATION REPORT No. KSP1401-0272-001_1, 1403-0232-001, 1405-0047-001_1, Evaluation of Exposure to Lime Dust, 06/05/2014, dust measurements were made for a worker performing combined tasks and covering each of the scenarios indicated above. The average exposure concentration in this study was 1.07 mg/m^3. The application of RMM ensure that the exposure is below the AEL of 0.3 mg/m^3

Systemic Effects

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

With regard to the systemic effects, the systemic UL (equivalent to an AEL) value for calcium (42 mg kg $^{-1}$ day^{-1}) will be compared with the calcium internal body burdens arising from dermal and inhalation exposures to hydrated lime. It is important to ensure that the calcium body burden arising from exposure to hydrated lime contributes minimally to the overall calcium UL, as a significant part of the UL depends on other sources of exposure to calcium, mainly through the diet.

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

With regard to the local irritative effects, no threshold/NOAEC/AEC has been identified for the occurrence of such effects on the skin and eye. Therefore, for these routes of exposure, as risks cannot be assessed, exposure needs to be prevented by the implementation of risk mitigation measures. For the inhalation route of exposure, the external hydrated lime exposure concentrations will be compared with the relevant AEC value. An AEC value to be used for short-, medium- and long-term inhalation exposure scenarios of 0.3 mg m^{-3} is proposed by dividing the NOAEC of 1 mg m^{-3} by an overall AF of 3.2 (default for dynamic intraspecies differences).

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

Systemic effects of calcium

The human exposure study presented by the applicant represents a worst case regarding operator exposure. This worst case is presented below to contrast the acceptable systemic exposure with realistic worst case operator exposure.

Inhalation exposure – treatment of manure – manual handling of bags – a worst case		
Tier 1	Maximum concentration [mg m^{-3}] – measured task duration 19-36 min	1.6-23.2
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40)	0.04-0.58

Inhalation exposure – treatment of manure – manual handling of bags – a worst case (8 hour)		
Tier 1	Maximum concentration [mg m^{-3}]	2.58
Tier 2	In-mask concentration estimate [mg m^{-3}] RPE during loading only (wpf 40)	0.07

Dermal exposure – treatment of manure – removal of empty bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569
Tier 2	PPE and full face RPE [mg]	28.45
Dermal exposure – treatment of manure – manual handling of bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569
Tier 2	PPE and full face RPE [mg]	28.45

Systemic exposure – treatment of manure – manual handling of bags – a worst case (8 hour)		
Tier 1	Maximum concentration [mg m^{-3}]	2.58 (100% calcium)*8*1.25 25.8mg /60kg =0.43 mg/kg bw day
Tier 2	In-mask concentration estimate [mg m^{-3}] RPE during loading only (wpf 40)	0.7 (100% calcium)*8*1.25 7mg /60kg =0.12mg/kg bw day

Dermal exposure – treatment of manure – removal of empty bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569*(100% absorption)/60 =9.5 mg/kg bw day
Tier 2	PPE and full face RPE [mg]	28.45 =0.5 mg/kg bw day
Dermal exposure – treatment of manure – manual handling of bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569*(100% absorption)/60 =9.5 mg/kg bw day
Tier 2	PPE and full face RPE [mg]	28.45 =0.5 mg/kg bw day

Systemic exposure – treatment of manure – manual handling of bags – a worst case (8 hour)		
Tier 1	9.5 mg kg bw day dermal + 0.43 mg kg bw day inhalation =10 mg/kg bw day	2.58 (100% calcium)*8*1.25 25.8mg /60kg =0.43 mg/kg bw day 569*(100% absorption)/60 =9.5 mg/kg bw day
Tier 2	0.5 mg kg bw day dermal + 0.12 mg kg bw day inhalation =0.62 mg/kg bw day	0.7 (100% calcium)*8*1.25 7mg /60kg =0.12mg/kg bw day 28.45 =0.5 mg/kg bw day

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

Risk characterisation for the product

Systemic effects of calcium (Tier 1 exposure assessment) Tier 1, systemic risk assessment for the effects of calcium (UL=42 mg kg $^{-1}$ d^{-1})

Exposure scenario	**Dermal burnt dolomitic lime exposure (mg d^{-1})**	**Dermal Ca exposure (mg d^{-1})***	**Dermal Ca body burden (mg kg bw^{-1} d^{-1})$**	**Inhalation burnt dolomitic lime full shift or cleaning task (mg m^{-3})**	**Inhalation Ca exposure (mg m^{-3})***	**Total Ca body burden (mg kg bw^{-1} d^{-1})£**	**Total Ca body burden (%UL)**	**Total body burden << 42 mg kg bw $^{-1}$ d^{-1}**	**Unacceptable risk€**
Mixing and loading – manual handling of bags	569	569	**9.5**	2.58	2.58	**10**	**23.8%**	YES	NO

European Dietary Intake mean and 97.5 percentile mg/day (SCA 2003)

County	Type of survey	N	Method	Suppliments	Mean	97.5%
Austria	Individual	4972	7-day weighted 3-day weighted 24 recall	Not defined	834	1678
Germany	Individual(M) Individual(F)	2006	7-day record	No	753 683	1731 1421
Ireland	Individual(M) Individual(F)	1339	7-day record	Yes	949 742	1657 1340
Netherlands	Individual	5958	2-day record	No	944	1970
UK	Individual(M) Individual(F)	1087 1110	7-day weighted	yes	940 730	1607 1317

The table above details the daily calcium intake from a number of European counties including Ireland. The maximum noted 97.5 percentile daily consumption is that of the German male at 1731 mg/day or 28.85 mg/kg bw/day (assuming 60kg body weight).
When this consumption is added to the worst case operator exposure of 10mg kg bw day the total of 38.85 mg/kg bw day is below the upper band health level of 42 mg/kg bw day.

Worst case Local effects

Inhalation exposure – treatment of manure – manual handling of bags – a worst case (8 hour)		
Tier 1	Maximum concentration [mg m^{-3}]	2.58
Tier 2	In-mask concentration estimate [mg m^{-3}] RPE during loading only (wpf 10)	0.258

The AEC is not exceeded when RPE is worn in the above worst-case scenario.

Non-professional exposure

There are no non-professional uses claimed.

Exposure of the general public

Scenario [9]: Indirect – Bystander exposure to products used in animal accommodation

Description of Scenario [9]		
The in-use concentration of the product contains up to 65 % w/w of the potential range of component substance (calcium hydroxide), the rest being calcium carbonate. Bystanders may be exposed to the products either from incidental dermal exposure or by incidental inhalation exposure to dusts present after spreading. Dermal exposure The main hazard is to the dry product. As the products will have reacted during application, the local hazard will be low. Inhalation exposure: Dusts formed from treated floors. Bystanders may raise dusts from walking in treated floors. As the dusts formed from mixing and loading applications where high levels of dust are expected have been measured to be on average equivalent to the IOELV of 1 mg/m³ respirable fraction (8h-TWA), the exposure from this scenario is considered to be negligible.		
	Parameters	Value
Tier 1	Body weight[1]	60 kg
	Frequency	Daily

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

Calculations for Scenario 9

[Please include any relevant calculations in Annex 3.2]

Summary table: Local exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated dermal exposure**	**Estimated oral exposure**	**Estimated total exposure**
Scenario [9]	1	Negligible	Negligible	Not applicable	Negligible

Further information and considerations on scenario [9]

The dry products are skin irritants and cause serious damage to the eyes. Care should be taken to prevent bystanders from entering accommodations when spreading has just taken place. Dusts should be allowed to settle before re-entry.
The general public should not handle dry bedding treated with unreacted lime.

Combined scenarios

No combined scenarios are applicable.

Monitoring data

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

Dietary exposure

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

Residue definitions

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

List of scenarios

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

Information of non-biocidal use of the active substance

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

Residue definitions

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

Estimating Livestock Exposure to Active Substances used in Biocidal Products

An estimation for exposure to livestock is not required.

The substance is used extensively in agriculture as a plant protection product and for neutralisation of soil. Maximum application rates to soil from agricultural use: 1700 kg CaO/ha or 2244 kg $Ca(OH)_2$/ha. Under these conditions of use, EFSA has determined that the substances are pharmacologically active substances for which an MRL in foodstuffs of animal origins is not required.
The hazards attributed to the substance are local effects from contact with the dry product and from inhalation of the dusts. There are no systemic effects identified for livestock from indirect exposure to lime in the quantities proposed for biocidal use, which are substantially lower than those for other agricultural use.
Livestock will not be present during the application of the products and will only be exposed once the product has been in contact with moisture.

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

An estimation for transfer is not required.

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

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

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

There are no non-professional use applications claimed.

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

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

The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. The formulation takes place as part of the active substance manufacturing process.
The substance does not undergo any further formulation steps before use.
The substances are registered up to Annex X under REACH under calcium oxide EC No. 215-138-9.
Exposure to the substance during manufacturing is already addressed through Regulation 793/93/EEC and information is not required under Regulation 528/2012.

Summary of exposure assessment

Summary table: estimated exposure from professional uses

Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m^3)**	**Estimated dermal exposure (mg/min)**	**Total Exposure for semi-quantitative assessment (mg/m^3)**
Scenario 1	1	10	305	10
	2	0.077	3.05	0.077
Scenario 2	1	2.58	305	2.58
	2	0.11	3.05	0.258
Scenario 3	1	2.58	305	2.58
	2	0.258	3.05	0.258
Scenario 4	1	0.125	0.03	0.125
	2	<1.0	0.03	<1.0
Scenario 5	1	1.07	228	1.07
		0.214	228	0.214
	2	0.107	228	0.107
Scenario 6	1	2.58	228	2.58
	2	0.258	228	0.258
Scenario 7	1	Negligible	Negligible	Negligible
Scenario 8	1	Negligible	Negligible	Negligible

Risk characterisation for human health
In accordance with BPR Guidance on the BPR, Vol III Huan Health – Assessment and Evaluation (Parts B+C) v 2.1 February 2017, the biocidal products are classified in respect to local effects. The products will not be used at concentrations below which the classification for local effects is not appropriate, therefore systemic exposure is secondary to the local effects. The risk assessment will be qualitative in respect to the dermal exposure as no

threshold concentration level has been determined for the dermal hazard and semi-quanitative with respect to inhalation.

Reference values to be used in Risk Characterisation

Reference	Reference	Value
AECshort-term	BPR CAR IOELV	0.3 mg/m^3 1 mg/m^3
AECmedium-term	BPR CAR IOELV	0.3 mg/m^3 1 mg/m^3
AEClong-term	BPR CAR IOELV	0.3 mg/m^3 1 mg/m^3
ARfD		Not applicable
ADI		Not applicable

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

Maximum residue limits or equivalent

Residue definitions

Calcium hydroxide is listed as a basic substance (approval date 01/07/2015) in accordance with Regulation (EC) No. 1107/2009. (Implementing Regulation (EU) No 540/2011). It is included in Annex IV to (EC) No. 396/2005

Calcium oxide is listed in Annex II of Regulation 2377/90. The substance has been evaluated and a conclusion has been established that a MRL is not required for the protection of public health.

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

Specific reference value for groundwater

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

Risk for industrial users

No industrial uses have been identified.

Risk for professional users

Systemic effects

The Scientific Committee on Food (SCF) has set an oral Tolerable Upper Intake Level (UL) for calcium of 2500 mg d^{-1} (SCF, 2003; http://ec.europa.eu/food/fs/sc/scf/out194_en.pdf). The UL is defined as the highest level of total (from all sources) chronic daily intake of a nutrient judged unlikely to pose a risk of adverse health effects to humans. It applies to all groups of the general population, including sensitive individuals, throughout the life stage. Therefore, provided exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the UL of 2500 mg d^{-1} (42 mg/kg bw/day for a 60 kg human), adverse effects from excess calcium would not be expected. The UL for calcium applies to adults, including pregnant and lactating women, but not to children.

The worst case 8-hour exposure data has been combined with expected maximal exposure through diet and compared to the aforementioned UL and safe systemic exposure is expected.

This finding supports the focus on local effects in the risk assessment.

Local effects

Hazard	**Exposure**									**Risk**
Hazard category	*Effects in terms of C&L*	*Additional relevant hazard information*	*PT*	*Who is exposed?*	*Tasks, uses, processes*	*Potential exposure route*	*Frequency and duration of potential exposure*	*Potential degree of exposure (mg/m^3)*	*Relevant RMM & PPE*	*Conclusion on risk*
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	2 3	Professional	1: Opening bags	Dermal inhalation	60 minutes daily	0.077	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied. - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	2 3	Professional	2: Tipping bags into hopper	Dermal inhalation	60 minutes daily	0.11	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	3	Professional	3: Manual spreading of dry product - indoors	Dermal inhalation	60 minutes daily	0.0749	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3)	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable

									- LEV	
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	3	Professional	4: Automated spreading of dry product - indoors	Dermal inhalation	60 minutes daily	<1.0	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	2 3	Professional	5: Manual cleaning of mixing or spreading equipment	Dermal inhalation	10 minutes daily	0.214	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	2 3	Professional	6: Disposal of empty bags	Dermal inhalation	10 minutes daily	0.214	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied - Filtering half masks (FFP3) - LEV	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable
HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	3	Professional	7: Manual disposal, using spade/shovel, to manure waste	Dermal inhalation	60 minutes daily	Negligible	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable

HIGH	Skin irritant 2: H315 Eye Damage 1: H318 STOT single exposure 3: H335	AEC = 0.3 mg/m^3	3	Professional	8: Automated disposal, using tractor, to manure waste	Dermal inhalation	60 minutes daily	Negligible	Technical and organisational RMM adequate for the high hazard category are achievable: professional RMM excluding risk for skin and inhalation exposure use of appropriate gloves and mask where necessary. Other RMM to reduce dust concentrations may be applied:	Acceptable: No exposure expected since +Technical and organisational RMM adequate for the high hazard category are achievable

Conclusion

The use scenarios are acceptable in terms of risk from the local and systemic effects of the products.

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

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

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

Risk for non-professional users

No non-professional uses are claimed.

Risk for the general public

Systemic effects

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

Systemic effects are not relevant for the general public because dietary exposure to calcium is expected to be very significantly higher than any product exposure.

Local effects

Scenario No	Hazard		Exposure information		
	Hazard category	Effects	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMMs
Scenario 9	Low	AEC = 0.3 mg/m^3	Incidental exposure – infrequent, daily	Negligible	None

Conclusion

Bystanders may raise dusts from walking in treated floors. As the dusts formed from mixing and loading applications where high levels of dust are expected have been measured to be on average equivalent to the IOELV of 1 mg/m^3 respirable fraction (8h-TWA), but levels of dust from low impact applications are less than the AEL of 0.3 mg/m^3 the exposure from this scenario is considered to be negligible.

Risk for consumers via residues in food

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

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

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

Risk assessment for animal health

A risk assessment for animal health is not required.

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

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

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

Risk assessment for the environment

Environmental fate and behaviour

No additional data on the fate and behaviour of the active substance (calcium dihydroxide) has been submitted. Instead, the applicant is relying on read-across from the active substance data for calcium dihydroxide to the Calcium dihydroxide products family. The eCA deems this to be acceptable in this case as the products in the family are blends of the active substance, calcium dihydroxide (15-65%) and a calcium carbonate filler (35-85%). Both of which are naturally occurring inorganic substances. For completeness a summary of the fate and distribution of hydrated lime in the environment *adapted* from the May 2016 Assessment report is presented below. Statements relating the PEC to the background concentrations were removed as they related to the representative product that was assessed during the EU evaluation of calcium dihydroxide and not the current intended uses.

The eCA notes that the calcium carbonate filler is a plant protection product active substance. The representative uses of calcium carbonate in the EU assessment was as a repellent for use in forestry and orchard. Calcium carbonate is virtually insoluble in water, but the solubility of calcium carbonate varies depending on the interaction of several environmental factors. Dissociation can produce calcium and carbonate ions. Carbonate is produced from various natural resources, particularly carbonate-based rocks and indirectly through respiration of aquatic plants during the hours of darkness. The dissolution products of calcium carbonate are naturally occurring in the environment. Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). In some regions it is the water bearing rock material of groundwater aquifers.

Overview of Calcium dihydroxide Environmental fate and behaviour -

<u>Fate in the Aquatic Compartment</u>

Calcium hydroxide is an odourless solid, which has a low solubility of 1.26/1.85 g/L at 20°C/9°C respectively (EU CAR Hydrated Lime, 2016). The soluble component can dissociate into Ca^{2+} and OH^- ions. The dissociation products Ca^{2+} and OH^- are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. For this reason, the performance of any degradation test with hydrated lime is scientifically unjustified. The eCA notes similar comments were made in relation to calcium carbonate in the 2011 EFSA conclusion.[2]

Studies that investigated the impact of addition of hydrated lime on the pH of different test media and on the pH of two water-sediment systems were submitted during the EU active substance review. These studies and their endpoints have been considered relevant because the main toxic effect of hydrated lime is likely to be caused by temporal pH changes in the environment. The more relevant of the two available studies was that of Egeler and Gilberg (2007), in which the pH development of two natural water-sediment systems sampled from Germany was investigated. Hydrated lime was added at concentrations ranging between 14.8 and 100 mg L^{-1} to the water phase and changes in pH were monitored for up to 168 h. Upon addition of hydrated lime to the overlying water, a dose-dependent transient increase

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[2] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbonate. EFSA Journal 2011;9(7):2298. [28 pp.] doi:10.2903/j.efsa.2011.2298. Available online: www.efsa.europa.eu/efsajournal

in the pH of the water phase was observed. The relative increase in pH following addition of the test substance was noted to be highest in the system with the lowest total hardness (Unterbach Creek system). The water pH was noted to have returned to levels comparable with control systems (pH 7.60 - 7.73) in test concentrations of ≤ 75 mg L^{-1} by the final 7 d sampling point.

Fate in Air

According to the Assessment report (2016) a justification was provided for the non-submission of data on the basis that hydrated lime is expected to have vapour pressures well below 10^{-5} Pa and that exposure via air is not expected. Whilst an estimation using simple calculations could be used to address this data point (e.g. the estimation methods of the Atmospheric Oxidation Program) irrespective of the vapour pressure, for substances such as hydrated lime, such calculations would be largely meaningless as the potential for exposure via air, and subsequent phototransformation in air would be expected to be negligible as it is inorganic/basic substance.

Fate in the Terrestrial Compartment

Standard aerobic degradation studies in soil are not considered necessary for hydrated lime. This is because upon addition to soil, the soluble component would simply dissociate to its respective ion constituents where they would form part of existing chemical cycles in the natural environment. The eCA notes similar comments were made in relation to calcium carbonate in the 2011 EFSA conclusion.[2] Two studies that investigated the impact of addition of hydrated lime on the pH of different soil systems were considered relevant because as in the aquatic compartment, the main toxic effect of hydrated lime is likely to be caused by temporal pH changes in the environment.

In the first study (Schiffner, 2007a) the pH development of a natural and an artificial soil were investigated. Hydrated lime was added at concentrations up to 4.44 g kg^{-1} dry soil and the pH was measured for up to 6 weeks. Upon addition of hydrated lime to the soils, a dose dependent increase in the pH was observed. The relative increase in pH following addition of the test substance was noted to be marginally higher in the artificial soil system. The soil pH was noted to rise to between 10 and 11 pH units in both soils immediately after addition of the hydrated lime at the highest test concentration (note that initial pH levels in untreated controls were 5.49 for the natural soil and 5.89 for the artificial soil). A decrease in pH of approximately 2 pH units was observed within 72 h following addition. By the end of the 6 week study the pH in the test soils was noted to be elevated above control levels at all concentrations. However, the final pH was within the normal range for typical agricultural soils at all concentrations tested (pH range from 5.88 to 7.95). The estimated 'DT_{50}' and 'DT_{90}' values (buffering capacity) were determined assuming hockey stick kinetics to reflect the bi-phasic pattern of pH changes observed in the treated soils. Fits were generally good statistically (chi^2 and t-tests) and visually (classical and residual plots). A DT_{50} of 0.742 h is proposed up to a break point of 6 h, and a DT_{50} of 372 h is proposed for the time period after the break point. The kinetic modelling endpoints were considered appropriate for direct use in the environmental exposure assessment. In general, in the soils tested the pH fell back to within *ca.* pH 8 within 1 week of application at all concentrations.

In the second study (Schiffner, 2008), the pH development within mixed natural soil after application with hydrated lime treated sewage sludge was investigated. Sewage sludge was treated with four concentrations of hydrated lime ranging from 187.5 to 520 g kg^{-1} wet sludge (dry solids content of sludge was reported to be 25 %). After incubation for 24 h at room temperature, the treated sludge was added to mixed natural soil resulting in nominal hydrated lime concentrations between 1.25 and 3.65 g kg^{-1} dry soil. The pH of the amended soil was also measured for up to 24 h. As with the previous study, upon addition of hydrated lime treated sewage sludge to soil, a dose-dependent increase in pH was observed. The relative impact on pH following addition of hydrated lime direct to soil was noted to be marginally higher than the impact of applying comparable rates of hydrated lime treated sewage to soil. Even though the lowest rate tested was elevated above that which would be proposed for treating sewage sludge (EU representative use-40 kg/m^3), only a relatively minor impact on the final soil pH was noted at this treatment level. This was in contrast with the more pronounced effect on soil pH that was observed either when testing higher sewage sludge applications rates or when testing the effect of direct application of hydrated lime to soil. Both studies submitted as part of the EU active substance evaluation did not provide sufficient information on the soils used to allow any comparison with any areas of the EU. However, the results from this study are likely to at least be indicative of the likely behaviour in terms of temporal pH changes when a soil is either directly treated with hydrated lime or when soil is amended with hydrated lime treated sewage sludge.

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

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

In addition to standard endpoints, further background information was provided in the EU CAR on the distribution of hydrated lime in the environment and the use of hydrated lime in agriculture as a measure to counteract soil acidification. With respect to the distribution in the environment, brief summaries of the basic chemical reactions undertaken by the constituents of lime when they are released to the environment were provided. Since these reactions are all well understood processes of the natural calcium (and magnesium) cycles they have not been reproduced in detail here.

In summary, the level of calcium in soil is governed by the equilibrium between soluble, exchangeable and solid forms. Weathering is enhanced by carbonic acid (CO_2 produced by respiration of organisms dissolved in water). Exchangeable calcium is the dominant ion on soil colloid surfaces and by replacing H^+ ions in exchange sites it largely determines soil pH. In many soils the steady downward movement of water leaches Ca^{2+} ions over time, H^+ ions take their place on exchange sites and soils become more acidic.

Table 1.2.8-1. gives and overview of environmental effects of adding hydrated lime to water and soil compartments (-based on data reported in the A.S. CAR)

Table 1.2.8-1. Overview of environmental effects of adding hydrated lime to water and soil compartments (-based on data reported in the A.S. CAR)

Compartment	pH Changes
Water compartment Hydrated lime Test 14.8 and 100 mg L^{-1} to the water phase pH were monitored for up to 168 h.	pH changes The water pH was noted to have returned to levels comparable with control systems (pH 7.60 - 7.73) in test concentrations of ≤ 75 mg L^{-1} by the final 7 d sampling point.
Soil 4.44 g hydrated lime kg^{-1} dry soil (natural +artificial) pH was measured for up to 6 week	pH changes pH was noted to rise to between 10 and 11 pH units in both soils immediately (from pH 5.49/5.89 natural/artificial soil respectively) A decrease in pH of approximately 2 pH units was observed within 72 h following addition. By the end of the 6 week study the pH in the test soils was noted to be elevated above control levels at all concentrations Final pH was within the normal range for typical agricultural soils at all concentrations tested (pH range from 5.88 to 7.95). At the lowest dose tested (444 mg kg^{-1}) the maximum initial pH was 7.52, declining to 6.41 within 24 h. Kinetics The estimated DT_{50} and DT_{90} values were determined assuming hockey stick kinetics to reflect the bi-phasic pattern of pH changes observed in the treated soils. A DT_{50} of 0.742 h is proposed up to a break point of 6 h, and a DT_{50} of 372 h is proposed for the time period after the break point. The kinetic modelling endpoints were considered appropriate for direct use in the environmental exposure assessment. In general, in the soils tested the pH fell back to within *ca.* pH 8 within 1 week of application at all concentrations.
Soil with lime treated sludge Sewage sludge was treated with four concentrations of hydrated lime ranging from 187.5 to 520 g kg^{-1}wet sludge (dry solids content of sludge was reported to be 25 %). After incubation for 24 h at room temperature, the treated sludge was added to mixed natural soil resulting in nominal hydrated lime concentrations between 1.25 and 3.65 g kg^{-1} dry soil. The pH of the amended soil was also measured for up to 24 h.	Dose-dependent increase in pH was observed. The relative impact on pH following addition of hydrated lime direct to soil was noted to be marginally higher than the impact of applying comparable rates of hydrated lime treated sewage to soil. The lowest rate tested was elevated above that which would be proposed for treating sewage sludge (EU representative use 40 kg/m^3), only a relatively minor impact on the final soil pH was noted at this treatment level. This was in contrast with the more pronounced effect on soil pH that was observed either when testing higher sewage sludge applications rates or when testing the effect of direct application of hydrated lime to soil.

Effects assessment on the environment

No new data on environmental effects is presented. The applicant is relying on read-across from the active substance data for calcium dihydroxide to the Calcium dihydroxide products family. The products in the family are blends of the active substance, calcium dihydroxide (15-65%) and the inert filler calcium carbonate (35-85%). Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts.
A summary of the effects assessment *adapted* from the May 2016 Assessment report is presented below.

Effects assessment

The assessment factors (AF) used to define the PNEC's for the environmental compartments of concern have been taken from the ECHA Guidance[3] in support of Commission Directive 93/67/EEC (new notified substances) and Directive 98/8/EC (biocidal products)' (EC, 2003).

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

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

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

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[3] Guidance on BPR: Vol IV Environment Parts B+C, Version 2.0 October 2017

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

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

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

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

Aquatic Compartment

Predicted No Effects Concentration in STP

The PNEC was calculated from the 3 h EC_{50} of against sewage sludge micro-organisms, in accordance with ECHA Guidance[4] (Table 19):

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

$PNEC_{stp}$ = 3004 µg l^{-1}

Predicted No Effects Concentration in Surface Waters

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[4] Guidance on BPR: Vol IV Environment Parts B+C, Version 2.0 October 2017

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

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

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

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

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

$PNEC_{water}$ = 491 µg l^{-1}

Predicted No Effects Concentration in Sediments

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

Predicted No Effects Concentration in Soil

For the effects assessment of the soil compartment, endpoints are available for earthworms, plants and terrestrial microorganisms. All the values presented are in terms of mg a.s. kg^{-1} dry weight (dw) of soil (AR UK, 2016).

Acute

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

Chronic

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

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

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

$PNEC_{soil}$ = 108 mg kg^{-1} dwt

Primary and Secondary Poisoning

Predicted No Effects Concentration in Biota

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

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

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

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for

	manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

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

Data waiving	
Information requirement	Effects on other specific, non-target organisms.
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

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

Data waiving	
Information requirement	Trials on non-target organisms.
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.There is no scientific justification for further studies to be performed.

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

Data waiving	
Information requirement	Ingestion of biocidal product by non-target organisms.
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed.

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

No new data is presented. No new data on environmental effects is presented. The products in the family are blends of the active substance and the inert filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.

As stated in the summary of the fate assessment from the Assessment Report above hydrated lime is widely used as a measure to counteract soil acidification. Hydrated lime rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and hydrated lime status of highly deficient soils. These data suggest that the quantities of hydrated lime used exceed the maximum quantities applied due to the biocidal uses. However, it should be noted that for agricultural liming, in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via biocidal use to ensure that the total neutralising value of the material applied remained within the relevant guidelines.

Further information on the secondary ecological effect is not therefore required to address the biocidal uses.

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

Calcium dihydroxide is used to disinfect the floors of animal accommodation (PT3 use). It is removed with manure on cleaning of accommodations, with the spent $Ca(OH)_2$/manure mix either sent to manure storage or for disposal, normally incineration. It will not be released to a facility drain as the type of waste makes it physically impossible to send to a STP/drain. Consequently, the foreseeable routes of entry into the environment on the basis of the use envisaged are mainly via indirect emissions:

Indirect routes: to soil, groundwater and surface water via manure applications containing hydrated lime residues.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment.
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. These substances are naturally occurring inorganic compounds. Read-across to the active substance

	data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for further studies to be performed. The Applicants justification is considered acceptable as the products in the family are blends of the approved EU active substance, calcium dihydroxide (15-65%) and a filler calcium carbonate (35-85%). Both of which are naturally occurring inorganic substances. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.

Leaching behaviour (ADS)

Data waiving	
Information requirement	Leaching behaviour
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and a calcium carbonate filler. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic compounds. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for leaching studies to be performed based on the natural occurrence of limestone. The Applicants justification is considered acceptable as the products in the family are blends of the approved EU active substance, calcium dihydroxide (15-65%) and the filler calcium carbonate (35-85%). Both of which are naturally occurring inorganic substances. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.

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

Data waiving	
Information requirement	Distribution and dissipation in water
Justification	No new data on environmental effects is presented. The products in the family are blends of the active substance and the filler calcium carbonate. Calcium carbonate is the starting material for manufacture of the active substance. The substances are naturally occurring inorganic salts. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products. There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca^{2+} and OH^- ions in nature.

	The Applicants justification is considered acceptable as the products in the family are blends of the approved EU active substance, calcium dihydroxide (15-65%) and the filler calcium carbonate (35-85%). Both of which are naturally occurring inorganic substances. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Distribution and dissipation in air
Justification	The eCA notes no new data is presented and no data is considered According to the Assessment report (2016) a justification was provided for the non-submission of data on the basis that hydrated lime is expected to have vapour pressures well below 10^{-5} Pa and that exposure via air is not expected. Whilst an estimation using simple calculations could be used to address this data point (e.g. the estimation methods of the Atmospheric Oxidation Program) irrespective of the vapour pressure for substances such as hydrated lime, such calculations would be largely meaningless as the potential for exposure via air, and subsequent phototransformation in air would be expected to be negligible. The products in the family are blends of the active substance and a calcium carbonate filler. The substances are naturally occurring inorganic substances. Read-across to the active substance data set is therefore applicable to the blended products and data on the active substance is applicable for the products.

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

Data waiving	
Information requirement	Overspray study; surface waters
Justification	The eCA notes no new data is presented and no data is considered required as the biocidal products are used for the disinfection of indoor floor surfaces of animal accommodations. The product are spread onto the floors of animal accommodations using manual or automated techniques. The biocidal products are not sprayed near to surface waters. Consequently, an overspray study is not considered required in this case

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

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

2.2.8.2 Envrionmental Exposure assessment -General information

During the EU active substance assessment several MS recommended a risk assessment based on a *qualitative* approach, particularly since the dissociation products of the lime variants (Ca^{2+}, Mg^{2+} and OH-) form parts of existing chemical cycles in the natural environment. For the terrestrial compartment, this involves the calculation of the lime application rate to grassland/arable land (via manure/slurry spreading) due to the intended uses of the lime product and comparison with routine agricultural use of lime to control soil pH. Applications resulting in a lower environmental loading are considered safe. According to the EU CAR for the active substance, up to *'16 tons/ha per year (as CaO)'* is applied to lime deficient agricultural soils that are extremely acidic (in some member states). In Ireland, practically all manure/slurry is applied to grassland. If the lime application for Irish grassland exceeds 7.5 tonnes/ha (i.e., in situations where the soils are very acidic), the Irish research and development authority, Teagasc, recommends applying a maximum of 7.5 tonnes/ha with the remainder applied after two years. For established grassland or other situations where there is no, or only minimal, soil cultivation, no more than 7.5 tonnes/ha should be applied in one application. It is important that soils are not over-limed as this can result in undesirable pH changes, low availability of micronutrients, especially magnesium, manganese, boron. In (some) Irish soils there is also an increased risk of inducing a copper deficiency in grazing animals as a result of increased molybdenum availability. To protect the Irish environment, manure applications containing lime residues as a result of biocide applications cannot exceed 7.5 tonnes/ha ($CaCO_3$ equivalents)

In the original environmental exposure assessment, the applicant performed the calculations with an application rate of 1 kg a.s./m^2. The assessment was modified by the eCA to bring it in line with the ESD for PT3 and recent EU technical agreements. Following completion of the environmental exposure assessment, the application rate was subsequently changed as a result of the eCA efficacy evaluation. The finalised application rates of the calcium dihydroxide product are presented below:

Finalised application rates of the calcium dihydroxide product

Calcium dihydroxide content in product (%)	**Amount of product (kg/m^2)**	**Amount of $Ca(OH)_2$ (kg/m^2)**	**Amount of $CaCO_3$ (kg/m^2)**
15	1	0.15	0.85
20	0.75	0.15	0.6
30	0.5	0.15	0.35
40	0.375	0.15	0.225
50	0.3	0.15	0.15
65	0.23	0.1495	0.0805

All products deliver an application rate of 0.15 kg a.s/m^2. Consequently, the calculations presented hereunder, which were performed with an application rate of 1 kg a.s./m^2 overestimate the environmental exposure of the active substance (Tier 1/Tier 2 (incorporating buffer capacity) ~14.27/0.27 tonnes a.s./ha/yr grassland, respectively). Using the ESD defaults, along with an $F_{slurry/manure}$ of 1 (which is based on the applicants calculations)[5], an application rate of 0.150 kg a.s/m^2 results in a maximum environmental

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[5] The ESD $F_{slurry/manure}$ default is 0.5. The accompanying ECHA spreadsheet for PT3 suggests this is for spraying applications. The ESD for PT18(2006) suggests an emission factor of 0.9 to slurry/manure for sprinkling application in animal housing. This is considered appropriate for sprinkling applications as practically all of the product will end up in the manure/slurry storage facility at the end of the disinfection process. An $F_{slurry/manure}$ of 0.9 is considered

loading of ~40.37 kg a.s /ha/yr to grassland land (via manure/slurry applications) for the veal calves scenario when the buffering capacity of the active substance is taken into account. Environmental emissions associated with applications to arable land are predicted to be lower (10.1 kg a.s /ha/yr). Applications to other animal housing units result in lower application rates. The original environmental exposure assessment (presented below) was NOT updated to reflect these changes as the new application rates do not impact the overall conclusion of the assessment.

Overview of environmental exposure assessment for an application rate of 1 kg a.s/ha

Assessed PT	PT 3
Assessed scenarios	Scenario 1: Application to manure Please refer to the next section for further details
ESD(s) used	Qualitative argument The Applicant suggests the biocidal application rates to soil from the claimed PT 3 rates (disinfection of animal housing) are lower than the expected agricultural rate of 16 tonnes/ha documented in the EU PT3 Calcium dihydroxide CAR.
Approach	EU PT3 CAR
Distribution in the environment	---
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes Service life: No
Remarks	The relevance of the assessed scenario for the intended use (disinfection of floor surfaces of animal accommodations) will be discussed in the next section.

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appropriate for the 'inert' filler calcium carbonate. However, the emission factor is considered conservative for the active substance as calcium dihydoxide is highly reactive with organic matter according to data presented in the EU CAR ('DT_{50}', (specifically buffering capacity) is 0.742 d up to 6 hr). Considering, a 2 hr contact time (*cf* efficacy section) and the likely presence of some organic matter on the floor surface of animal accommodations (after washing), the fraction directed to slurry is likely to be less than 0.9. An emission factor ($F_{slurry/manure}$ default of 0.5 is considered sufficiently for calcium dihydroxide (*CF* Union authorisation of comparable lime products).

Emission estimation

The calcium dihydroxide product family is intended for use as a disinfectant of indoor floor surfaces of animal accommodations (specifically cattle). This is a veterinary hygiene use (Product Type (PT) 3). PT 3 covers the use of disinfectants to control animal pathogens, prevent animal diseases, increase production and improve the quality of animal products. The Applicant suggests the biocidal application rates to soil from the claimed PT 3 rates are lower than the expected agricultural rate of 16 CaO tonnes/ha documented in the Calcium dihydroxide PT3 CAR. An overview of the Applicant's calculation is presented on the next page.

Environmental loading of $Ca(OH)_2$ from the disinfection of animal housing (cattle)- *Applicant's calculation*

Calculation of the rate of $Ca(OH)_2$ application per 1 m^3 of liquid manure (kg/m^3)

- Treatment will take place at least once per year: 1 kg a.s./m^2
- Using the accommodation areas as stated in the Human Health exposure assessment this equates to
  Manual spreading: 1 kg/m^2 x 160 m^2 = 160 kg $Ca(OH)_2$
  Automated spreading: 1 kg/m^2 x 3,390 m^2 = 3,390 kg $Ca(OH)_2$

Amount of liquid manure generated by cattle in one week

125 cattle (ESD Default) x 66 L liquid manure/cow/d x 7 d/week = 57,750 L/week

- Which according to the Applicant is equivalent 144 m^3 of manure (57,750 /400)
- Assuming ~400 kg *manure* /1 m^3 liquid. The eCA disagrees with this calculation.

Rate of $Ca(OH)_2$ application per 1 m^3 manure (kg/m^3) is = 3,390 kg Lime / 144 m^3 =
23.5 kg Lime/m^3 manure

- This calculation assumes one application per week
- The (max) use of $Ca(OH)_2$ for treatment of manure documented in the EU PT3 CAR is 40 kg /m^3 manure.

The Applicant then calculated the amount of lime (kg/ha) applied to agricultural land based on the method presented in the EU CAR and the P-emission standard (*cf* EU PT3 CAR). This involves multiplying the concentration of active substance in manure (kg/m^3 of manure) and the maximum application rate of manure on grassland/arable land respecting the emission standard of 85 kg P_2O_5/ha/year (in units of m^3 of manure/year/ha soil). This results in the maximum application rate of active substance applied to grassland/arable land per year per hectare (tonnes/year/ha): of 1.3 tonnes/ha/yr, **Table 2.2.8.2-1**

Table 2.2.8.2-1. Calculation of the rate of lime application to agricultural land

Reg	**Amount of manure per <u>cow</u> (L anim./day)**	**P_2O_5 prod. (kg P_2O_5/anim/day)**	**Amount of P_2O_5 in manure (kg P_2O_5/L)**	**Emission Standard P (kg P_2O_5/ha/yr)**	**Max appl. rate of liquid manure (m^3/ha. yr)**	**Rate of $Ca(OH)_2$ app per 1 m^3 <u>liquid manure</u> (kg/m^3)**	**Lime dose (kg/ha/yr)**	**PEC (mg/kg <u>wwt</u>) <u>Tier 1</u>**	
		PT3 ESD defaults						**5 cm Grass**	**20 cm Arable**
PT 3 EU CAR	66 (EU CAR)*	0.10466	0.00158575	85	53.60#	40 (App. Rate)	2,144 (2.14 tonnes/ha/yr)	2,522	630
PAR Intended use $Ca(OH)_2$					53.60	23.5	1,259 (~1.3 tonnes/ha/yr)	1,481	370

*66 L manure/anim./day is specified in the EU PT3 $Ca(OH)_2$ CAR for dairy cows and originated from the OECD Task *'Emission Scenario Document for Insecticides for Stables and Manure Storage Systems'*

Via 85 kg P_2O_5/ha/yr//0.001585758 kg P_2O_5/L = 53.90 x10^3 L/ha = 53.60 m^3/ha

- The EU PT3 $Ca(OH)_2$ CAR reports the following application rates
  Dairy Cattle: 2,144/1,947 kg/ha based on the P/N emission standard respectively
  Beef cattle:1,623/1,180 kg/ha based on the P/N emission standard respectively
  Veal calves:1,674/2,939 kg/ha based on the P/N emission standard respectively
  The highest rate of hydrated lime was associated with Fattening pigs 2,958 kg/ha/yr based on the N* emission standard (250 kg N/ha/yr, which is the derogation limit in some MS)However, in the EU CAR the max application rate was limited to 50 m^3/ha (for PEC calculations) which corresponds to 2,000 kg a.s/ha (via 50 m^3/ha x 40 kg a.s./m^3)The EU calculation is for the disinfection of manure/slurry. The lime is directly mixed with its substrate. The environmental loading of lime is via manure to agricultural land.

<u>eCA comments</u>

When lime is spread on a substrate such as a floor the Applicant should have adapted the standard ESD PT3 scenario for the disinfection of animal housing. The area used in the Applicant's calculation is not in agreement with the specified floor areas in the ESD for PT3. The eCA also considers the Applicant's back calculated rate of calcium dihydroxide for manure to be erroneous. In addition the Applicant's PEC calculation does not support the (realistic worse case) intended use pattern in which the application interval is 1 d. Consequently, the eCA is not relying on the Applicant's PECs for risk assessment. The Applicant's calculation is also assuming the fraction of active substance in the product is 100%. This is conservative. In reality depending on the product in the biocide product family the calcium dihydroxide (active substance) content varies from 15-65 %. The corresponding filler content of calcium carbonate ranges from 35-85 %. More realistic estimates of exposure were calculated by the eCA using an adapted version of the standard ESD PT3 scenario for disinfection of animal housing in which the Application interval was set to 1 d (i.e., the intended use pattern) and it was assumed that 100 % (Fslurry/manure =1) of the biocide reached the slurry pit. This is conservative as the ESD default is 0.5. Although the Applicant suggests a biocide application interval of 1 d, the eCA considers it very unlikely that the *entire* floor housing area (e.g. ESD defaults: 1,170/370 m^2 cows/beef cattle respectively) would be disinfected every day in most cases. For example, the ESD default for the disinfection of beef cattle/calves housing is 365/160 d respectively. However, dairy facilities are more likely to be cleaned on a regular basis (e.g., daily). **Table 2.2.8.2-2** summarises the Tier 1 PECs obtained by the eCA.

The PECs associated with the application of manure to agricultural land containing lime residues applied in cattle housing ranged from 2,054 mg/kg wwt to ~16,793 mg/kg wwt (after a single application of manure and ignoring 'degradation'). The corresponding Tier 1 maximum application <u>annual</u> application rate is 14.27 t/ha. This is (Tier 1) higher than what was assessed at EU level (max 2.00 t/ha). However, the eCA notes for products applied as powder or granular formulation to slurry/manure the EU Environmental Working group[6] agreed to use a *qualitative* assessment for the soil compartment. In the qualitative assessment, the emissions are calculated[7]and compared to routine agricultural use of lime to control soil pH. According to the CAR, EU wide GAP practices recommends application rates up to '16 tons/ha' per year (as CaO) in lime deficient soils in some member states. The Application rates documented in **Table 2.2.8.2-2** are less than this.

Table 2.2.8.2-2a. eCA <u>Tier 1</u> PECsoil of Calcium dihydroxide (1 kg/m^2 <u>floor</u> area) after manure application (containing Calcium dihydroxide residues from animal housing disinfection) to agricultural land (arable/grassland)

Animal Housing Category	**N Animals (ESD PT3)**	**PECgrs-N <u>Annual</u> (n =4)**	**PECars-N (n=1)**	**Back calculated Application rate (Max)**
		mg/kg <u>wwt</u>		
		5 cm	**20 cm**	**tonnes/ha Tier 1**
		Tier 1	**Tier 1**	
Dairy cows	100	6,905	1,726	5.87
Beef cattle	125	2,054	514	1.75
Veal calves	80	16,793	4,198	**14.27(max app. rate)**

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[6] WGI2020_ENV_7-5 - Assessment of lime product Final minutes 1 (15)
Item 7.5: E-consultation on the procedure of the environmental exposure assessment of products with the a.s. hydrated lime, burnt lime and dolomitic burnt lime-Results of the e-consultation are planned to be discussed at WG ENV I 2020

[7] Emissions are calculated assuming an application rate of 50 m^3/ ha or using the appropriate ESD PT3 scenario (170 kg N /ha/year)

T1 = Tier 1 no 'degradation'

Notes

- The lime ($Ca(OH)_2$) remains on the floor of the animal housing accommodation so it could potentially mix with (unremoved) manure/slurry. The lime is removed with manure on cleaning of accommodations (after ~2 hr), with the spent $Ca(OH)_2$/manure mix either sent to manure storage or for disposal. It will not be released to drains as the type of waste makes it physically impossible to send to STP/drain. Manure mixed with $Ca(OH)_2$ can also be left in storage for use on fields.

- Except where otherwise stated the PECs were calculated in accordance with the procedure described in the ESD for PT3. In the eCA calculations it is assumed only the floor area is treated. The fraction of disinfectant emitted to the manure storage facility was set to one. The rate of Applications used in these calculation is 1 kg a.s./m^2. This is conservative as only 65% of the product is $Ca(OH)_2$. This calculation indirectly accounts for the additional calcium loading arising from the calcium carbonate filler etc.

- Concentration of the active ingredient in soil are reported for grassland (grs)/arable (ars) land and are based on the nitrogen immission standards (*Cf* EU TAB)

- The eCA notes the estimated (max) PEC with the EU defaults is conservative from an Irish perspective as lower PECs are predicted when using Irish specific data. Although the PECs are lower, they would not change the need for a Tier 2 assessment for Irish national authorisation (Annex 2.2).

The Tier 1 application rates are outside the *maximum* recommended use rate of agricultural lime ($CaCO_3$) in Ireland (up to 7.5 t/ha/yr[8]). However, the EU CAR documents that lime ($Ca(OH)_2$) is highly reactive with organic matter. Residues resulting from former applications during the manure storage period are considered negligible due to extremely fast 'degradation' for lime (DT_{50} is 0.742 hr during the first 6 hr). Much of this 'degradation' (actually buffering in manure or sludge) occurs prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). Consequently, the last application of lime directed to manure/slurry is considered for emission calculations. In addition some of the $Ca(OH)_2$ is likely to have been neutralised during the disinfection of the floor surface.

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[8] In Ireland, the main source of lime is from limestone quarries. Here, the rock is ground to a fine material suitable for spreading on the land. Limestone needs to dissolve in the soil before it can be fully utilised and this process can take up to two years. Smaller limestone particles are available much more rapidly and will react with the soil and raise pH much faster than coarse materials. The ability to neutralise soil acidity depends on both the purity (CCE) and the particle size of the liming material. DAFM SI 248 (1978) lays down standards for lime (ground/granulated. The Irish Agriculture and Food development Authority (Teagasc) suggests to apply lime (ground calcium carbonate, 65% < 3.35 mm, 35% < 0.1 mm, moisture < 3%), in a 3-5 year cycle.

In Ireland calcium based limestone is generally made up of greater than 95% calcium carbonate ($CaCO_3$). Dolomitic Limestone or Magnesium based limestone is typically 55% Calcium Carbonate and 45% Magnesium Carbonate

High annual rainfall leads to a large removal of lime each year. Grassland (the dominant land use in Ireland) typically requires between 0.5 - 1 t/ha/yr of lime (ground $CaCO_3$). (This is equivalent to a mass of 0.74 t/ha/yr $Ca(OH)_2$). In Ireland Teagasc suggests typical *maintenance* lime requirement of 2.5 to 5.0 t/ha once every 5 years depending on regional location and rainfall (i.e. typically higher rates may be required in the West).

The maximum recommended rate of lime in a single application is 7.5 tonnes ground limestone/ha (equivalent to a mass of 5.55 t $Ca(OH)_2$/ha). Where more lime is recommended, the balance is applied two years later. The recommended application rate for granulated lime which is ground much more finely (< 0.1 mm) than ground limestone is generally three times lower as it reacts faster. Adapted from Teagasc -Advice on Liming Add life to your land and profit to your business Weblink (https://www.teagasc.ie/media/website/environment/soil/Advice-on-Liming-Leaflet.pdf

Consequently, the fraction of $Ca(OH)_2$ directed to the slurry pit is likely to be less than one. Therefore, in Tier 2 calculations 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 calculation of the $Ca(OH)_2$ emissions. Napp-manure is therefore equal to 1 in Tier 2 calculations, **Table 2.2.8.2-2b.** A similar type of refinement was taken into account in the EU assessment in Tier 2 calculations.[9] The resulting maximum application rate for the current product resulted from applications to animal housing associated with veal calves (0.27 t a.s./ha, annual manure applications to grassland, n = 4). Application to veal cattle housing is unlikely to be a major use in Ireland as this is currently not considered a viable industry in Ireland due to an annual six to eight week calving period (Vs a 52 week market) and a lack of market in Ireland for this type of product.[10]

Table 2.2.8.2-2b. eCA Tier 2 PECsoil of Calcium dihydroxide (1 kg/m² floor area) after manure application (containing Calcium dihydroxide residues from animal housing disinfection) to agricultural land (arable/grassland)

Animal Housing Categorgy	N Animals (ESD PT3)	PECgrs-N (n =1)		PECars-N (n=1)	Back calculated Application rate
		mg/kg wwt			
		5 cm		20 cm	t/ha Tier 1
		Tier 1		Tier 1	
		1 appl	4 appl	1 appl	
Dairy cows	100	32.6	130	8.1	
Beef cattle	125	9.7	39	2.4	
Veal calves	80	79.2	317	19.8	~0.07 t/ha (n=1) 0.27 t/ha annual (n=4) application to grassland

Tier 2 = In Tier2 calculations residues resulting from former applications during the manure storage period are considered negligible due to extremely fast 'degradation' for lime (DT_{50} is 0.742 hr during the first 6 hr). Much of this 'degradation' (actually buffering in manure or sludge) occurs prior to application of the lime amended material to agricultural land (AR of Hydrated lime, 2016). Consequently, only the last application of lime directed to manure/slurry is considered for emission calculations. This methodology is discussed in the " *E-consultation on the procedure of the environmental exposure assessment of products with the a.s. hydrated lime, burnt lime and dolomitic burnt lime" (WGI2020_ENV_7-5 - AS-assessment of lime products Final minutes)*. The eCA calculation assumes the manure/slurry is applied on the same day and no 'degradation' occurs. The eCA notes this procedure is somewhat different to the approach documented in the PT3 CAR. These PECs associated with the single application were refined assuming 'degradation' (1 d).

Calves scenario –grassland (n=1)

PEC = $\frac{100 \times 1\ kg/m^2 \times 160\ m^2 \times 1\ (=Fslurry) \times 170\ kg\ N/ha/yr}{1{,}700\ kg/m^2 \times 0.05\ m \times (0.02382\ kg\ N/\ veal\ cattle/d \times 80\ veal\ cattle \times 53\ d \times 4\ manure\ app)}$ = 79.21 mg/kg wwt per manure appl.

Note to Ecotoxicology

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[9] EU PT3 CAR $Ca(OH)_2$ PEC Tier 1= 2,666 mg/kg dwt(2,000 kg a.s./ha),Tier 2 9.49 mg/kg dwt.

[10] Emma Gilsenan"*Why is a veal industry in Ireland not possible?*" Agriland- November 2, 2019, https://www.agriland.ie/farming-news/why-is-a-veal-industry-in-ireland-not-possible/

For (quantitative) risk assessment purposes, it is sufficient to consider one application as accumulation between manure applications is unlikely as the calcium and hydroxide ions are highly mobile in the environment. In addition the PEC calculation assumes the slurry (containing spent $Ca(OH)_2$ residues) is applied on the same day the animal housing unit is disinfected. In reality there would be a time lag. This would allow the $Ca(OH)_2$ to rapidly 'degrade'. This conclusion only applies to $Ca(OH)_2$.

Calcium carbonate

The lime product contains calcium carbonate as a filler (35-85% depending on the particular product). The eCA notes calcium carbonate is a plant protection product active substance that is used as a repellent on deciduous and coniferous trees in forestry (EU representative uses). Calcium carbonate is also the main ingredient of agricultural lime in Ireland. However, calcium carbonate is also the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). In some regions it is the water bearing rock material of groundwater aquifers. After application of the calcium dihydroxide product, the calcium carbonate is directed to the slurry pit along with spent calcium dihydroxide. Some sedimentation may occur in the slurry tank as calcium carbonate has very low solubility. Calcium dihydoxide is more soluble and reactive. When the slurry is spread on the land any unreacted calcium carbonate could act as a source of lime. In some scenarios (specifically 250 kg N/ha derogation farms, dairy cow scenario) the level of calcium carbonate added to grassland from slurry application containing spent lime residues may exceed natural liming limits in Ireland. This is reduced to an acceptable level (-below natural liming limits) with a 2 d interval between biocide applications (please refer to Annex 2.2 for further details).

Ecotoxicology should consider the impact of pH changes on the environment as part of the risk assessment.

Potential overlap of slurry application (containing $Ca(OH)_2$) and lime ($CaCO_3$) applications was *not* considered in the EU CAR. However, this is considered unlikely. If lime has been applied first, Teagasc recommends avoiding slurry application for three months. If the slurry is first applied, Teagasc recommends leaving it a week before spreading lime. In both cases it is highly likely the fast-reacting $Ca(OH)_2$ would have dissipated.

Environmental exposure assessment summary for the Terrestrial compartment

All the uses of the Calcium dihydroxide product family lead to lower environmental exposure to lime (specifically $Ca(OH)_2$) relative to agricultural liming in Ireland (7.5 tonnes /ha, which is equivalent ~5.55 tonnes $Ca(OH)_2$). In some scenarios (*specifically* 250 kg N/ha derogation farms, dairy cow scenario) the level of the inert filler calcium carbonate (a form of lime) added to grassland from slurry application containing spent lime residues may exceed natural liming limits in Ireland. This is reduced to an acceptable level (below natural liming limits) with a 2 d interval between biocide applications. A restriction will be placed on the product label.

Uses	**Max. emissions of $Ca(OH)_2$ to grassland soil (agricultural land, in tonnes/ha/year)**
PT3	Cattle Tier 1 /Tier 2
Disinfection of indoor floor surfaces of animal accommodations	14.27/0.27

- Applications rates are based on data presented in Table 2.2.8.2-2a and Table 2.2.8.2-2b
- Using Irish specific data results in lower emission rates (Annex 2.2)

PEC_{groundwater}

The application of manure containing spent hydrated lime to soil could result in groundwater exposure. However, the maximum application rate associated with the application of manure containing lime residues (Tier 2 0.27 tonnes $Ca(OH)_2$/ha) is less than the maximum lime application rate applied in agriculture to control pH in Ireland (1 t/ha-7.5 t/ha calcium carbonate, which is equivalent to 0.74 t/ha -5.55 tonnes/ha $Ca(OH)_2$ assuming 100% purity). The levels are also lower than 16 t/ha. The EU PT3 CAR for the active substance suggests up to '16 tons/ha' per year (as CaO) can be applied to lime deficient soils in some member states as part of routine agriculture.

When dissociation occurs, hydrated lime dissociates into Ca^{2+} and OH^-. The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. In terms of the groundwater compartment Ca^{2+} ions are expected to be major constituents in many groundwater zones.

The application of manure containing spent hydrated lime to soil could also result in exposure of groundwater to the inert filler calcium carbonate. The maximum possible loading of calcium carbonate to the terrestrial compartment via slurry applications (4.28 t/ha) is within typical agricultural maintenance levels. Calcium carbonate is naturally present in the environment as inorganic mineral (limestone). Calcium carbonate is almost insoluble in water. Solubility varies depending on the interaction of several environmental factors. When dissociation occurs, calcium carbonate is transformed to calcium and carbonate ions in the presence of water. Carbonate is naturally produced from various natural resources, particularly carbonate-based rocks and respiration of aquatic plants during the hours of darkness. Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). In some regions it is the water bearing rock material of groundwater aquifers Overall any calcium carbonate reaching groundwater from the intended use is expected to be negligible in comparison to naturally occurring background levels and from agricultural use of lime products.

Overall, no further detailed assessment is considered necessary in this case. This is consistent with the approached adopted for the EU assessment of the active substance. In addition, the parametric drinking water limit of 0.1 µg/L for *organic* pesticides, usually used as a decision-making criterion regarding groundwater exposure is not applicable to inorganic compounds such as $Ca(OH)_2$. Parametric drinking water quality standards have not been set in Council Directive 98/83/EC for calcium ions and hydroxide/ carbonate ions.

PEC in aquatic compartment (STP, surface water and sediment)

The application of manure containing spent hydrated lime to soil could result in surface water exposure via runoff. However, the maximum application rate associated with the application of manure containing lime residues is less than the application rate applied in agriculture to control pH in Ireland and the EU. Please refer to the soil exposure section for further details. During the E-consultation on the procedure of the environmental exposure assessment of products with the a.s. hydrated lime, burnt lime and dolomitic burnt lime the EU Working Group agreed that a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage system is not relevant for lime products.[6] When dissociation occurs, hydrated lime dissociates into Ca^{2+} and OH^-. The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. In terms of the surface water compartment Ca^{2+} ions are expected to be major constituents in many surface water bodies. Similar conclusions apply to the calcium carbonate filler. In addition, according to BPR Vol IV Part B+C (2017), chapter 2.3.7.5.1, no runoff from soil to surface water after manure application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

$PEC_{sediment}$

Upon contact with water hydrated lime will react with CO_2 dissolved in water to form poorly soluble $CaCO_3$ that would precipitate under neutral conditions. This precipitation was noted to occur at the highest concentration levels in the studies that were performed to investigate the development of pH in different water. $CaCO_3$ would be expected to be ubiquitous in the natural aquatic environment and the additional source via the biocidal uses of hydrated lime would not be expected to increase levels significantly above existing background levels. On this basis no requirement for the calculation of a formal $PEC_{sediment}$ was identified.

PEC_{STP}

Calcium dihydroxide is used to disinfect the floors of animal accommodation (PT3 use). It is removed with manure on cleaning of accommodations, with the spent $Ca(OH)_2$/manure mix either sent to manure storage or for disposal, normally incineration. It will not be released to a facility drain as the type of waste makes it physically impossible to send to a STP/drain. As noted in the EU CAR there is a theoretical possibility for point source contamination of sewage treatment plants to occur following runoff from individual contaminated farmyards entering drainage systems connected to local treatment plants. However, widespread contamination of farmyards with lime would not be expected to be significant in farming operations of a high standard where best practice is routinely followed. In addition, this route of exposure would not be expected to form part of the normal use of the hydrated lime-based products and therefore should not form part of the routine exposure assessment. In addition, in Ireland it is very unlikely that farmyard drainage systems are *connected* to local treatment plants. In the event that such point source contamination did occur, it is not expected that the risk would be any higher than already predicted to occur in surface water via runoff following the broad scale use on agricultural land.

As a precaution 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, can be directed to a sewage treatment plant".*

2.2.8.3 Risk characterisation

The risk characterisation is performed for the biocidal family calcium dihydroxide for the disinfection of animal housing. The product contains a maximum of 65 % w/w of the active substance calcium dihydroxide (1 kg product/m^2 floor area, 15-65 % w/w calcium hydroxide), the rest being calcium carbonate.

The biocidal product contains no substance of concern. Therefore, the risk characterisation is based on the risk characterisation of the active substance at the maximum intended use rate (Max. 1 kg of product/m^2 floor area, 65 % w/w $Ca(OH)_2$) with respect to the environmental exposure and the intended use.

Atmosphere

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

Conclusion to the risk assessment

There is no concern for the atmosphere from the proposed uses.

Sewage treatment plant (STP)

During the discussion of the lime product families at the WG-I-2020 meeting it was agreed the emission and effect of lime to STP can be assessed qualitatively when it is used as disinfectant in animal housing.
The main route of environmental exposure resulting from the biocidal use of hydrated lime is expected to arise following the broad scale application of treated manure to agricultural land. There is theoretically the potential for point source contamination of sewage treatment plants to occur following runoff from individual contaminated farmyards entering drainage systems connected to local treatment plants. However, widespread contamination of farmyards with lime would not be expected to be significant in farming operations of a high standard where best practice is routinely followed. In addition, this route of exposure would not be expected to form part of the normal use of the hydrated lime-based products and therefore should not form part of the routine exposure assessment.

In the event that such point source contamination did occur, it is not expected that the risk would be any higher than already predicted to occur in surface water via runoff following the broad scale use on agricultural land.

Conclusion to the risk assessment

There is no concern for the STP from the proposed uses.

Aquatic compartment

During the discussion of the lime product families at the WG-I-2020 meeting it was agreed that a quantitative assessment of the aquatic compartment after indirect releases via run-off or drainage system is not relevant for lime products.

Following manure application (containing calcium dihydroxide residues from animal housing disinfection) to soil the most likely route of entry to adjacent surface water bodies would be expected to be via surface runoff. For surface waters which are fed by run-off from agricultural soils, dissociation is a relevant process. Therefore, in the case of raining events which lead to run-off, the active substance comes in contact with water and will dissociate as well into Ca^{2+} and OH^-. According to the a.s. AR (UK, 2016), "the dissociation products are not further degradable either chemically or biologically because they consist of simple basic structures, which cannot be broken down any further. These ions would be expected to form part of existing chemical cycles in the natural environment.
Overall, the natural reactions of the lime components in the manure would be expected to significantly reduce the exposure levels following treatment and thus reduce the potential for significant levels of lime in runoff from treated fields.

Conclusion to the risk assessment

There is no concern for the aquatic compartment from the proposed uses.

Terrestrial compartment

During the discussion of the lime product families at the WG-I-2020 meeting, it was agreed that a qualitative assessment of the terrestrial compartment could be performed because the dissociation products of the lime variants (Ca^{2+}, Mg^{2+} and OH^-) form parts of existing chemical cycles in the natural environment. The qualitative assessment involves the calculation of lime emissions on grass and arable land due to the biocidal claimed uses and the comparison with routine agricultural use of lime to control soil pH.

According to the CAR, EU wide good agricultural practices recommends application rates to neutralise agricultural soil up to 16 tons/ha per year (as CaO) in lime deficient soils. However, in Ireland lime application rates are lower (max 7.5 tonnes/ha ($CaCO_3$)).

The back calculated application rates for calcium dihydroxide presented in table 2.2.8.3-1 below after manure application (containing calcium dihydroxide residues from animal housing disinfection) to agricultural land were compared to the application rate applied in agriculture to control pH in Ireland (1 tonnes/ha-7.5 tonnes/ha calcium carbonate, which is equivalent to ~0.74 tonnes/ha -5.55 t/ha $Ca(OH)_2$ assuming 100% purity) (See section 2.2.8.2- Table 2.2.8.2-2a).

Table 2.2.8.3-1 Summary of application rates (max back calculated) of Calcium dihydroxide (1 kg/m² floor area) after manure application (containing Calcium dihydroxide residues from animal housing disinfection) to agricultural land (grassland)

Animal Housing Category	**Emissions to soil (agricultural land, in tonnes/ha/year)**	
	Tier 1*	Tier 2*
Dairy cows	5.87	n.r.
Beef cattle	1.75	n.r
Veal calves	14.27 (max app. rate)	0.07 tonnes/ha (n=1) 0.27 tonnes/ha annual (n=4) application to grassland

n.r: not relevant
* See table 2.2.8.2-2a

All the uses of the calcium dihydroxide product for the disinfection of animal housing that lead to emissions to soil will generate application rates of lime on agricultural soil lower than the maximum agricultural use of lime spread to correct grasssland pH and maintain soil fertility in Ireland (7.5 tonnes/ha/year ($CaCO_3$), see Table 2.2.8.3-1 and Table 2.2.8.2-2a).

Therefore, the use of the calcium dihydroxide product leads to acceptable risk to the terrestrial compartment.

As noted above, the PEC calculation only applies to $Ca(OH)_2$. The application of manure containing spent hydrated lime to soil could also result in exposure to the inert filler calcium carbonate. Calcium carbonate is a naturally occurring inorganic substance and is almost insoluble in water. When dissociation occurs, calcium carbonate is transformed to calcium and carbonate ions in the presence of water. Carbonate is naturally produced from various natural resources, particularly carbonate-based rocks and respiration of aquatic plants during the hours of darkness.

As mentioned in section 2.2.8.2, in some scenarios (Dairy farms with a 250 kg N/ha derogation) the level of calcium carbonate added to grassland from slurry application contain spent lime residue may exceed natural liming limits. This is reduced to an acceptable level when a 2 d interval between biocide applications is implemented.

In addition to ensure that no unacceptable long-term pH changes in soil occur from spreading of manures or sewage sludges containing lime residues from the Calcium dihydroxide products, the soil pH should be monitored as part of routine agricultural practice.

As the use of the calcium dihydroxide product 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 the product in soil.

Conclusion to the risk assessment

There is no concern for the terrestrial compartment from the proposed uses.

Groundwater

The application of manure containing spent hydrated lime to soil could result in groundwater exposure. However, the maximum application rate associated with the application of manure containing lime residues (Tier 2 0.27 t $Ca(OH)_2$/ha) is less than the maximum lime application rate applied in agriculture to control pH in Ireland (1 t/ha-7.5 t/ha calcium carbonate, which is equivalent to 0.74 t/ha -5.55 t/ha $Ca(OH)_2$ assuming 100% purity). The levels are also lower than 16 t/ha. The EU PT3 CAR for the active substance suggests up to 16 tons/ha per year (as CaO) can be applied to lime deficient soils in some member states as part of routine agriculture.

When dissociation occurs, hydrated lime dissociates into Ca^{2+} and OH^-. The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. In terms of the groundwater compartment Ca^{2+} ions are expected to be major constituents in many groundwater zones.

The application of manure containing spent hydrated lime to soil could also result in exposure of groundwater to the inert filler calcium carbonate. The maximum possible loading of calcium carbonate to the terrestrial compartment via slurry applications (4.28 t/ha) is within typical agricultural maintenance levels. Calcium carbonate is naturally present in the environment as inorganic mineral (limestone). Calcium carbonate is almost insoluble in water. Solubility varies depending on the interaction of several environmental factors. When dissociation occurs, calcium carbonate is transformed to calcium and carbonate ions in the presence of water. Carbonate is naturally produced from various natural resources, particularly carbonate-based rocks and respiration of aquatic plants during the hours of darkness. Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). In some regions it is the water bearing rock material of groundwater aquifers Overall any calcium carbonate reaching groundwater from the intended use is expected to be negligible in comparison to naturally occurring background levels and from agricultural use of lime products.

Overall, no further detailed assessment is considered necessary in this case. This is consistent with the approached adopted for the EU assessment of the active substance. In addition, the parametric drinking water limit of 0.1 µg/L for *organic* pesticides, usually used as a decision-making criterion regarding groundwater exposure is not applicable to inorganic compounds such as $Ca(OH)_2$. Parametric drinking water quality standards have not been set in Council Directive 98/83/EC for calcium ions and hydroxide/ carbonate ions.

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

Primary and secondary poisoning

As agreed in the active substance CAR this point is not relevant because Lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca^{2+}, Mg^{2+}, and OH^{-}) in the environment.

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

Mixture toxicity

Not applicable

Aggregated exposure (combined for relevant emmission sources)

Not applicable

Overall conclusion on the risk assessment for the environment of the product
Overall, the risks are considered acceptable for the environment when the following risk mitigation measures (RMM) are implemented: • Do not apply the product if releases from animal housings, manure/slurry storage areas can be directed to a sewage treatment plant. • On farms that have a nitrogen derogation (250 kg N/ha/yr) the application interval between product applications in dairy housing is restricted to 2 day Recommendation • To avoid potential over liming, soil pH should be considered prior to spreading manures or slurry containing lime residues from calcium dihydroxide products. In addition soil pH should be monitored as part of routine agricultural practice to ensure the soil pH remains within acceptable norms. The above RMMs and recommendation should be placed on the product label and SPC.

Measures to protect man, animals and the environment

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

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

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

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

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

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

- On farms that have a nitrogen derogation (250 kg N/ha/yr) the application interval between product applications in dairy housing is restricted to 2 day

Recommendation
- To avoid potential over liming, soil pH should be considered prior to spreading manures or slurry containing lime residues from calcium dihydroxide products. In addition, soil pH should be monitored as part of routine agricultural practice to ensure the soil pH remains within acceptable norms.

The above RMMs and recommendation should be placed on the product label and SPC.

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

Assessment of a combination of biocidal products

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

Comparative assessment

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

ANNEXES[11]

List of studies for the biocidal product (family)

Table 1.1. Literature References generated from a Mixture/Product (including Literature References in any linked Substance)

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: ISO (the International Organization for Standardization)	Year: 2013	**Annex II/III requirement:** METHODS OF DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	IUCLID Document name: Analytical methods for determination in air	Title: ISO 17091:2013 Workplace air — Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide — Method by measurement of corresponding cations by suppressed ion chromatography Report no. ISBN 978 0 580 77732 5	Type of publication: publication			Yes
Author: Dr. Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these	IUCLID Document name: 6.7-01 65% Calcium	Title: Quantitative surface test for the evaluation of bactericidal activity	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime,	not specified	Yes

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

		claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Hydroxide Dirty EN 14349 Phase 2 Step 2 (non porous surface test - bacteria), BT-ARW-03-02, Woodhall, 2019	of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action, 65% Calcium hydroxide dirty conditions Modified EN 14349 2012(Phase 2 Step 2) Report no. BT-ARW-03-02 EN 14349		Clogrennane, Carlow, Ireland		
Author: Dr Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-02 65% Calcium Hydroxide Dirty EN 16437 Phase 2 Step 2 (porous surface test-bacteria), BT-ARW-03-02 - A1, Woodhall, 2019	Title: Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on porous surfaces without mechanical action, 65% Calcium hydroxide dirty conditions Modified EN 16437 2014 (Phase 2 Step 2) Report no. BT-ARW-03-02 EN 16437	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Clogrennane, Carlow, Ireland	not specified	Yes

Author: Dr Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-3 65% Calcium Hydroxide Dirty EN 16438 Phase 2 Step 2 (non porous surface test - yeast and fungi), BT-ARW-03-02, Woodhall, 2019	Title: Quantitative surface test for the evaluation of fungicidal or yeasticidall activity of disinfectants used in the veterinary area on non porous surfaces without mechanical action, 65% Calcium hydroxide dirty conditions Modified EN 13438 2014(P 2 S 2) Report no. BT-ARW-03-02 EN 16438	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Clogrennane, Carlow, Ireland	not specified	Yes
Author: Dr Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and	IUCLID Document name: 6.7-04 10% Calcium Hydroxide Dirty EN 14349 Phase 2 Step 2 (non porous surface test - bacteria),BT ARW-03-03 , Woodhall, 2019	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, 10% Calcium hydroxide dirty conditions Modified EN 14349 2012(Phase 2 Step 2)	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Clogrennane, Carlow, Ireland	not specified	Yes

		relevant **IUCLID Section No.** 6.7		Report no. BT-ARW-03-03 EN 14349				
Author: Dr Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-05 10% Calcium Hydroxide Dirty EN 16437 Phase 2 Step 2 (porous surface test - bacteria), BT-ARW-03-03, Woodhall, 2019	Title: Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on porous surfaces without mechanical action, 10% Calcium hydroxide dirty conditions Modified EN 16437 2014 (Phase 2 Step 2) Report no. BT-ARW-03-03 EN 16437	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Clogrennane, Carlow, Ireland	not specified	Yes
Author: Dr Chris Woodhall	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including	IUCLID Document name: 6.7-06 10% Calcium Hydroxide Dirty EN 16438 Phase 2 Step 2 (non porous surface test - yeast and fungi), BT-ARW-03-03,	Title: Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of disinfectants used in the veterinary area on non porous surfaces without mechanical action, 10% Calcium	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Clogrennane, Carlow, Ireland	not specified	Yes

		performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Woodhall, 2019	hydroxide dirty conditions Modified EN 13438 2014 (P 2 S 2) Report no. BT-ARW-03-03 EN 16438				
Author: Krowas D	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-07 EN 1656 Phase 2 Step 1, Suspension Test, Krowas, 2018 - 65%	Title: Bestimmung der bacterizidien Wirkung im Phase2/Stufe 1 Test. Quantitativier Suspensiontest Durchfuhrung nach DIN/EN 1656:2010 Report no. 0557A/18	Type of publication: study report	Source: NA Company Owner: Clogrennane	not specified	Yes
Author: Krowas D	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard	IUCLID Document name: 6.7-08 EN 14349 Phase 2 Step 2 Surface test, Krowas, D. , 2018 - 65%	Title: Bestimmung der bacterizidien Wirkung im Phase2/Stufe 2 Test. Quantitativier Oberflaschentest Durchfuhrung nach	Type of publication: study report	Source: NA Company Owner: Clogrennane	not specified	Yes

		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7		DIN/EN 14349 Report no. 0557A/18				
Author: Crane D., Burney C.	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-09 Calcium hydroxide Clean EN 14349 Phase 2 Step 2 (non porous surface test), MSL, 2018 - 80%+	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: Crane D., Burney C.	Year: 2018	**Annex II/III requirement:** Efficacy data to support these	IUCLID Document name: 6.7-10 Calcium	Title: Quantitative surface test for the evaluation of bactericidal activity	Type of publication: study report	Source: NA Company Owner: EuLA Brussels Belgium	not specified	Yes

		claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Hydroxide Dirty EN 14349 Phase 2 Step 2 (non porous surface test, MSL, 2018 - 80%+	of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action, Calcium hydroxide dirty conditions (Phase 2 Step 2) Report no. J000714-1				
Author: Crane D., Burney C.	Year: 2018	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-11 Calcium Hydroxide Clean EN 16437 Phase 2 Step 2 (porous surface test, MSL, 2018 - 80%+	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

Author: David Gleeson	Year: 2010	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-12 Report on the use of hydrated lime for cubicle bedding, Gleeson, 2010	Title: The effect of using hydrated lime as a bedding material on the microbial count on teats prior to calving and the infection levels post calving Report no. NA	Type of publication: study report	Company Owner: NA	not specified	Yes
Author: ,Amandine Carre,	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and	IUCLID Document name: 6.7-13 65% Calcium hydroxide, Simulated Use Test (Modified NF T 72-281) Bacteria - full veterinary surface organisms, HIgh Soil conditions, RE-13471019, Carre, 2020.	Title: Test Report No RE-1347/1019 Determination of microbicide activity of lime (65% Calcium hydroxide) according to a methodology modelled on NF T 72-281 (Bacteria Veterinary organisms) Report no. RE-1347/1019	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Carlow, Ireland R93 EV26	not specified	Yes

		relevant **IUCLID Section No.** 6.7						
Author: Amandine Carre,	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-14 65% Calcium hydroxide, Simulated Use Test (Modified NF T 72-281) Yeast, C. albicans , HIgh Soil conditions, RE-13471019, Carre, 2020.	Title: Test Report No RE-1347/1019 Determination of microbicide activity of lime (65% Calcium hydroxide) according to a methodology modelled on NF T 72-281 (Yeasticidal C. albicans) Report no. RE-1347/1019	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Carlow, Ireland R93 EV26	not specified	Yes
Author: Amandine Carre,	Year: 2020	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including	IUCLID Document name: 6.7-15 10% Calcium hydroxide, Simulated Use Test (Modified NF T 72-281) Bacteria - full veterinary surface organisms, HIgh	Title: Test Report No RE-1375/1019 Determination of microbicide activity of lime (10% Calcium hydroxide) according to a methodology modelled on NF T 72-281 (Bacteria Veterinary organisms) ,	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Carlow, Ireland R93 EV26	not specified	Yes

		performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Soil conditions, RE-1375/1019, Carre, 2020	Report no. RE-1375/1019				
Author: Amandine Carre	Year: 2021	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	IUCLID Document name: 6.7-16 15% Calcium hydroxide, Simulated Use Test (Modified NF T 72-281) S. uberis only, HIgh Soil conditions, RE-1539/1220, Carre, 2021	Title: Test Report No RE-1539/1220 Determination of microbicide activity of lime (15% Calcium hydroxide) according to a methodology modelled on NF T 72-281 (Bacteria Streptococcus uberis only) , Report no. RE-1539/1220	Type of publication: study report	Source: na Company Owner: Clogrennane Lime, Carlow, Ireland R93 EV26	not specified	Yes
Author: Amandine Carre,	Year: 2019	**Annex II/III requirement:** Efficacy data to support these claims, including any available standard	IUCLID Document name: 6.7-17 15% Calcium hydroxide, Simulated Use Test (Modified NF T 72-281)	Title: Test Report No RE-1422/0920 Determination of microbicide activity of lime (15% Calcium hydroxide) according to a methodology	Type of publication: study report	Source: NA Company Owner: Clogrennane Lime, Carlow, Ireland R93 EV26	not specified	Yes

		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Yeast, C. albicans , HIgh Soil conditions, RE-1422/0920 Carre, 2020	modelled on NF T 72-281 (Yeasticidal C. albicans) Report no. RE-1422/0920				

Output tables from exposure assessment tools

3.1. ENVIRONMENTAL EXPOSURE ASSESSMENT

Overview of EU CAR calculation for the disinfection of liquid manure with lime (General Background information)

The soil PEC arising from manure disinfection was estimated using the proposed default values from the OECD Task Force on Biocides *'Emission Scenario Document for Insecticides for Stables and Manure Storage Systems'* which were used to determine typical liquid manure production volumes. In combination with standard data on the emission standards for P_2O_5 and N they were used to determine the effective application rates of lime via treated manure. To demonstrate how these figures have been used to derive calculated lime application rates the example for dairy cattle will be shown below.

Hydrated lime application rate (g a.s/ha) associated with the application of animal manure (cattle) containing hydrated lime residues from manure/indoor disinfection events

- The OECD Emission Scenario document (ESD) provides default values for the daily amount of liquid manure per animal for dairy cattle as 66 L animal^{-1} d^{-1}.
- The OECD document also provides a default value for daily P_2O_5 production of 0.10466 kg animal^{-1} d^{-1}.
- The amount of P_2O_5 per litre of manure can be calculated as 0.10466/66 = 0.00159 kg L^{-1}.
- The P_2O_5 emission standard is 85 kg ha^{-1} year^{-1}. Therefore, the maximum application rate of liquid manure based on the P_2O_5 emission standard would be 85 kg ha^{-1} year^{-1}/0.00159 kg L^{-1} x 1 m^3/1000 L = 53.6 m^3 ha^{-1}.
- For a hydrated lime application rate of 40 kg dry hydrated lime per m^3 of liquid manure this equates to an application rate of 53.6 x 40 = 2,144 kg hydrated lime ha^{-1}.

However, the maximum application rate varies with the type of animal housing. The maximum calculated hydrated lime application rate derived from the default values for the different categories off animals housing is 2,958 kg lime ha-1 (fattening pigs scenario). This figure is derived from an application of 73.94 m^3 ha-1 of liquid manure, **Table 3-1.**

In reality, applications would not generally be recommended above 50 m^3 ha^{-1} in order to reduce the risks of runoff and odour problems arising from these levels of application rate. This upper application limit is stated in the CAR and is based on the UK Defra Code of Good Agricultural Practice for farmers, growers and land managers (2009). This equates to a hydrated lime application rate of 2,000 kg ha^{-1} assuming a manure treatment rate of 40 kg hydrated lime m^{-3}. This methodology was used in the EU assessment of the active substance.

Table 3.1-1. Calculated lime application rates based on default values from the OECD Task Force on Biocides "Emission Scenario Document for insecticides for stables and manure storage systems.

Category	Sub category	Daily amount of liquid manure per animal	Daily P_2O_5 production rate per animal	Daily N production rate per animal	Amount of P_2O_5 in one L liquid manure	Amount of N in one L liquid manure	Application rate of liquid manure calculated on P_2O_5* emission standard	Application rate of liquid manure calculated on N* emission standard	Application rate of $Ca(OH)_2$ calculated on P_2O_5* emission standard#	Application rate of $Ca(OH)_2$ calculated on N* emission standard#
		[L animal^{-1} d^{-1}]	*[kg animal^{-1} d^{-1}]*	*[kg animal^{-1} d^{-1}]*	*[kg l^{-1}]*	*[kg l^{-1}]*	*[m^3 ha^{-1}]*	*[m^3 ha^{-1}]*	*[kg ha^{-1}]*	*[kg ha^{-1}]*
Cattle	Dairy Cattle	66	0.10466	0.3389	0.00159	0.00513	53.60	48.69	2144	1947
	Beef cattle	34	0.07123	0.28819	0.00210	0.00848	40.57	29.49	1623	1180
	Veal calves	7	0.01422	0.02382	0.00203	0.00340	41.84	73.47	1674	2939
Pigs	Sows	21	0.05566	0.07106	0.00265	0.00338	32.07	73.88	1283	2955
	Fattening pigs	9	0.02033	0.03043	0.00226	0.00338	37.63	73.94	1505	**2958**
Poultry	Battery[a]	0.11	0.00122	0.00202	0.01109	0.01836	7.66	13.61	307	545
	Battery[b]	0.11	0.00111	0.00181	0.01009	0.01645	8.42	15.19	337	608
	Free range litter laying hens	0.11	0.00111	0.00171	0.01009	0.01555	8.42	16.08	337	643
	Free range litter broiler	0.08	0.00066	0.00156	0.00825	0.0195	10.3	12.8	412	512
	Free range turkeys	0.36	0.0023	0.00482	0.00639	0.01339	13.30	18.67	532	747
	Free range ducks	0.14	0.00164	0.00274	0.01171	0.01957	7.26	12.77	290	511

[a]: no treatment, laying hens [b]: deep pit, laying hens; compact, laying hens; belt drying, laying hens

* Emission standard for P_2O_5 in kg ha^{-1} a^{-1}: = 85 (NL) ** Em. standard for N in kg ha^{-1} a^{-1}: = 250 (based on the emission standard from various EU MS

Source: Adapted from the EU Competent Authority Report Hydrated Lime PT3 (May 2016, UK CA)

Applications would not generally be recommended above 50 m^3 ha^{-1} in order to reduce the risks of runoff and odour problems arising from these levels of application rate. This upper application limit is stated in the CAR and is based on the UK Defra Code of Good Agricultural Practice for farmers, growers and land managers (2009). This equates to a hydrated lime application rate of 2,000 kg ha^{-1} assuming a manure treatment rate of 40 kg hydrated lime m^{-3}. The PT3 assessment report for Hydrated lime ($Ca(OH)2$). states "*assuming incorporation of this applied dose over a 5 cm soil layer, no interception by crop canopy and a dry soil bulk density of 1500 kg m^{-3} the maximum initial pecsoil, local in agricultural soil would be **2667 mg kg^{-1}**. it should be noted that this pec assumes that there is no time lapse between treatment and application to agricultural soil; this clearly represents a worst-case assumption. Based on a revised kinetic assessment, a soil DT50 of 0.742 h was proposed up to a break point of 6 h, and a DT50 of 372 h was proposed for the time period after the break point. Using this value the PECsoil declined to **9.49 mg kg^{-1}** within 1 d (derived as hydrated lime equivalents). The use of a 1 d time period in calculating pecsoil is considered acceptable in this specific case, where much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of lime amended material to agricultural land.*

Derivation of 'degradation' endpoints for $Ca(OH)_2$ –Background information

The following information is adapted from the EU CAR for Calcium dihydroxide (Hydrated lime).

Test of development of pH in different soils

In the first study (Schiffner, 2007a) the pH development of a natural and an artificial soil were investigated. The artificial soil was prepared to mimic the soil used in the standard earthworm effects studies. However, a full textural characterisation of the test soils was not provided. In addition, details of the field sampling location of the natural reference soil were not provided. Hydrated lime was added at concentrations up to 4.44 g kg^{-1} dry soil and the pH was measured for up to 6 weeks.

Upon addition of hydrated lime to the soils, a dose-dependent increase in the pH was observed. The relative increase in pH following addition of the test substance was noted to be marginally higher in the artificial soil system. The soil pH was noted to rise to between 10 and 11 pH units in both soils immediately after addition of the hydrated lime at the highest test concentration (note that initial pH levels in untreated controls were 5.49 pH units for the natural soil and 5.89 pH units for the artificial soil). A decrease in pH of approximately 2 pH units was observed within 72 h following addition. By the end of the 6 week study the pH in the test soils was noted to be elevated above control levels at all concentrations. However, the final pH was within the normal range for typical agricultural soils at all concentrations tested (pH range from 5.88 to 7.95). Summary results are presented in **Table 3.1-7** below.

Table 3.1-7 Average pH values (determined in $CaCl_2$) measured in artificial and natural soils following addition of hydrated lime

Sample	$Ca(OH)_2$ g kg^{-1} DS*	0h	0.5h	1 h	2h	6h	12h	24h	72h	1w	2w	6w
Natural soil	0	5.49	5.53	5.60	5.50	5.42	5.40	5.49	5.47	5.46	5.36	5.33
	0.44	7.52	7.30	6.91	6.97	6.38	6.29	6.41	6.34	6.21	5.98	5.88
	0.89	8.06	7.83	7.59	7.52	7.10	6.86	6.93	6.84	6.76	6.47	6.43
	1.33	8.34	8.17	7.99	7.87	7.49	7.27	7.31	7.19	7.11	6.80	6.81
	2.23	9.08	8.58	8.74	8.49	8.12	7.87	7.81	7.66	7.62	7.44	7.42
	4.44	10.61	10.22	9.94	9.90	9.34	9.01	8.85	8.37	8.15	8.01	7.95
Artificial soil	0	5.89	5.95	5.96	5.97	5.81	5.82	5.85	5.90	5.89	5.90	5.82
	0.44	8.13	7.51	7.08	7.07	6.57	6.45	6.52	6.43	6.33	6.25	6.16
	0.89	8.85	8.26	7.98	7.84	7.23	7.06	7.05	6.85	6.74	6.57	6.46
	1.33	9.09	8.73	8.36	8.13	7.73	7.45	7.44	7.28	7.05	6.91	6.70
	2.23	9.78	9.22	8.87	8.80	8.23	7.96	7.87	7.75	7.56	7.41	7.16
	4.44	10.64	10.27	10.06	9.77	9.16	8.70	8.48	8.14	8.00	7.99	7.91

** Test item/kg soil dry weight*

Adapted from the EU CAR for hydrated lime Document IIIA, Section A7.2.2.4/01

The Applicant estimated DT$_{50}$ and DT$_{90}$ values (in h) by plotting pH versus time for the first 6 h. The Applicant proposed that over this short duration simple first order kinetics could be assumed as a rough approximation. The DT$_{50}$ values estimated by the Applicant ranged from 1.36 to 2.34 h (r^2 range from 0.6952 to 0.9158). The UK CA considered that it was clear from the results that simple first order kinetics did not apply to the pH reduction behaviour in soil over the whole timescale of the experiment (i.e. up to 6 weeks). A form of bi-phasic kinetics may have been more appropriate to describe the long-term behaviour, since the reduction in pH slowed over time. The DT_{50} values proposed by the Applicant should therefore only be considered as a rough approximation of the relatively rapid initial rate of H^+ concentration reduction over the first few h and should not be extrapolated to describe the behaviour over longer timescales. However, based on the graphical plots and r^2 statistics provided the UK CA accepted the short-term DT_{50} values proposed by the Applicant.

In general, in the soils tested the pH fell back to within normal levels (ca. pH 8) within 1 week of application at all concentrations. During the EU commenting round several Member States queried the use of degradation rates derived over short periods (i.e. using only the 6 h data) for extrapolation over the longer time periods being considered in the environmental risk assessment.

The UK CA accepted that the use of the 6 h data alone to define the DT_{50} is not appropriate when this is then extrapolated over longer durations. The UK CA therefore reconsidered the approach to deriving degradation rates from the submitted information. The data is obviously slightly novel in this case, with the pH data representing concentration data on a $\log_{10}$ scale which makes derivation of degradation rates more complex. The raw data all shows a consistent pattern of initial pH shock, followed by a short period of rapid pH decline, followed by a final period of much slower pH decline. The UK CA considered that it would be most appropriate to include consideration of the short fast decline period and the longer term decline as distinct phases. The simplest and most transparent way to implement this type of bi-phasic decline would be to use the hockey stick model – two sequential first order reactions separated by a single break point. The fast phase remains based on the 0-6 h data. This is followed by a single break point, and the slower phase would be based on the data from the remainder of the study i.e. up to 6 weeks. The UK CA considers this approach is consistent with the recommendation of the latest FOCUS degradation kinetics guidance. This approach would also be relatively easy to implement in the exposure assessment. This approach would mean that the fast decline phase is only applied to the timescales supported by the data. The introduction of the slow phase would be sufficient to cover the time period of concern for the exposure assessment. Hence no extrapolation of behaviour over longer periods would be necessary. This was a major concern with the current approach based on the 6 h data only based on the MS comments received. In light of these comments the kinetic assessment of the data has been completely revised.

As highlighted above the raw data in this case is relatively novel and does not allow for a standard kinetic assessment. The original DT_{50} values were based on linear regression of pH data, which itself is effectively H^+ ion concentration data on a $\log_{10}$ scale. Since the use of linear regression of log normalised data is no longer recommended by the FOCUS degradation kinetics guidance, the UK CA reconsidered how best to handle the data to allow for a more modern and compliant assessment. As a first step the UK CA converted the pH values to pOH values based on the following equation:

$$\text{pOH} = \text{pKw} - \text{pH}$$

where pKw is the self-ionisation constant of water, assumed to be approximately 14 at room temperature.

The advantage of this approach is that it allows OH^- concentrations to be estimated from the available pH data, allowing for a more standard form of kinetic assessment, since the OH^- concentrations decline over time (in contrast to the H^+ concentrations that increase over time). The reduction in pH appeared to be slightly faster in the artificial soil compared to the behaviour in the natural soil. For the purposes of conducting a conservative kinetic assessment the UK CA performed the assessment on the natural soil only. Revised values for pOH for the 5 concentrations tested in the natural soil are presented in **Table 3.1-8a** below.

Table 3.1-8a Average pOH-values –natural soil

Time (hours)	$Ca(OH)_2$ g/kg DS				
	0.44	0.89	1.33	2.23	4.44
	pOH				
0	6.48	5.94	5.66	4.92	3.39
0.5	6.7	6.17	5.83	5.42	3.78
1	7.09	6.41	6.01	5.26	4.06
2	7.03	6.48	6.13	5.51	4.1
6	7.62	6.9	6.51	5.88	4.66
12	7.71	7.14	6.73	6.13	4.99
24	7.59	7.07	6.69	6.19	5.15
72	7.66	7.16	6.81	6.34	5.63
168	7.79	7.24	6.89	6.38	5.85
336	8.02	7.53	7.2	6.56	5.99
1008	8.12	7.57	7.19	6.58	6.05

From the pOH values, concentrations of OH^- were derived (where pOH = $-\log_{10} [OH^-]$). These are presented in **Table 3.1-8b** below.

Table 3.1-8b. Average OH^- concentrations

Time (hours)	$Ca(OH)_2$ g/kg DS				
	0.44	0.89	1.33	2.23	4.44
	OH- concentration				
0	3.3E-07	1.1E-06	2.2E-06	1.2E-05	4.1E-04
0.5	2.0E-07	6.8E-07	1.5E-06	3.8E-06	1.7E-04
1	8.1E-08	3.9E-07	9.8E-07	5.5E-06	8.7E-05
2	9.3E-08	3.3E-07	7.4E-07	3.1E-06	7.9E-05
6	2.4E-08	1.3E-07	3.1E-07	1.3E-06	2.2E-05
12	1.9E-08	7.2E-08	1.9E-07	7.4E-07	1.0E-05
24	2.6E-08	8.5E-08	2.0E-07	6.5E-07	7.1E-06
72	2.2E-08	6.9E-08	1.5E-07	4.6E-07	2.3E-06
168	1.6E-08	5.8E-08	1.3E-07	4.2E-07	1.4E-06
336	9.5E-09	3.0E-08	6.3E-08	2.8E-07	1.0E-06
1008	7.6E-09	2.7E-08	6.5E-08	2.6E-07	8.9E-07

In a final step, the OH^- concentrations were normalised based on the day 0 values, setting the day 0 concentrations to 100%, and simply correcting all subsequent time points based on the day 0 value and the individual time point data. This process would not affect the

DT_{50} s derived, however it did allow for easier implementation in standard kinetic fitting software. The normalised OH^- % values are presented in **Table 3.1-8c** below.

Table 3.1-8c. OH^- concentrations normalised to percentage values based on day 0 values

Time (hours)	$Ca(OH)_2$ g/kg DS				
	0.44	**0.89**	**1.33**	**2.23**	**4.44**
	OH- % relative to day zero values				
0	100	100	100	100	100
0.5	60.3	58.9	67.6	31.6	40.7
1	24.5	33.9	44.7	45.7	21.4
2	28.2	28.8	33.9	25.7	19.5
6	7.2	11.0	14.1	11.0	5.4
12	5.89	6.31	8.51	6.17	2.51
24	7.76	7.41	9.33	5.37	1.74
72	6.61	6.03	7.08	3.80	0.58
168	4.90	5.01	5.89	3.47	0.35
336	2.88	2.57	2.88	2.29	0.25
1008	2.29	2.34	2.95	2.19	0.22

The normalised data were used in revised kinetic fitting performed by the UK CA using the CAKE v3.1 software. Sequential fitting was performed, firstly for the % data from 0 to 6 hours (i.e. up to the 6 hour break point of the hockey stick kinetic), then from 6 hours to 6 weeks (1008 hours). Fitting was performed using the iteratively reweighted least squares optimiser. Results are summarised in Table 4.1d.

For the data up to the 6 h time point, the geometric mean DT50 across the 5 concentrations tested was 0.742 h. Fits were generally good statistically (chi^2 and t-tests) and visually (classical and residual plots). As an example, the classical graphical fit for the 0.44 g/kg concentration is presented in **Figure 3.1-1a**

For the data from the 6 h time point to study end (i.e. post break point), the geometric mean DT_{50} across the 5 concentrations tested was 224 h. Since the DT_{50} value for the highest concentration tested appeared to be an outlier (significantly lower than the other 4 concentrations tested) this value was excluded in the calculation of a revised conservative geometric mean of **372 h** (15.5 days, n = 4). Fits were generally good statistically (chi^2 and t-tests) and visually (classical and residual plots). As a further example, the classical graphical fit for the 0.44 g/kg concentration is presented in **Figure 3.1-1b**.

Overall the UK CA considered the revised kinetic assessment resulted in acceptable values to be used in an updated environmental exposure assessment. A DT_{50} of 0.742 h is proposed up to a break point of 6 h, and a DT_{50} of 372 h is proposed for the time period after the break point.

Table 3.1-8d. Summary of revised kinetic fitting using CAKE 3.1

Parameter	$Ca(OH)_2$ g/kg DS				
	0.44	**0.89**	**1.33**	**2.23**	**4.44**
	Values derived based on 0 to 6 h data (up to break point of hockey stick kinetic)				
DT50 (hours)	0.697	0.817	1.14	0.747	0.464
Chi^2	16.4	13.7	10.8	27.4	15.9
Prob > t	<0.05	<0.05	<0.05	0.09	<0.05
Visual fit	good	good	good	acceptable	good
	Values derived based on 0 to 6 h data (up to break point of hockey stick kinetic)				
DT50 (hours)	409	384	300	405	29.7
Chi^2	13.6	12.7	14	16.9	15.7
Prob > t	<0.05	<0.05	<0.05	<0.05	<0.05
Visual fit	good	good	good	good	good

Observations and Fitted Model:

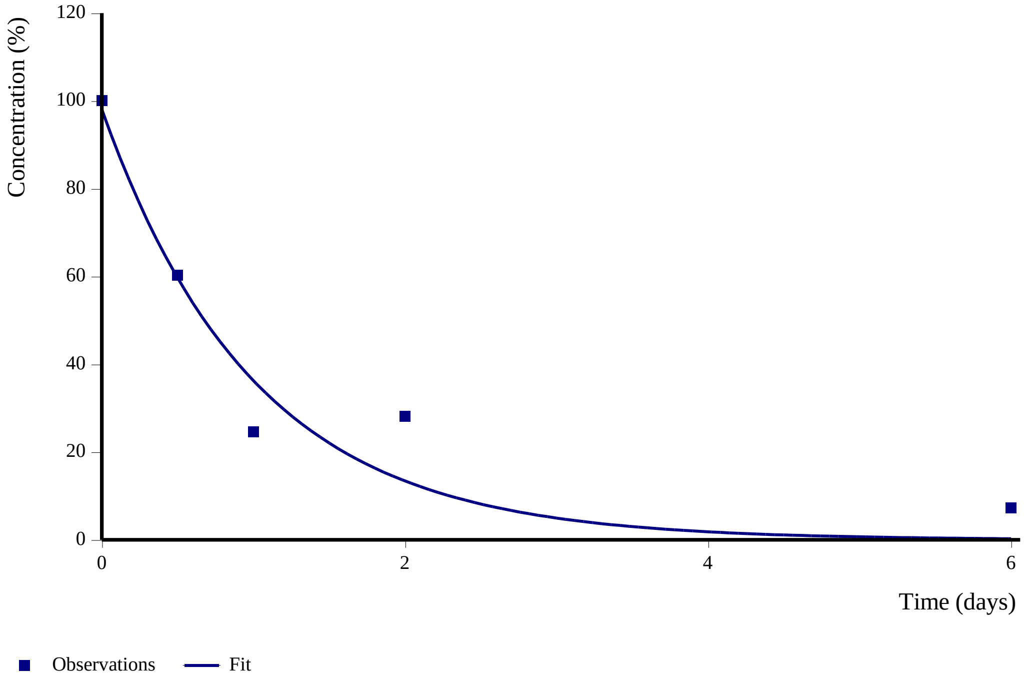

Figure 3.1-1a. Graphical presentation of fitting to OH^- concentration data (0-6 h) for the 0.44 g/kg concentration [DT_{50} = 0.697 h. chi^2 = 16.4%] [note scale is actually hours]

Graphical Summary:

Observations and Fitted Model:

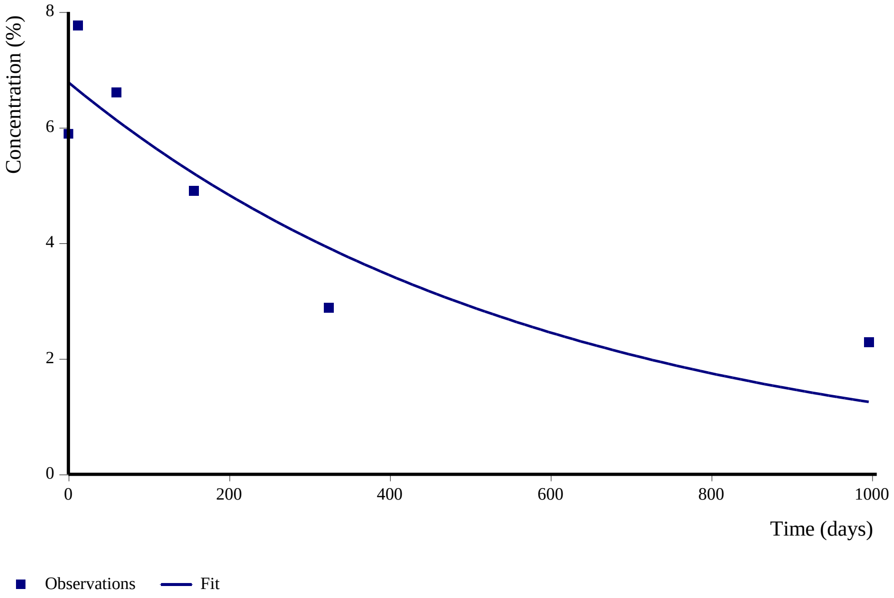

Figure 3.1-1b. Graphical presentation of fitting to OH^- concentration data (6 h to 6 week data) for the 0.44 g/kg concentration [DT_{50} = 409 h, chi^2 = 13.6%] [note scale is actually hours]

Conclusion

Although the study was not conducted to an agreed protocol (since none exists that would fully encompass the intended design of the study) nor to GLP, the UK CA considers that the study was sufficiently robust to be used for the purposes of risk assessment. The UK CA accepted the study because although it was not conducted in accordance with any agreed protocol, we did not consider that any agreed protocol existed that encompassed the intended design of the study (i.e. to test the pH change of a natural and artificial soil over time). The study was very simple and there were no major reporting or methodological deficiencies that affected the quality of the results. The study could have been conducted to GLP, and could have tested a wider range of better characterised natural soils. Minimal analysis of the natural soil used was reported. In addition, a single natural soil with a relatively low pH of 5.4 units was tested. It was not therefore possible for the UK CA to comment on the applicability of the results from this single soil to other areas of the EU. However, in order to avoid the potential raising of soil pH above acceptable levels the UK CA considers it unlikely that lime amended manure or sewage sludge would be applied to neutral or alkaline soils as part of normal good agricultural practice.

The UK CA considers that results for this single soil are therefore likely to be at least indicative of the likely behaviour in terms of temporal pH change in other areas of the EU. The pH of the soils tested would also be expected to be reasonably representative of the soils that would be most likely to receive the highest application rates of lime from a soil improvement perspective.

Overall the CA for the EU active substance considered the revised kinetic assessment to be acceptable for use in an updated environmental exposure assessment. A DT_{50} of 0.742 h is proposed up to a break point of 6 h, and a DT_{50} of 372 h is proposed for the time period after the break point

2.2. ENVIRONMENTAL EXPOSURE ASSESSMENT-***IRISH SPECIFIC DATA***

Depending on the nitrogen immision standard (170 kg N/ha /250 kg N/ha) and Irish specific data, the maximum back calculated application rate to grassland from a lumped application of slurry containing $Ca(OH)_2$ from the proposed use of the product (1 app/d in cattle housing) is 8.16/11.99 g a.s./ha respectively (Tier 1).

Table 2.2-1: eCA Tier 1 Back calculated application rates arising from manure application (containing Calcium dihydroxide residues from animal housing disinfection, 1 kg a.s/m^2) to agricultural land (grassland, 5 cm)-Irish specific data*

Animal Category	**App rate $Ca(OH)_2$ (t/ha) for 170kg N/ha**	**App rate $Ca(OH)_2$ (t/ha) for 250 kg N/ha**
Tier 1: 1 application of $Ca(OH)_2$ per day		
Dairy cow	8.16	11.99
Beef cattle	2.83	4.15
Veal cattle	5.17	7.60
Tier 2: Allowing for buffering capacity (lumped application of manure to grassland)#		
Dairy cow	0.05-0.13	0.078-0.19
Beef cattle	0.02-0.04	0.027-0.07
Veal cattle	0.03-0.08	0.049-0.12

Tier 1 application rates with a 1 d interval are independent of storage time.

Calculations assume the formulation is 100 % active substance.

PECs depend on the duration of the storage period (-dilution effect)

* The eCA notes the estimated (max) PEC with the EU defaults is conservative from an Irish perspective as lower PECs are predicted when using Irish specific data. For the average amounts of manure, liquid wastes (waste water), slurry and phosphate produced per animal per day, the ESD for PT3 uses data from Montforts (1999) and Montfoort et al. (1996) in combination with data from Van Eerdt (1998). The ESD acknowledges these values can be replaced when specific data is available. Data is available for Ireland (Teagasc/ S.I. No. 605/2017). This data is considered more appropriate for Irish risk assessment purposes when considering risk mitigation measures. The PEC calculations presented above also take into account the manure storage periods relevant for Ireland.

Incorporating buffering capacity in Tier 2 simulations reduces the application rate to << 5.6 tonnes a.s./ha $Ca(OH)_2$. This is below levels associated with agricultural liming in Ireland (7.5 tonnes $CaCO_3$/ha which is equivalent to 5.55 tonnes $Ca(OH)_2$/ha.

In *some* scenarios such as dairy farms with a 250 kg N/ha derogation the level of calcium carbonate (a form of lime) added to grassland from slurry application containing spent lime residue may exceed natural liming limits. This is reduced to an acceptable level with a 2 d interval between biocide applications is implemented.

Predicted calcium carbonate loading to grassland from $Ca(OH)_2$ applications (Back calculated application rate)

Animal Category	**Calcium carbonate** **App rate (tonnes /ha) for 170kg N/ha#**	**Calcium carbonate** **App rate (tonnes /ha) for 250 kg N/ha#**
Tier 1: 1 application of $Ca(OH)_2$ per day		
Dairy cow	6.93	10.19
Beef cattle	2.40	3.53
Veal cattle	4.396	6.46
Tier 2: 1 application of $Ca(OH)_2$ every second day		
Dairy cow	3.47	5.09

Notes

Calculations are for the 85 % calcium carbonate product (1 kg product/m^2, worse case scenario from a calcium carbonate perspective). The calculations assume there is accumulation of calcium carbonate between successive biocide applications in the manure storage facility as calcium carbonate has poor soluibity and lower reactivity relative to the active substance. In addition calcium carbonate is reported to be an inert filler and no data is presented in the CAR regarding its reactivity with organic matter.

The PECs are conservative as the Fslurry/manure is likely to be 0.9 rather 1 for $CaCO_3$. This has a negligible impact on the PEC estimates. The additional contribution from the active substance to the total lime loading is considered negligible.

New information on the active substance

ISO 17091:2013: Workplace air — Determination of lithium hydroxide, sodium hydroxide, potassium hydroxide and calcium dihydroxide — Method by measurement of corresponding cations by suppressed ion chromatography

Residue behaviour

NOT APPLICABLE

Summaries of the efficacy studies (B.5.10.1-xx)[12]

Please see the efficacy section for this information

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[12] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

Confidential annex

Other