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

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

(submitted by the evaluating Competent Authority)



NEUTRALAC® SL25

Product type 2

Calcium dihydroxide

Case Number in R4BP: BC-KK038992-25

Evaluating Competent Authority: FR

Date: [16 February 2021]

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# CONCLUSION

The biocidal product NEUTRALAC® SL 25 based of 25% of calcium dihydroxide, is an aqueous suspension type 2 biocidal product aimed to be used for the disinfection of sewer treatment plants sludges by professional users.

**Physico chemical properties and analytical methods**

The biocidal product is a ready to use aqueous suspensions of calcium dihydroxide. The appearance is an off white to beige suspension. The pH of the products is around 12. Non GLP data (viscosity, appearance, flowability, wet sieve test) following one month storage in PET packaging have been provided.

A deposit can be observed before and after storage due to the low solubility and suspensibility of Lime in aqueous solution, consequently, FR CA recommends an agitation before application and the product should be kept under continuous agitation during the application.

Additionally, concern related to pourability of the products can be raised due to the significant volume of deposit and low solubility of Lime in aqueous solution. According to this statement, FR CA recommends to rinse the commercial packaging several time after use to remove the deposit. Moreover, FR CA recommends to use these packagings only with Milk of Lime or related Lime products.

Additionally, the product should be protected from frost and they should not be stored at a temperature higher than 30°C, kept tightly closed in original packaging and away from acids.

The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties and it is not classified corrosive to metals.

The analytical methods for the active substance are applicable to the product. Since methods proposed are based on international standards and mainly based on ICP/AAS detectors, no further validation data are necessary.

**Efficacy**

 The product NEUTRALAC® SL25 has shown a sufficient efficacy:

- For the disinfection of sewage sludge, against bacteria, yeast, fungi, virus and nematode eggs.

The effective final use concentration of the product and contact time are variable.

pH should be > 12 during the exposure time.

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

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

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

**Resistance:**

Literature searches have not revealed indication of resistance to lime.

**Risk for consumers via residues in food**

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

**Risk for human health**

The risk is acceptable for professional users considering the following RMM:

For Mixing and loading:

* Minimisation of splash and spills,
* Avoid contact with contaminated tools and objects
* Wear appropriate gloves, protection coverall and goggles during loading of the product

During the manipulation of treated sewage sludge:

* Wear protective gloves and protection coverall during the manipulation of treated sewage sludge.
* During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the PEL of 14 mg/m3 for this gas. During the cleaning step, we consider the concentration of Ammonia to be below than the one during the application step. Therefore, the wear of an APF40 at minima is considered conservative enough during the cleaning of the equipment.

During cleaning of the equipment:

* Wear appropriate gloves, protection coverall and goggles during cleaning of equipment
* Wear respiratory mask adapted to reduce the exposure to dust (AFP 40 at minima) and ammoniac release.

**Risk for environment**

Acceptable risks for the environment are foreseen for the intended uses.

As indicated in the CAR of the active substances, the use should respect the following RMM:

“Before each application of lime-treated material, soil analysis conducted in accordance with good agricultural practices should be carried out to ensure that it will not lead to unacceptable long term pH changes in soil.”

# Authorized uses for NEUTRALAC® SL 25:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organism**  | **Application rate validated**  | **Field of use**  | **Primary packaging : type : bulk, individual wrapping** |
| Professionals  | Bacteria, yeasts, fungi, viruses, nematode eggs | The dose must be high enough to achieve a pH of > 12 during the exposure time needed.Contact time: 1 to 24 hours.Several weeks for nematodes | IndoorOutdoor | IBC made of HDPE (1m3) equipped with an electrical stirrer or with a recirculating pump.Container made of stainless steel up to 25 t equipped with an electrical stirrer (IDRA container). |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| NEUTRALAC® SL25 |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Chaux de la Tour |
| **Address** | 1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France |
| **Authorisation number** | FR-2021-0006 |
| **Date of the authorisation** | 16/02/2021 |
| **Expiry date of the authorisation** | 15/02/2031 |

#### Manufacturer(s) of the products

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

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

|  |  |
| --- | --- |
| **Active substance** | Calcium dihydroxide |
| **Name of manufacturer** | Chaux de la Tour |
| **Address of manufacturer** | 1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France |
| **Location of manufacturing sites** | 1 chemin des Chaux de la Tour, 13 820 Ensues La Redonne, France  |

### Product composition and formulation

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

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 [x]

#### 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 expressed as Ca(OH)2)  |
| **Structural formula** | Ca(OH)2 |

#### Candidate(s) for substitution

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

#### Information on the substance(s) of concern

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

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (technical) (%)** |
| --- | --- | --- | --- | --- | --- |
| Calcium dihydroxide | Calciumdihydroxide | Active substance | 1305-62-0 | 215-137-3 | 25.0 |

#### Information on technical equivalence

Not applicable. The active substance is supplied from approved supplied sources evaluated as part of the EU reference source specifications.

#### Information on the substance(s) of concern

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

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

No endocrine disruption properties have been identified in the assessment report of Calcium dihydroxide

There is no indication of concern regarding the ED properties of any of the co-formulants contained in the product NEUTRALAC® SL25, hence the product is not considered as an endocrine disruptor.

Please refer to Confidential Annex of the PAR.

#### Type of formulation

|  |
| --- |
| SD: Suspension concentrate for direct application(concentrated suspension of calcium dihydroxide - ready to use) |

### Hazard and precautionary statements[[2]](#footnote-3)

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

| **Classification** |
| --- |
| Hazard category | Skin irritation, category 2Eye damage, category 1STOT SE 3 |
| Hazard statement | H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation |
|  |
| **Labelling** |
| Signal words | Danger |
| Hazard statements | H315: Causes skin irritationH318: Causes serious eye damageH335: May cause respiratory irritation |
| Precautionary statements | P302+P352 IF ON SKIN: Wash with plenty of soap and water.P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTRE or doctor/physician. P261: Avoid breathing dust/fume/gas/mist/vapours/spray.P264: Wash … thoroughly after handling.P271: Use only outdoors or in a well-ventilated area.P280: Wear protective gloves/protective clothing/eye protection/face protection. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.P312: Call a POISON CENTRE/doctor/…if you feel unwell.P321: Specific treatment (see … on this label).P332+P313: If skin irritation occurs: Get medical advice/attention.P362+P364: Take off contaminated clothing and wash it before reuse.P403+P233: Store in a well-ventilated place. Keep container tightly closed.P405: Store locked up.P501: Dispose of contents/container in accordance with national regulation. |
|  |
| Note |  |

### Authorised use(s)

#### Use description

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

|  |  |
| --- | --- |
| **Product Type** | TP2 |
| **Where relevant, an exact description of the authorised use** | The product is dosed into the sewage sludge and mixed by means of a blender. The treated sludge may have three destinations - agricultural use, incineration or landfill. |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses, nematode eggs. |
| **Field of use** | IndoorOutdoor |
| **Application method(s)** | Automatic or semi-automatic direct application |
| **Application rate(s) and frequency** | The product is mixed with the sewage sludge in an open mixer. The product can be loadedusing semi- or fully automated processes.Contact time: 1 to 24 hrs for bacteria, yeast, fungi and viruses, to several weeks for nematodes eggs  |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | IBC made of HDPE (1 m3) equipped with an electrical stirrer or with a recirculating pump.Container made of stainless steel up to 25 t equipped with an electrical stirrer (IDRA container). |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * The dose must be high enough to achieve a pH of > 12 during the exposure time needed.
* Application rate recommended:

Apply at 0.7 litres – 6.9 litres of product containing 25% w/w Ca(OH)2 per m3 of sludge (0.8 kg - 8 kg of product containing 25% w/w Ca(OH)2 per kg of dry weight sludge).* The application dose should be set to achieve a rate of 20 - 50% of the dry solids weight of sludge.
* The rate may vary between applications. The user should ensure efficacy of the treatment with laboratory trials.
* Comply with the instructions for use.
* Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder.
* The product is used as provided.
* Application is semi-automated.
* The products should be agitated before application and should be kept under continuous agitation in order to avoid deposits during the application.
* Rinsed several times the commercial packaging with water after use.

Used commercial packaging for milk of lime or related Lime product only. |

#### Risk mitigation measures

|  |
| --- |
| * For Mixing and loading :
	+ Minimisation of splash and spills,
	+ Avoid contact with contaminated tools and objects
	+ Wear appropriate gloves, protection coverall and goggles during loading of the product
* During the manipulation of treated sewage sludge:
	+ Wear protective gloves and protection coverall during the manipulation of treated sewage sludge.
	+ During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the PEL of 14 mg/m3 for this gas. During the cleaning step, we consider the concentration of Ammonia to be below than the one during the application step. Therefore, the wear of an APF40 at minima is considered conservative enough during the cleaning of the equipment.
* During cleaning of the equipment:
	+ Wear appropriate gloves, protection coverall and goggles during cleaning of equipment
	+ Wear respiratory mask adapted to reduce the exposure to dust (AFP 40 at minima) and ammoniac release.
 |

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

|  |
| --- |
| * Impaired consciousness: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.
* Keep the container or label available.
* Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
* Mouth contact/Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.
* Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur.
* Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
 |

#### Instructions for safe disposal of the product and its packaging

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

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

|  |
| --- |
| * Shelf life:1 month.
* Protect from frost.
* Do not store at a temperature higher than 30°C.
* Keep away from acids.
 |

### Other information

|  |
| --- |
| - |

### 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)** |
| IBC tanker equipped with an electrical stirrer or with a recirculating pump. | 1 m3 | HDPE | Closed | Trained professional, professional | Y |
| Container equipped with an electrical stirrer (IDRA container). | Up to 25 t | Stainless steel | Closed | Trained professional, professional | Y |

### Documentation

#### Data submitted in relation to product application

See Annex 3.1

#### Access to documentation

EuLA consortium is the applicant supporting the approval of the active substance calcium dihydroxide at European level. A letter of access to the active substance dossier is not necessary as Chaux de la Tour is part of EuLA consortium.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – Disinfection of sewage sludge

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | The product is dosed into the sewage sludge and mixed by means of a blender. The treated sludge may have three destinations - agricultural use, incineration or landfill. |
| Target organism (including development stage) | Bacteria, yeasts, fungi, viruses, nematode eggs |
| Field of use | Indoor, outdoor |
| Application method(s) | Direct application |
| Application rate(s) and frequency | The product is mixed with the sewage sludge in a open mixer. The product is loaded via a pipe.Apply at 0.7 litres – 6.9 litres of product containing 25% w/w Ca(OH)2 per m3 of sludge (0.8 kg - 8 kg of product containing 25% w/w Ca(OH)2 per kg of dry weight of sludge).The application dose should be set to achieve a rate of 20 - 50% of the dry solids weight of sludge, and must be high enough to achieve a pH of > 12 for a minimum of 3 hours. Note; the rate may vary between applications, and is determined after laboratory trials. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | IBC made of HDPE (1 m3) equipped with an electrical stirrer or with a recirculating pump.Container made of stainless steel up to 25 t equipped with an electrical stirrer (IDRA container). |

###

### Physical, chemical and technical properties

The product is ready to use. It is aqueous suspension of calcium dihydroxide and it is applied semi-automatically. Some data have been provided for NEUTRALAC® SL 30 which is similar to NEUTRALAC® SL 25 (only active substance content in the biocidal products is changing, from 25 to 30% w/w). Extrapolation is acceptable.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **GLP** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | / | Not available | Liquid, suspension of calcium dihydroxide in water |  SDS “Mixture of calcium dihydroxide with water” | / | Acceptable  |
| Colour at 20 °C and 101.3 kPa | / | Not available | White to beige | SDS “Mixture of calcium dihydroxide with water” | / | Acceptable |
| Odour at 20 °C and 101.3 kPa | / | Not available | No odour | SDS “Mixture of calcium dihydroxide with water” | / | Acceptable |
| Acidity / alkalinity | CIPAC MT31 | Not availableCa. 98% w/w | The pH of the product in suspension is the pH of a saturated solution of calcium di-hydroxide: 12.4.pH of aqueous solution saturated at 25°C: 12.40.24 – 0.26 % m/m as NaOH0.07 for the product | SDS NEUTRALAC® SL 25Merck IndexCAR and statement | N/ | No tests have been provided for pH and alkalinity. Only data based on the SDS/label are available. In the CAR, there are no products similar to milk of lime, so no extrapolation is possible. Data from SDS and literature have been considered sufficient. |
| Relative density / bulk density | / | Not available | Density: 1.06-1.38g/cm3 at 20°C1.16 g/cm3 fo NEUTRALAC® SL25 | SDS NEUTRALAC® SL 25 and Statement | / | Results provided by the applicant are only based on SDS/label or statement. Even if a test according to standard method should have been provided, FR CA considers that data are sufficient considering the kind of active substance and the composition of the product. |
| Storage stability test – **accelerated storage** | waiver |  | Supsension of calcium dihydroxide are settling and must be stirred before use.After 3 months in an IBC, or a tank, it is difficult to empty the product.If the product is stored, for more than two days, under stirring in contact with air; the calcium dihydroxide can react with the CO2 of the air and form calcium carbonate, so the purity of the active substance will decrease. |  |  | Data from the CAR are not suitable for Milk of Lime. Only a statement from the applicant has been provided.A storage stability study including appearance, technical properties (pH, alkalinity, wet sieve test, pourability), stability of packaging (including physical compatibility with stainless and HDPE) is missing. Since no study is available, FR CA recommends to store the product below 30°C. |
| Storage stability test – **long term storage at ambient temperature** | not reported  | NEUTRALAC® SL 30 | Suspension of calcium dihydroxide are settling and must be stirred before use.After 3 months in an IBC, or a tank, it is difficult to empty the product.If the product is stored, for more than two days, under stirring in contact with air; the calcium dihydroxide can react with the CO2 of the air and form calcium carbonate, so the purity of the active substance will decrease.An assessment of the stability of NEUTRALAC® SL 30 (similar composition at 30% of calcium hydroxide instead of 25%) following 1 month in PET bottle at 20°C has been performed.After 5 inversions, the product flows easily. A slight deposit is generally observed but resuspension is found acceptable. In one case, a deposit of 20% is noticed.Wet sieve test before and after 28 day: 1.3-1.5% on a 90µm sieve and no residue on a 600µm sieve.A graph of settling vs. time has also been submitted and shows that a deposit up to 25% can be reached. A graph of the viscosity of the product with time has been provided. Viscosity remains stable upon storage.Based on tests and knowledge, suspensions of calcium dihydroxide can be stored for one month, and resuspended for use. | AS dossier: Doc. No.: 245-001; CB3.7/01Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | Data from the CAR are not suitable for Milk of Lime. Qualitative data on product similar to NEUTRALAC SL 25 has been submitted (viscosity, settling, appearance, resuspension, flowability, wet sieve test). Even if the study report is not performed under GLP and the methods used are not clearly reported, the results show that a deposit is generally observed following storage.The results confirm that the product should be shake before application and should be kept under continuous agitation during the application, in order to avoid deposit in the bottom. Only pH is missing after storage. However, due to the type of product, it can be assumed that pH will remain around 12 even after one month.Concerns related to pourability of the products can be raised due to the significant volume of deposit and low solubility of Lime in aqueous solution. The applicant states that it can be difficult to empty the product packaging after use. According to this statement, FR CA recommends to rinse the commercial packaging several time after use to remove the deposit. Moreover, FR CA recommends to use these packagings only with Milk of Lime or related Lime products.With the available data, FR CA considers that the product is stable up to 1 month at ambient temperature.  |
| Storage stability test – **low temperature stability test for liquids** |  |  |  |  |  | As the product is a liquid, it should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | No reaction of light on the product.Storage temperature over 30°C, can evaporate the water and concentrate the suspended calcium dihydroxide.After 3 months in an IBC, or a tank, it is difficult to empty the product.If the product is stored, for more than two days, under stirring in contact with air; the calcium dihydroxide can react with the CO2 of the air and form calcium carbonate, so the purity of the active substance will decrease.No corrosivity to steel has been observed. |  |  | Active substance is not light sensitive. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waiver |  | Suspension of calcium dihydroxide are settling and must be stirred before use.After 3 months in an IBC, or a tank, it is difficult to empty the product.If the product is stored, for more than two days, under stirring in contact with air; the calcium dihydroxide can react with the CO2 of the air and form calcium carbonate, so the purity of the active substance will decrease. |  |  | The product should be protected from frost and kept under 30°C. Considering the low solubility and suspenbility of Lime in water, FR CA recommends an agitation before application and a continuous agitation during application. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Waiver | NEUTRALAC® SL30 | 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 limeand 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 forbulk transportation of wet lime products. A test on corrosion has also been performed to demonstrate that hydrated lime is not classified according to CLP regulation:Test specimens (1020 carbon steel, 7075 aluminium) were accurately weighed and then exposed to a 30% aqueous solution of hydrated lime. Different conditions were tested for each material: one specimen in the vapour space, one at the liquid/vapour interface (partial immersion), one in the solution near the top of the liquid phase and one in the settled suspension near the bottom of the liquid phase. Each specimen was exposed in a separate test vessel using 1200mL of test solution. The assembled test vessels were placed in a heated bath and the solution temperature was maintained for 7 days at 55°C. After 7 days, the specimens were removed, cleaned, rinsed and warm air-dried. The procedure complies with the one described in UN Manual of tests and criteria Section 37.Results:The corrosion rates of the exposed specimens were calculated based on mass loss measurements. In all case and for both material (stainless and aluminium), the corrosion rates were below 1mm/year (maximum noticed: 0.72mm/year for aluminium half immersed). Consequently, the corrosion rates are below the threshold limit of 6.25mm/year, meaning that the aqueous solution of hydrated lime (30%) is not corrosive. An additional report has been provided demonstrating that solutions at 40% are not corrosive to metals (steel and aluminium) following 60 days at 55°C (corrosion rate below 6.25mm/y).  | StatementCTL REF 29392-1R, 2012&BAM evaluation metal corrosivity of Milk of Lime 11 Jan 2000 | /Not precised | For metal packaging, the applicant has submitted a corrosion study. The results demonstrate that an aqueous solution of 30% and 40% w/w hydrated lime is not corrosive to stainless and aluminium. FR CA considers that the method is identical to the one described in Manuel RTDG (test C1). Consequently, as the biocidal product is not classified as corrosive to stainless steel, FR CA considers that the product is compatible with stainless steel packaging. |
| Wettability | Waiver |  | The test is not appropriate for the use of lime products diluted in water for paints for walls. |  |  | Not relevant  |
| Suspensibility, spontaneity and dispersion stability | Waiver |  | The test is not appropriate for suspension of calcium dihydroxide in water. Milk of lime can also be diluted to a defined concentration in a holding tank, if necessary for application. In pH controlled systems, milk of lime can be dosed directly from the mixing vessel. The mixing vessel is equipped with a plastic coated agitator. For use, the application solution is pumped from the bottom of the mixing vessel (ca. 20 cm above ground) to the dosing equipment. The described equipment has been designed taking into account the specific properties of the Hydrated lime products. The product does not dissolve in water and will require agitation to remain in suspension. The standard tests for wettability/ suspensibility are therefore scientifically unnecessary. |  |  | Due to the low solubility of lime, the products should be kept under continuous agitation during application. Suspensibility is not relevant for this kind of product since the active part is related to pH. |
| Wet sieve analysis and dry sieve test | EN 12518 (wet sieving) | NEUTRALAC® SL30 | Milk of Lime meets the criteria of the wet sieving described in the standard EN 12518: w% refusal at 90µm < 5.5, and at 600µm < 0.1. | Wet sieving : UUID :f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | Acceptable. |
| Emulsifiability, re-emulsifiability and emulsion stability | Waiver |  | The test is not appropriate for the use of lime products diluted in water for paints for walls. |  |  | Not relevant  |
| Disintegration time |  |  | Not applicable |  |  | Not relevant  |
| Particle size distribution, content of dust/fines, attrition, friability | EN 12485 (laser diffraction) | NEUTRALAC® SL30 | Laser diffraction

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| --- | --- |
| Particle diameter (µm) | Cumulative % passing |
| 1 | 16.0 |
| 2 | 31.1 |
| 5 | 52.1 |
| 10 | 66.9 |
| 20 | 78.3 |
| 32 | 84.0 |
| 40 | 87.3 |
| 45 | 89.0 |
| 50 | 90.6 |
| 63 | 94.3 |
| 80 | 97.4 |
| 90 | 98.4 |
| 125 | 99.8 |
| 160 | 100.0 |
| 200 | 100.0 |

 | Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | Acceptable.  |
| Persistent foaming | Waiver |  |  |  |  | Not relevant as the product is a ready to use formulation. Additionally, there is no surfactant in the biocidal product. No foam is expected to be formed. |
| Flowability/Pourability/Dustability | not reported | NEUTRALAC® SL30 | An assessment of the stability of the similar product NEUTRALAC® SL 30 following 1 month in PET bottle at 20°C has been performed.After 5 inversions, the product flows easily. A slight deposit is generally observed but suspensibility is found acceptable. In one case, a deposit of 20% is noticed. | Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | A qualitative assessment has been provided. Even if the test has not been performed according to a standard method, data are considered sufficient.The results confirm that the product should be shacked before the application and should be kept under continuous agitation during the application, in order to avoid deposit in the bottom. Additionally, concern related to pourability of the products can be raised due to the significant volume of deposit and low solubility and suspensibility of Lime in aqueous solution. According to this statement, FR CA recommends to rinsed the commercial packaging several time after use to remove the deposit. Moreover, FR CA recommends to use these packagings only with Milk of Lime or related Lime products. |
| Burning rate — smoke generators | Waiver |  |  |  |  | Not relevant  |
| Burning completeness — smoke generators | Waiver |  |  |  |  | Not relevant  |
| Composition of smoke — smoke generators | Waiver |  |  |  |  | Not relevant  |
| Spraying pattern — aerosols | Waiver |  |  |  |  | Not relevant |
| Physical compatibility | Waiver |  | According to long-time experience, suspension of calcium dihydroxide can be stored without any problems in tanks, IBC made of steel, PE and or HDPE containers. |  |  | Compatibility with stainless and PET has been demonstrated. Since the products are water based formulation, compatibility with HDPE is acceptable. |
| Chemical compatibility | Waiver |  | Keep away from acids and nitro compounds.Aluminium should not be used for transport and storage. |  |  | Acceptable due to the type of active substance. Reaction with acid may be exothermic. Reaction of calcium dihydroxide with water is not exothermic (in contradiction of CaO with water). According to the SDS, aluminium should be avoided, due to the formation of Ca(Al(OH)4)2 and dihydrogen, when mixed with water and calcium dihydroxide. However, this is not confirmed with the corrosion test, since aluminium has been regarded as stable. Such recommendation is therefore from the responsibility of the applicant. |
| Degree of dissolution and dilution stability | Waiver |  | As the product does not dissolve the powder will eventually settle out of solution. To retain the slurry, the mixture must be agitated. It is therefore scientifically unecessary to perform the study as the product will not dissolve in the water.  |  |  | As a deposit can be observed after storage and due to low solubility of Lime in aqueous solution, FR CA recommends an agitation before application and the product should be kept under continuous agitation during the application. |
| Surface tension | Waiver |  | Surface tension: 72.5 mN/m for a 90% saturated solution of CA(OH)2 (98.2%w/w) | CAR | Y (CAR) | Acceptable.The test from the CAR is reliable and covers this point.  |
| Viscosity | Waiver |  | Below 350 mPa.s for the 25% concentration. | Statement and Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb | / | Values on viscosity have been provided by the applicant. Even if a test according to standard method should have been provided, data are considered sufficient and acceptable. |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The biocidal product is a ready to use aqueous suspension of calcium dihydroxide. The appearance is an off white to beige suspension. The pH of the products is 12.4. Non GLP data (viscosity, appearance, flowability, wet sieve test) following one month storage in PET packaging has been provided, therefore the shelf life of the product is set to 1 month. A deposit can be observed before and after storage due to the low solubility and suspensibility of Lime in aqueous solution, consequently, FR CA recommends an agitation before application and the product should be kept under continuous agitation during the application.Additionally, concern related to pourability of the products can be raised due to the significant volume of deposit and low solubility of Lime in aqueous solution. According to this statement, FR CA recommends to rinse the commercial packaging several time after use to remove the deposit. Moreover, FR CA recommends to use these packagings only with Milk of Lime or related Lime products.**Shelf life:** 1 month**Labelling:**Protect from frost.Do not store at a temperature higher than 30°C.Keep away from acids.Dispose the packaging and any other waste in an appropriate collection circuit.Rinsed several times commercial packaging with water after use.Used commercial packaging for Milk of Lime or related Lime product only.The product should be agitated before application and should be kept under continuous agitation during the application. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **GLP** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | Waiver |  | Not explosive |  |  | The active substance is not classified, neither the formulants. The product is not explosive. |
| Flammable gases | Waiver |  |  |  |  | Not applicable. |
| Flammable aerosols | Waiver |  |  |  |  | Not applicable. |
| Oxidising gases | Waiver |  |  |  |  | Not applicable. |
| Gases under pressure | Waiver |  |  |  |  | Not applicable. |
| Flammable liquids | Waiver |  | In Ca(OH)2, Calcium and Oxygen are in their respective preferred oxidation state. Consequently, flammability can be excluded. |  |  | The active substance is not classified flammable, neither the formulants. The product is not flammable.According to the SDS, products are also not classified flammable according to EU A10 test. |
| Flammable solids | Waiver |  |  |  |  | Not relevant  |
| Self-reactive substances and mixtures | Waiver |  | 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 |  |  | Acceptable. The active substance is not classified, neither the formulants. The product is not self reactive |
| Pyrophoric liquids | Waiver |  | In Ca(OH)2, Calcium and Oxygen are in their respective preferred oxidation state.The active substance and hence the products are not pyrophoric. |  |  | Acceptable. The active substance is not classified, neither the formulants. .  |
| Pyrophoric solids | Waiver |  |  |  |  | Not relevant  |
| Self-heating substances and mixtures | Waiver |  | The active substance and hence the products will react exothermically with water. |  |  | Acceptable. The active substance is not known to be self heating, neither the formulants.  |
| Substances and mixtures which in contact with water emit flammable gases | Waiver |  | In contact with water, the active substance and hence the products will not emit flammable gases |  |  | The product is already an aqueous formulation. Calcium oxide reacts with water to form calcium hydroxide. This reaction is exothermic. However calcium hydroxide in water will only increase alkalinity of the solution, since Ca2+ and OH- are formed. Consequently, for calcium hydroxide, data are not relevant.  |
| Oxidising liquids | Waiver |  | Not oxidising |  |  | Acceptable. The active substance is not classified, neither the formulant.  |
| Oxidising solids | Waiver |  | Not applicable |  |  | Not relevant  |
| Organic peroxides | Waiver |  | Not applicable |  |  | Not relevant. |
| Corrosive to metals | Waiver |  | Experience indicates thatpaper bags lined with plastic (to prevent contact with moisture), plastic bags,steel, stainless steel andAluminium do not reactsignificantly 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, whereasAluminium is unsuitable ascontainer materials for bulktransportation of wet limeproducts.A test on corrosion has also been performed to demonstrate that hydrated lime is not classified according to CLP regulation:Test specimens (1020 carbon steel, 7075 aluminium) were accurately weighed and then exposed to a 30% aqueous solution of hydrated lime. Different conditions were tested for each material: one specimen in the vapour space, one at the liquid/vapour interface (partial immersion), one in the solution near the top of the liquid phase and one in the settled suspension near the bottom of the liquid phase. Each specimen was exposed in a separate test vessel using 1200mL of test solution. The assembled test vessels were placed in a heated bath and the solution temperature was maintained for 7 days at 55°C. After 7 days, the specimens were removed, cleaned, rinsed and warm air-dried. The procedure complies with the one described in UN Manual of tests and criteria Section 37.Results:The corrosion rates of the exposed specimens were calculated based on mass loss measurements. In all case and for both material (stainless and aluminium), the corrosion rates were below 1mm/year (maximum noticed: 0.72mm/year for aluminium half immersed). Consequently, the corrosion rates are below the threshold limit of 6.25mm/year, meaning that the aqueous solution of hydrated lime (30%) is not corrosive. An additional report has been provided demonstrating that solutions at 40% are not corrosive to metals (steel and aluminium) following 60 days at 55°C (corrosion rate below 6.25mm/y).  | CTL REF 29392-1R, 2012&BAM evaluation metal corrosivity of milk of lime 11 Jan 2000 | Not precised | Acceptable.For metal packaging, the applicant has submitted a corrosion study. The results demonstrate that an aqueous solution of 30% w/w hydrated lime is not corrosive to stainless and aluminium. RMS considers that the method is identical to the one described in Manuel RTDG (test C1). Consequently, as the biocidal products is an aqueous suspension with 25% w/w Ca(OH)2, they can be considered as not corrosive. |
| Auto-ignition temperatures of products (liquids and gases) | Waiver |  | In Ca(OH)2, Calcium andOxygen are in their respective preferred oxidation state.Consequently, flammability can be excluded. |  |  | Acceptable.According to the assessment report, the substance will decompose at a temperature higher than 450°C, and will lead to the formation of CaO and H2O. CaO will then decompose at a temperature higher than 2500°C. According to SDS, no self ignition is noticed below 400°C (SDS, method UE A.16).Formulant are also not expected for self-ignited in the conditions of use. |
| Relative self-ignition temperature for solids | Waiver |  | In Ca(OH)2, Calcium andOxygen are in their respectivepreferred oxidation state.Consequently, flammability can be excluded. |  |  | Not relevant for liquid formulation.  |
| Dust explosion hazard |  |  | Not applicable. |  |  | Nor relevant for liquid formulation.  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and oxidizing properties and it is not classified corrosive to metals.  |

### Methods for detection and identification

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

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Active substance (CaO, MgO)* | Gravimetric,Volumetric,EDTA,Pyrophosphate,Insoluble matter | N/A | N/A | N/A | See Table below | N/A | ASTM C25-99 (1999) |
| *Active substance (Na, Mg)* | X-ray spectrometric analysisCa as % CaOMg as % MgO | 5 |  |  | 53,34753,68354,30455,59955,8370,1760,2160,6370,9191,406 |  | 0,28 % 0,30 % 0,23 % 0,20 % 0,26 %  8,52 % 2,78 % 1,10 % 1,09 % 3,49 %    |  | ASTM C1271-99 (1999) |
| *Active substance**(calcium, magnesium, oxide and hydroxide.* | ICPAA | 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 12048DIN EN 14397-2 |

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| **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. |

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| **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 Ca2+ and Mg2+ 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. |

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

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| **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 they 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. |

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| **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. |

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| **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 (Mg2+ and Ca2+) 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 and the nature of the active/residues the requirement for more detailed analysis of the active/residues in food or feedstuffs is considered unnecessary. |

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| **Conclusion on the methods for detection and identification of the product** |
| The analytical methods for the active substance are applicable to the product. The ISO method for detection of the substance in air is applicable to monitor workplace exposures. Since methods proposed are based on international standards and mainly based on ICP/AAS detectors, no further validation data are necessary. |

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

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

The products is ready to use for the disinfection of sludge prior to spreading on the land (PT2) or prior incineration. The product is applied directly into the substrate.

The product is for professional users only.

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

Disinfectant product intended to control bacteria, yeast, fungi, viruses and nematode eggs in sewage sludge.

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

#### Effects on target organisms, including unacceptable suffering

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

#### Mode of action, including time delay

Several effects of calcium dihydroxide are known:

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

2) Increase in free / non-ionised ammonia (NH3) - Proteolytic activity in biodegrading organic matter results in high concentrations of nitrogenous compounds. The high pH associated with lime activity is sufficient to convert any ammonium ions (NH4+) into free / non-ionised ammonia gas (NH3). Ammonia gas diffuses into bacterial cells, altering chemical equilibrium between intra and extra-cellular environments, and impeding essential enzymatic function to bring about cell death. Free non-ionised ammonia has also been shown to be destructive to viruses. However, only in closed systems, in which loss of gaseous ammonia is prevented, can concentrations relevant for a synergistic effect with high pH be reached.

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

#### Efficacy data

**General information on lime-based products**

Whatever the intended uses, efficacy tests have been performed with calcium oxide and/or calcium dihydroxide active substance.

Both active substances and products may be referred to as “lime”. Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime (Ca(OH)2). It is, however, sometimes used to describe limestone products. The raw material for all lime-based products is a natural stone: limestone, which is composed almost exclusively of calcium carbonate (CaCO3).

* Calcium oxide (CaO) is also known as Burnt lime or Quicklime, obtained from the calcination (removal of CO2) above 900°C of limestone.
* Calcium dihydroxide (Ca(OH)2) is also known as hydrated lime or slaked lime, obtained from the hydration (addition of water) of quick lime.

Calcium oxide will form calcium dihydroxide in contact with water.

**Efficacy data for NEUTRALAC® SL25 product**

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

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

In terms of microbiological pollution, sludge frequently contains various agents introduced by wastewater such as bacteria, viruses and parasites.

Simulated-use tests have been performed in order to demonstrate efficacy of lime to disinfect sewage sludge.

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

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

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

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

In a second study (6.7.02), inactivation kinetics of Ascaris eggs were established in different situations (contaminated sludge with milk of lime and heat, naturally contaminated sludge treated with slaked lime and heat, naturally contaminated sludge treated with quick lime, and sludge treated at full scale with quick lime). Indeed, Ascaris eggs are the most resistant to liming, and hence, may serve as indicators of hygienic quality of biosolids.

=> Depending on the experimental situation, the inactivation threshold period was found to fluctuate between 5 and 75 min at 55°C, and between 1 and 8 min at 60°C, pH should be maintained at 12 or more.

In the third study (6.7.03), the disinfectant effect of hydrated lime added to raw sewage sludge was investigated with special consideration of the influence on the following digestion process. In preliminary investigations in laboratory scale, the necessary pH-value and contact time of the sludge/lime mixture for a safe inactivation of salmonellas as test microorganisms were determined. In a further laboratory experiment, the effect of the high alkalinity of the limed raw sludge on the following digestion process was investigated for a mean hydraulic retention time of 20 days. No adverse effects could be recorded. *Salmonella senftenberg* as tested microorganism was inactivated by a pH of 12.8 within 3 hours (4 log reduction) in the preliminary laboratory experiments and in the large-scale experiment in the sewage treatment plant as well. No adverse effects on the digestion process nor the gas quality were observed.

Based on these efficacy data, the efficacy of calcium hydroxide is demonstrated for the disinfection of sewage sludge, against bacteria, virus and nematodes. Effective treatment is principally the result of raised pH (>12), that should be maintained during the contact time needed with regard to the situation. It should be noticed that as no effect of temperature is expected for calcium hydroxide, contact time is longer than the one with calcium oxide.

No data has been provided for yeast and fungi, among the pathogens of epidemiological relevance. Ascaris eggs are the most resistant to liming, and, hence, may serve as indicators of hygienic quality of biosolids. Indeed, French legislation considers a sludge treatment as sanitising if the end-product contains less than 3 viable helminth eggs per 10 g of TS[[3]](#footnote-4). The United States Environmental Protection Agency[[4]](#footnote-5) proposes, as implicit objective of the Class A treatment, to reduce Salmonella sp., enteric viruses and viable helminth ova to below detectable limits. In the case of helminth ova, the detectable limit is defined, as less than 1 viable helminth ova per 4 g total solids biosolids (dry weight basis). Therefore considering that both Ascaris eggs is the most resistant to liming and efficacy is demonstrated in the frame of this dossier against Ascaris eggs (below a threshold less than 1 viable helminth egg per g of TS), efficacy for calcium hydroxide is considered as proven also for yeast, fungi and virus.

|  |
| --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Disinfectant for sewage sludge | PT2 – Use 1 | Burnt Lime specified according to the "Building Lime Standard" EN 459-1 as "CL 90".Calcium Oxide content was 93.7%. The reactivity was defined as T60 =2.5 minutes and Tmax =73C. Mean density was 0.95kg/L. | Bacteria (2,3.103 – 23.106 CFU/g)*Salmonella senftenberg, Streptococci, Clostridium perfringens, E.coli*Virus (2,3.105-6,16.106 TID50 / ml)*Bovine parvovirus, ECBO* Nematodes*Ascaris suum eggs*Culture collection, except Ascaris eggs source unknown | Simulated studyDirect mixing of sewage sludge with the biocidal productThe test was applied on two different scales: one to simulate small scale use (mixers of 130 L and 145 L) and the second to simulate industrial scale treatment (cavity mixer-unknown volume).For the small scale tests, burnt lime was homogeneously mixed into the substrates. The mixture was sampled at intervals to determine the numbers of viable bacteria, viruses or Ascaris eggs.For the industrial scale test, the mix was pumped and piled for storage. Samples were taken from the stored material at intervals, to determine the numbers of viable bacteria, viruses or Ascaris eggs. | 0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solidsContact time: 1-24 hours, until 8 weeks for *Ascaris suum*temperatures and pH values were recorded over the time | 0.9 – 1.1 kg burnt lime / kg dried sludgeSmall scale test :pH>12.9Industrial scale test:Efficacy criteria achieved:5 log reduction bacteria4 log reduction viruses3 log reduction nematode eggs | 6.7-01R.I=2 |
| Disinfectant for sewage sludge | PT2 – Use 1 | Milk of lime (Ca(OH)2 suspension in waterDry hydrated lime (Ca(OH)2Burnt lime (CaO) | Nematodes*Ascaris suum* eggs(Sludge from pig slaughter houses)Sludge A: 924 ± 295 eggs per 10 g solidTotal solids: 33%Sludge B132 ± 108 eggs per 10 g solidTotal solids: 15% | Simulated-use tests:1), Artificially contaminated milkof lime was heated to 50°C, 55°C and 60°C. 2) Naturally contaminated sewage sludges were treated with slaked lime (40% weight slakedlime per weight of sludge dry solids) and afterwards heated to either 50°C or 60°C. 3) Naturally contaminated sewage sludge was treated withquick lime at a predetermined dose in order to reach 50°C, 55°C and 60°C. 4) Sewagesludge was treated at full scale with a predetermined dose of quick lime in order to reach temperaturesranging from 50°C to 60°C and stockpiled. When the stockpile target temperature was reached, bags containing Ascaris eggs were inserted in it. | Contact time : 5-160 minutespH ≥12 | Inactivation threshold: duration required to reach a level of inactivation at which no viable egg was detected per g of solid sludge (TS)Inactivation threshold is:- in milk of lime and heat, is equal to 70, 5 and 2 min, respectively at 50°C, 55°C and 60°C- with quick lime, is equal to 120 min at 50°C, to 45 min at 55°C, and 5 min at around 60°C - with slaked lime and heat, is higher than 128 min at 50°C, and ranges between 4 and 8 min at 60°C - is equal to 75 min at 55°C and 5 min at 60°C in the industrial situation (quicklime)=> This study has demonstrated that in the four investigated situations, either 75 min at 55°C or 8 min at 60°C will lead to a negligible level of viable Ascaris eggs | 6.7-02RI=2 |
| Disinfectant for sewage sludge | PT2 – use 1 | Calcium dihydroxide (10% Ca(OH)2 in water: milk of lime) | Bacteria*Salmonella senftenberg (*108 CFU/mL)Coliforms (106 CFU/mL)  | Simulated tests Direct mixing of sewage sludge with the biocidal product | Two laboratory scale pilot-plant tests were used for the trial proper (Digester 1 and Digester 2), that were fed with dry sludge (the sludge had a mean hydraulic retention time of 20 days). Step 1: The sludge was fed through the digesters for 20 days. Step 2: Days 21-39 Digester 1 was fed with 10% milk of lime to pH=12.8 and given 3 hours agitation. Step 3: From day 30 to day 50, raw sludge was inoculated with Salmonella and only Digester 1 was treated with lime.Raw sludge from both digesters inoculated with Salmonella. Digester 1 is treated with decreasing amounts of Lime (pH is reduced from 12.9 from 11.6), Digester 2 is also treated with Lime. | Step 1: The total bacterial and coliform counts of raw sludge and digested sludge are in the same order. No impact of the digestion on the level of contamination.Step 2: in Digester 1, after 3 hours contact time, 3 to 4 log reduction is obtained for bacteria (no coliforms isolated).Step 3: Salmonellas and coliforms were never isolated and total germ count were reduced by 6 logsStep 4: in Digester 1, Salmonella and coliforms are detected, while in Digested 2 (treated for the first time), total germs decreased of 3 log. | 6.7-03RI=2 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product NEUTRALAC® SL25 has shown a sufficient efficacy:- For the disinfection of sewage sludge, against bacteria, yeast, fungi, virus and nematode eggsThe effective final use concentration and contact time are variable. pH should be > 12 during the exposure time.The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to dry weight of the substrate. The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented |

#### 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 (NH3)
* 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.

#### Known limitations

There are no known limitations for the biocidal products

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product NEUTRALAC® SL25 has shown a sufficient efficacy:

- For the disinfection of sewage sludge, against bacteria, yeast, fungi, virus and nematode eggs

The effective final use concentration and contact time are variable.

pH should be > 12 during the exposure time

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

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

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

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

Non applicable

### Risk assessment for human health

In order to avoid unnecessary animal experiment, no study was conducted. Classification is determined following the CAR of the active substance and by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | The product is considered irritant to the skin. |
| Justification for the value/conclusion | The product is an aqueous suspension of the active substance, Therefore considering the content of the active substance in the product, a classification Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is needed.This conclusion is in accordance with the data of the CAR, in which a suspension of Ca(OH)2 was tested.  |
| Classification of the product according to CLP and DSD | The product is classified Skin irritant cat 2, H315 (Causes Skin Irritation). |

***Eye irritation***

|  |
| --- |
|  **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | The product is considered to cause serious eye damage |
| Justification for the value/conclusion | No new data on eye irritation was provided. The classification is determined using the calculation method of CLP Regulation. Considering the content of the active substance in the product, a classification Eye Dam.1 H318 (in accordance with Regulation EC/1272/2008) is needed. |
| Classification of the product according to CLP and DSD | Product is classified as Eye Dam.1 (H318: Cause serious eye damage). |

***Respiratory tract irritation***

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | No new data on irritation in the respiratory tract was provided. The classification is determined using the calculation method of CLP Regulation. Considering the content of the active substance in the product, a classification STOT SE 3 H335 is needed. |
| Classification of the product according to CLP and DSD | Product is classified as STOT SE 3 H335 (in accordance with Regulation EC/1272/2008). |

***Skin sensitization***

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitising to the skin |
| Justification for the value/conclusion | No new data on skin sensitisation was provided. Therefore, the classification is determined according to the CLP Regulation. No classification for skin sensitisation is required. |
| Classification of the product according to CLP  | No classification for skin sensitisation is required. |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | No new data on respiratory sensitisation was provided. Therefore, the classification is determined according to the CLP Regulation. No classification for respiratory sensitisation is required.  |
| Classification of the product according to CLP and DSD | No classification for respiratory sensitisation is required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | Not acutely toxic via oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute oral toxicity. Therefore, no classification for acute inhalation toxicity is required. |
| Classification of the product according to CLP  | No classification for acute oral toxicity is required. |

*Acute toxicity by inhalation*

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | Not acutely toxic via inhalation. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute inhalation toxicity. Therefore, no classification for acute inhalation toxicity is required. |
| Classification of the product according to CLP  | No classification for acute inhalation toxicity is required.  |

*Acute toxicity by dermal route*

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute dermal toxicity. Therefore, no classification for acute dermal toxicity is required. |
| Classification of the product according to CLP  | No classification for acute dermal toxicity is required. |

***Information on dermal absorption***

|  |
| --- |
| **Data waiving** |
| Information requirement | Dermal absorption |
| Justification | No study is available. However, according to the CAR of the active substance, a dermal absorption value of 100 % of the applied dose of calcium is a reasonable worst-case. |

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, no co-formulant has been identified as SOC..

***Available toxicological data relating to a mixture***

Not relevant.

#### Exposure assessment

NEUTRALAC® SL25 is used for disinfection of sewage sludge (PT2) by professionals.

The product is packed in containers up to 25t or IBC tanker.

The potential exposure of operator results from loading the product to the process and from the cleaning of the equipment.

Milk of lime is often supplied as a biocide for lime stabilisation delivered in bulk tankers or IBC through a pipe. Handling of milk of lime under these conditions involves the closed transfer of the product, via a pipe connected to the tankers, to the silo. Therefore, no exposure is expected during application of the product.

The main contents of the lime variants are calcium, magnesium and their oxides and hydroxides. According to the CAR of the active substance, a quantitative systemic assessment of **calcium and magnesium** and a quantitative local assessment of Ca(OH)2 for inhalation route are performed.

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

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

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| 1. | Loading | PrimaryLoading of product to system | Professionals |
| 2. | Cleaning and maintenance | PrimaryManual cleaning of mixing or spreading equipment. | Professionals |

***Industrial exposure***

Not relevant

***Professional exposure***

*Scenario [1] : Loading of product to system*

| **Description of Scenario [1]** |
| --- |
| NEUTRALAC® SL 25 is a suspension packed in containers up to 25t or IBC tanker. Considering the high volume of the packaging, it is considered that the loading will be performed by (semi-) automated transfer/pumping. During this step, the operator has to connect the container to the system. The product is then transferred to the sewage sludge through closed systems. Calcium dihydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected.To determine the dermal exposure, RISKOFDERM Toolkit Connecting lines Model is used (HEEG opinion 1).A duration of 10 minutes is taken into consideration.  |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration  | 25% |  |
| Assumed calcium fraction | 13.5% |  |
| Assumed magnesium fraction | 0.57% |  |
| Duration (min) | 10 |  |
| Dermal exposure – Hand only (mg/min) | 0.92 | RISKOFDERM Toolkit  |
| Dermal absorption | 100% | Default value, CAR |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |

**Calculations for Scenario [1]**

**Systemic exposure- calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] | Tier 1/ no PPE | n.r. | 2,07E-02 | 2,07E-02 |

**Systemic exposure - magnesium**

| **Summary table: systemic exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [1] | Tier 1/no PPE | n.r. | 8,74E-04 | 8,74E-04 |

*Scenario [2]: Cleaning and maintenance- Manual cleaning of mixing or spreading equipment*

|  |
| --- |
| **Description of Scenario [2]** |
| Routine cleaning and maintenance of equipment are required.There is no readily available data to predict exposures for this scenario. Although, NEUTRALAC® SL 25 is a liquid, the exposure during the cleaning of the equipment will be equal or inferior to the cleaning of the equipment after treatment with a product in powder. Therefore, the same approach than the approach proposed in the CAR of the active substance is applied. The BEAT model “Cleaning of spray equipment” is used to determine the dermal exposure.For inhalation exposure, it is assumed that the air concentrations would not be higher than the predicted air concentration for manual loading of bags of powder. In the CAR, this exposure is determined according to one study.The task duration is 30 min according to the CAR. (see Annex for reports) |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration  | 25% |  |
| Assumed calcium fraction | 13.5% |  |
| Assumed magnesium fraction | 0.57% |  |
| Duration (min) | 30 |  |
| Dermal exposure – Hand (mg b.p/min) | 35.6 | BEAT  |
| Dermal exposure – Body (mg b.p/min) | 19.1 | BEAT |
| Inhalation (mg b.p/m3)  | 23.2 | ART; during task |
| Inhalation absorption | 100% | Default value, CAR |
| Dermal absorption | 100% | Default value, CAR |
| Inhalation rate | 1.25 | m3/h |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| Tier 2 | RPE = APF 40 | 40 | HEEG Opinion 9, 2010 |

**Calculations for Scenario [2]**

**Systemic exposure- calcium**

| **Summary table: systemic exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | 3,27E-02 | 3,70E+00 | 3,73E+00 |

**Systemic exposure – magnesium**

| **Summary table: systemic exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | 1,38E-03 | 1,56E-01 | 1,57E-01 |

**Local exposure - Calcium dihydroxide**

| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** |
| --- | --- | --- |
| Scenario [2] | Tier 1/no PPE | 5.8 |
| Scenario [2] | Tier 2/APF 40 | 0.145 |

***Exposure of the general public***

The product is used for treatment of sewage sludge by professionals. The general public will not be exposed to these uses.

***Monitoring data***

None

***Dietary exposure***

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

*Information of non-biocidal use of the active substance :*

**Calcium hydroxide** is listed as a plant protection product (PPP) basic active substance in accordance with Regulation (EC) No. 1107/2009 (approval date 01/07/2015).It is included in Annex IV of the Regulation to (EC) No. 396/2005 and thus no MRL is required from PPP uses.

Calcium hydroxide is listed in table 1 of Regulation No. 37/2010 annex, as allowed pharmacologically active substances for which MRL in foodstuffs of animal origins is not required.

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

Residue definitions :

When dissolved in water, calcium hydroxide dissociates into Ca2+ and OH-. Calcium is a natural constituent of the body and an essential element of the human diet.

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant Protection Products | Fungicide on various crops | No MRL required for calcium hydroxide. |
| 2. | Fertiliser  | Application to agricultural soils | - |
| 3. | Veterinary medicinal products | All food producing species  | No MRL required |
| 4. | Food additives  | Added to some food categories  | « Quantum satis » |
| 5. | Food supplements  | Mineral added to food  | Calcium UL = 2500 mg/d for adults  |

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

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

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

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

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

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

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

Only professional uses are intended in this dossier.

***Summary of exposure assessment***

**Systemic exposure- calcium**

| **Scenarios and values to be used in risk assessment**  |
| --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] – manual loading | Professionals | Tier 1/no PPE | 2,07E-02 |
| Scenario [2] – cleaning equipment | Professionals | Tier 1/no PPE | 3,73E+00 |

**Systemic exposure- magnesium**

| **Scenarios and values to be used in risk assessment**  |
| --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] – manual loading | Professionals | Tier 1/no PPE | 8,74E-04 |
| Scenario [2] – cleaning equipment | Professionals | Tier 1/no PPE | 1,57E-01 |

**Local exposure - Calcium dihydroxide**

| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** |
| --- | --- | --- |
| Scenario [2] – cleaning equipment | Tier 1/no PPE | 5.8 |
| Scenario [2] – cleaning equipment | Tier 2/APF 40 | 0.145 |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation- calcium

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AEC short, medium & long-term | human volunteers (respiratory tract) | 1 mg/m3 | 3.2 | - | 0.3 mg/m3 |
| AEL short, medium & long-term (UL calcium) | - | - | - | - | 42 mg/kg bw/day |
| ARfD | Not applicable |
| ADI | Not applicable |

 Reference values to be used in Risk Characterisation - **magnesium**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AEL short, medium & long-term (UL magnesium) | - | - | - | - | 4.2 mg/kg bw/day |

**Maximum residue limits or equivalent**

See Summary table of other (non-biocidal) uses.

**Specific reference value for groundwater**

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

***Risk for industrial users***

Not relevant.

***Risk for professional users***

Systemic effects (calcium)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **UL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **<< 13% UL (yes/no)** |
| Scenario 1- loading | 1/no PPE | 42 | 2,07E-02 | 0.05% | yes |
| Scenario 2- Cleaning and maintenance | 1/no PPE | 42 | 3,73E+00 | 9% | yes |

Systemic effects- magnesium

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **<< 13% UL (yes/no)** |
| Scenario 1- loading  | Tier 1/no PPE | 4.2 | 8,74E-04 | 0.02% | yes |
| Scenario 2- Cleaning and maintenance  | Tier 1/no PPE | 4.2 | 1,57E-01 | 4% | yes |

Combined scenarios- calcium

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **<< 13% UL (yes/no)** |
| **Scenario 1+ scenario 2 (worst case)** | 1/no PPE | 42 | 3,75E+00 | 9% | yes |

Combined scenario- magnesium

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **<< 13% UL (yes/no)** |
| **Scenario 1+ scenario 2 (worst case)** | 1/no PPE | 4.2 | 1,58E-01 | 4% | yes |

The systemic exposures to calcium and magnesium are inferior to 13% of UL for each task and combined exposure.

**Local exposure - Calcium dihydroxide**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEC****mg/m3** | **Estimated uptake****mg/m3** | **Estimated uptake/ AEC (%)** | **Acceptable****(yes/no)** |
| Scenario [2]- cleaning | Tier 1/no RPE | 0.3 | 5.8 | **1933%** | **Yes** |
| Scenario [2]- cleaning | Tier 2b/RPE (APF= 40) | 0.3 | 0.145 | **48%** | **yes** |

The concentration of calcium dihydroxide is superior to AEC during cleaning of the equipment when no RPE is worn.

The concentration is inferior to AEC when a RPE with an APF 40 is worn.

***According to the guidance on the BPR for human health, a qualitative local risk assessment is performed since NEUTRALAC***® ***SL 25 is classified H315, H319 and H335.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Hazard** | **Characteristics of the product** | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | **Risk** |
| *Hazard category* | *Effects in terms of C&L* | *Additional relevant hazard information* | *PT*  | *Who is* *exposed?* | *Tasks,* *uses,* *processes* | *Potential* *exposure* *route* | *Frequency* *and* *duration* *of* *potential* *exposure* | *Degree* *of potential* *exposure**(mg/m3)* | *Conclusion on risk assessment*  |
| LOW | Skin irritant 2: H315 STOT single exposure 3: H335  | AEC = 0.3 mg/m3 | 2 | Professional | 1: loading2: cleaning | Dermal |

|  |
| --- |
| More than few minutes but equal to or less than few hours per day  |

 | controlled exposure, | Considering that the product will be applied by a professional, technic and organizational RMM are followed. The risk is acceptable considering the following RMM. 1 and 2: - Minimisation of splashes and spills;- Avoidance of contact with contaminated tools and objects;- Wear:* Substance/ task appropriate gloves
* Protection coverall

2:Wear:- Face shield - Substance/ task appropriate respirator mask |
|  High hazard | Eye dam. 1, H318 |  |  | Professional | 1: loading2: cleaning  | Dermal | Few minutes perday or less | High level of containment,practically no exposure; nosplashes, no hand to eye transfer,no (liquid or solid) aerosolformation | Considering that the product will be applied by a professional, technics and organizational RMM are followed. The risk is acceptable considering the following RMM: 1 and 2: Wear chemical goggles  |

***Risk for non-professional users***

Not relevant.

***Risk for the general public***

**Systemic effects**

Not relevant

**Local effects**

Not relevant

**Conclusion**

The risk is acceptable for professional considering the following RMM:

For Mixing and loading and Cleaning of the equipment:

* Minimisation of splash and spills,
* Avoid contact with contaminated tools and objects
* Wear appropriate gloves, protection coverall and goggles during loading of equipment.

During the manipulation of treated sewage sludge:

* Wear protective gloves and protection coverall during the manipulation of treated sewage sludge.
* During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to estimate and prevent an exposure greater than the PEL of 14 mg/m3 for this gas. During the cleaning step, we consider the concentration of Ammonia to be below than the one during the application step. Therefore, the wear of an APF40 at minima is considered conservative enough during the cleaning of the equipment.

During cleaning of the equipment:

* Wear appropriate gloves, protection coverall and goggles during cleaning of equipment.
* Wear respiratory mask adapted to reduce the exposure to dust (AFP 40 at minima) and ammoniac release.

Moreover, the addition of calcium dihydroxide to sewage may lead to the production of ammonia gas.

It is very difficult to predict the likely air concentrations that would prevail in treatment plants and whether they are likely to exceed such exposure limits. During the treatment of sewage sludge, the wear of air fed or canister RPE specific for Ammonia gas, is recommended in absence of collective management measures to prevent an exposure greater than the PEL of 14 mg/m3 for this gas. During the cleaning step, we consider the concentration of Ammonia to be below than the one during the application step. Therefore, the wear of an APF40 at minima is considered conservative enough during the cleaning of the equipment

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

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

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

Not relevant.

### Risk assessment for animal health

Not relevant.

### Risk assessment for the environment

NEUTRALAC® SL 25 is a PT2 product containing calcium dihydroxide, hydrated lime (CAS 1305-62-0) that is applied for disinfection of sewage sludge (PT02). The product is an aqueous suspension of the active substance, which is a naturally occurring inorganic salt.

No environmental SoCs were identified for the NEUTRALAC® SL 25 and no metabolites are formed that would need to be addressed in a risk evaluation for the environment. The following risk assessment is therefore based on the data obtained from the active substance only (CAR, Calcium dihydroxide, Hydrated lime, CAS 1305-62-0, Product Type 2: Disinfectants and algaecides not intended for direct application to humans or animals, RMS UK, September 2016).

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

#### Effects assessment on the environment

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

Ecotoxicological data about the biocidal product NEUTRALAC® SL25 are not available. Therefore, all data pertaining to the active substance are derived from the Calcium dihydroxide, hydrated lime CAR (2016).

***Further Ecotoxicological studies***

No data required.

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

No data available.

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

No data available.

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

No data available.

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

Further information on the secondary ecological effect is not required.

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

Indirect routes: to soil and groundwater from uses in sewage sludge.

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

No data available.

***Leaching behaviour (ADS)***

No data available.

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

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

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

**Distribution**

Hydrated lime would simply dissociate to its respective ion constituents (Ca2+ and OH-) where they would form part of existing chemical cycles in the natural environment.There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca2+ and OH- ions in nature.

**Dissipation**

Hydrated lime would simply dissociate to its respective ion constituents (Ca2+ and OH-) where they would form part of existing chemical cycles in the natural environment.There is no scientific justification for distribution and dissipation studies to be performed given the abundance of Ca2+ and OH- ions in nature.

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

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

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

No data available.

**Dissipation**

No data available.

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

Not relevant for the use of NEUTRALAC® SL25.

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

Not relevant for the use of NEUTRALAC® SL25.

***PNECs* :**

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

|  |
| --- |
| **Summary of PNECs of the active substance Calcium dihydroxide** |
| **Compartment** | **Species** | **Endpoint** | **Safety factor** | **PNEC (Hydrated lime equivalents)** |
| Surface water | *Daphnia magna* | 48h EC50 = 49.1 | 100 | 0.491 mg/L |
| Sediment | *-* | - | - | Not relevant |
| Microorganisms (STP) | *Activated sludge* | 3h EC50 = 300.4 mg/L | 100 | 3.004 mg/L |
| Soil | *Spinacia oleracea* | 21d NOECplant = 1080 mg.kg-1 dw\* | 10 | 108 mg.kg-1 dw\* |
| Bird | *-* | - | - | Not relevant |
| Mammal | *-* | - | - | Not relevant |

\*For the effects assessment of the soil compartment, endpoints are presented in terms of mg a.s/kg dry weight (dw) of soil. This is consistent with the application rates for the PT2 uses all being expressed as rates per dry solid weight of sludge. For consistency, dry weight has been used for the PT3 use patterns.

According to the CAR, various MS recommended a risk assessment based on a qualitative approach, particularly since the dissociation products of the lime variants (Ca2+, Mg2+ and OH-) form parts of existing chemical cycles in the natural environment. In addition, for the terrestrial compartment, the contribution to the total environmental loading of lime from the biocidal use may be much less significant than from the routine agricultural use of lime used to amend soil pH and maintain soil fertility (a use of the active substance that is outside the scope of the BPR).

Thus, the PNEC values will not be always used in the risk assessment (especially for the terrestrial compartment). As proposed during the assessment of the active substance at European level, a qualitative risk assessment will be conducted. For the terrestrial compartment, it involves the calculation of lime emissions on arable land due to the biocidal claimed uses and the comparison with routine agricultural use of lime to control soil pH (application rates to neutralise agricultural soil up to 16 tons/ha per year (as CaO) in lime deficient soils.)

####  Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Scenario 1: Application to sewage sludge |
| ESD(s) used | Not applicable.  |
| Approach | Qualitative assessment is performed in accordance with the approach used in the active substance CAR. |
| Distribution in the environment | Vol IV Part B+C (2017) |
| Groundwater simulation | No |
| Confidential Annexes | No  |
| Life cycle steps assessed | Scenario 1:Production: NoFormulation NoUse: YesService life: No |
| Remarks |  |

***Emission estimation***

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

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

The product is mixed with sewage sludge in an open mixer by professionals. After the disinfection process, the treated sludge is spread on agricultural fields. Therefore, an indirect exposure to soil is considered.

This use has been assessed in the CAR of the active NEUTRALAC SL25:

|  |  |  |
| --- | --- | --- |
|  | **Representative product of the CAR Hydrated Lime, 2016** | **NEUTRALAC SL25 product** |
| Fraction of a.s in the product (-) | 1 | 0.25 |
| Maximal application rate of the product (in % of dry solid weight of sludge) | 50 | 800(i.e. 6900 L Neutralac® SL25/t of dry solid weight of sludge, considering a product density of 1.16) |
|  |
| Application rate of the a.s (in % of dry solid weight of sludge) | 50 | 200 |

It has been demonstrated that the use of the representative product of the CAR generates applications of lime in agricultural soil lower than 16t/ha/year. The same reasoning can be used for the product NEUTRALAC® SL25 (see table below).

|  |
| --- |
| **Input** |
| Application rate of the a.s for the use described in the CAR | 50% of dry solid weight of sludge | 200% of dry solid weight of sludge |
| Maximal application rate of sludge in agricultural land per year | 5000 kg dry solid sludge/ha/year |
| **Output** |
| Amount of lime added to the sludge during the treatment  | 2500 kg | 10000 kg |
| Total dry weight of treated sludge after the treatment | 7500 kg | 15000 kg |
| Concentration of a.s in the final 5000 kg actually landed in agricultural lands per ha per year | 5000/7500 \* 2500 = 1.667 t/ha/year | 5000/15000 \* 10000 = 3.333 t/ha/year |

As the use of NEUTRALAC® SL25 will generate application of lime in agricultural soil lower than the routine agricultural uses of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of NEUTRALAC® SL25 on soil.

Moreover, according to BPR Vol IV Part B+C (2017), chapter 2.3.7.5.1, no runoff from soil to surface water after sludge application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** |
| --- |
|  | Freshwater | Freshwater sediment | STP | Air | Soil | Groundwater |
| TP2 – disinfection of sewage sludge –Scenario 1 | No | No | No | No | Yes | Yes |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** |
| Input  | Value  | Unit | Remarks |
| Molecular weight | 74.09 | g/mol | (IIB, 2016) |
| Vapour pressure | <1.0E-05 | Pa | Not conducted as melting point above 300°C. It can be assumed the vapour pressure is <10 -5 Pa. (CAR 2016) |
| Water solubility (at 0°C) | 1.85 | g/L | (CAR, 2016) |
| Log Octanol/water partition coefficient | <<3 | Log 10 | (CAR, 2016) |
| Organic carbon/water partition coefficient (Koc) | 0 | L/kg | Worst-case specified in the CAR of 2016 |
| Henry’s Law Constant | - | Pa/m3/mol | Not applicable (CAR, 2016) |
| Biodegradability | *-*  |  | Not applicable 6(CAR, 2016) |
| DT50 for biodegradation in surface water | - | d or hr (at 12ºC) | When dissolved in water, Hydrated lime dissociates into Ca2+ and OH-, which are chemically and biologically not further degradable (CAR, 2016) |
| DT50 for hydrolysis in surface water | - | d or hr (at 12ºC /pH)  | When dissolved in water, Hydrated lime dissociates into Ca2+ and OH-, which are chemically and biologically not further degradable (CAR, 2016) |
| DT50 for photolysis in surface water | - | d or hr | Not applicable, see Hydrolysis (CAR, 2016) |
| DT50 for degradation in soil (T0 to T=6h after application of lime in soil) | 0.752 | hr | (CAR, 2016) |
| DT50 for degradation in soil (T=6h to T=+∞ after application of lime in soil) | 372 | hr | (CAR, 2016) |

***Calculated PEC values***

As the use generates lower emissions than the routine agricultural uses of lime applied to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of NEUTRALAC® SL25 on soil. A qualitative assessment is deemed sufficient as proposed during the assessment of the active substance at the European level.

***Primary and secondary poisoning***

Primary poisoning

As the product is mixed with sewage sludge or manure, it is not considered to be sufficiently appetent to bird or mammals. Therefore, they would not be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca2+, Mg2+, and OH-) in the environment.

#### Risk characterisation

***Atmosphere***

For hydrated lime, exposure via air (and subsequent phototransformation in air) would be negligible based on its structure and its expected low vapour pressure (<<1.0E-05 Pa).

Due to the negligible exposure, no formal risk assessment of air compartment is considered necessary.

###### ***Aquatic compartment (surface water, sediment and sewage treatment plant)***

According to BPR Vol IV Part B+C (2017), chapter 2.3.7.5.1, no runoff from soil to surface water after sludge application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

###### ***Terrestrial compartment***

The use of NEUTRALAC® SL25 to treat sewage sludge leads to emissions to soil and will generate application rate of lime on agricultural soil lower than the routine agricultural use of lime spread to correct soil pH and maintain soil fertility (16T/ha/year, see table below).

|  |  |
| --- | --- |
| **Uses** | **Emissions to soil (agricultural land, in T/ha/year)** |
| **PT2** |
| 1 | 3.333 |

Therefore, the use of NEUTRALAC® SL25 to treat sewage sludge leads to acceptable risk to the terrestrial compartment.

###### ***Groundwater***

Hydrated lime dissociates into Ca2+ and OH- when in contact with water.

The dissociation products are not really degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, Ca2+ ions are major constituents in many groundwater zones and are probably present at concentrations greater than 1 mg/L under typical conditions due to natural weathering processes taking place in the overlying soil and rock formations. Although these natural weathering processes could also lead to groundwater leaching of applied lime residues, it is not expected that these processes will lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment is considered necessary and acceptable risks are foreseen for groundwaters.

***Primary and secondary poisoning***

Primary poisoning

As the product is mixed with sewage sludge or manure, it is not considered to be sufficiently appetent to bird or mammals. Therefore, they would not be at risk.

Secondary poisoning

This point is not relevant because lime can be considered to be omnipresent and essential in the environment. The biocidal uses described and assessed in this dossier do not significantly influence the distribution of the constituents (Ca2+, Mg2+, and OH-) in the environment.

***Aggregated exposure (combined for relevant emmission sources)***

No aggregated exposure is relevant for this dossier.

Nevertheless, it is recommended to verify the pH of the soil to be amended or of the spread sludge/manure in order not to have a pH disruption.



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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Acceptable risks for the environment are foreseen for the intended uses.As indicated in the CAR of the active substances, the use should respect the following RMM:“Before each application of lime-treated material, soil analysis conducted in accordance with good agricultural practices should be carried out to ensure that it will not lead to unacceptable long term pH changes in soil.”In France several norms and regulation ensure the correct spreading of lime treated materials on agricultural fields, including soil pH monitorings. Consequently, This specific RMM is not required.Please note that this specific RMM might justified in case the spreading of lime treated materials in agricultural soils is not subject to any regulation in some other MS. |

### Measures to protect man, animals and the environment

*[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]*

### Assessment of a combination of biocidal products

Not relevant.

# Annexes[[5]](#footnote-6)

## List of studies for the biocidal product

## Output tables from exposure assessment tools

## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[6]](#footnote-7)

## Confidential annex

## Other

##

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-3)
3. Journal officiel français. Technical prescriptions for the spreading of sludge on agricultural soils, permanent Code environment and nuisances (Prescriptions techniques applicables aux épandages de boues sur les sols agricoles, Code permanent environnement et nuisances), arrêté du 8 janvier 1998. Bulletin 245, 1998. p. 6605–12 [↑](#footnote-ref-4)
4. US EPA.Control of pathogens and vector attraction in sewage sludge. Report EPA/625/R-92/013. US EPA, Washington, DC, 1999. 151pp [↑](#footnote-ref-5)
5. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-6)
6. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-7)