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

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

(submitted by the evaluating Competent Authority)



MILK OF LIME

Product type(s) 2 & 3

Calcium dihydroxide

Case Number in R4BP: BC-CU038988-02

Evaluating Competent Authority: FR

Date: 04/05/2022

Table of Contents

[Table of Contents 2](#_Toc93420727)

[*1* CONCLUSION 6](#_Toc93420728)

[*2* ASSESSMENT REPORT 14](#_Toc93420729)

[2.1 Summary of the product assessment 14](#_Toc93420730)

[2.1.1 Administrative information 14](#_Toc93420731)

[**2.1.1.1** Identifier of the product family 14](#_Toc93420732)

[**2.1.1.2** Authorisation holder 14](#_Toc93420733)

[**2.1.1.3** Manufacturer(s) of the products of the family 14](#_Toc93420734)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 15](#_Toc93420735)

[2.1.2 Product family composition and formulation 16](#_Toc93420736)

[**2.1.2.1** Identity of the active substance 16](#_Toc93420737)

[**2.1.2.2** Candidate for substitution 16](#_Toc93420738)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product family 16](#_Toc93420739)

[**2.1.2.4** Information on technical equivalence 16](#_Toc93420740)

[**2.1.2.5** Information on the substance(s) of concern 16](#_Toc93420741)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product 17](#_Toc93420742)

[**2.1.2.7** Type of formulation 17](#_Toc93420743)

[2.1.3 Meta SPC 1 administrative information 17](#_Toc93420744)

[**2.1.3.1** Meta SPC identifier 17](#_Toc93420745)

[**2.1.3.2** Suffix to the authorisation number 17](#_Toc93420746)

[**2.1.3.3** Product type(s) 17](#_Toc93420747)

[2.1.4 Meta SPC 1 composition 17](#_Toc93420748)

[**2.1.4.1** Qualitative and quantitative information on the composition of the meta SPC 1 17](#_Toc93420749)

[**2.1.4.2** Type(s) of formulation of the meta SPC 1 17](#_Toc93420750)

[2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1 18](#_Toc93420751)

[2.1.6 Authorised use(s) fort he META SPC 1 18](#_Toc93420752)

[**2.1.6.1** Use description 18](#_Toc93420753)

[**2.1.6.2** Use-specific instructions for use 19](#_Toc93420754)

[**2.1.6.3** Use-specific risk mitigation measures 19](#_Toc93420755)

[**2.1.6.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 20](#_Toc93420756)

[**2.1.6.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 20](#_Toc93420757)

[**2.1.6.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 20](#_Toc93420758)

[**2.1.6.7** Use description 20](#_Toc93420759)

[**2.1.6.8** Use-specific instructions for use 20](#_Toc93420760)

[**2.1.6.9** Use-specific risk mitigation measures 21](#_Toc93420761)

[**2.1.6.10** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 21](#_Toc93420762)

[**2.1.6.11** Where specific to the use, the instructions for safe disposal of the product and its packaging 21](#_Toc93420763)

[**2.1.6.12** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 22](#_Toc93420764)

[**2.1.6.13** Use description 22](#_Toc93420765)

[**2.1.6.14** Use-specific instructions for use 22](#_Toc93420766)

[**2.1.6.15** Use-specific risk mitigation measures 22](#_Toc93420767)

[**2.1.6.16** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 23](#_Toc93420768)

[**2.1.6.17** Where specific to the use, the instructions for safe disposal of the product and its packaging 23](#_Toc93420769)

[**2.1.6.18** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 23](#_Toc93420770)

[**2.1.6.19** Use description 23](#_Toc93420771)

[**2.1.6.20** Use-specific instructions for use 24](#_Toc93420772)

[**2.1.6.21** Use-specific risk mitigation measures 24](#_Toc93420773)

[**2.1.6.22** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 24](#_Toc93420774)

[**2.1.6.23** Where specific to the use, the instructions for safe disposal of the product and its packaging 25](#_Toc93420775)

[**2.1.6.24** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 25](#_Toc93420776)

[**2.1.6.25** Use description 25](#_Toc93420777)

[**2.1.6.26** Use-specific instructions for use 25](#_Toc93420778)

[**2.1.6.27** Use-specific risk mitigation measures 25](#_Toc93420779)

[**2.1.6.28** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 26](#_Toc93420780)

[**2.1.6.29** Where specific to the use, the instructions for safe disposal of the product and its packaging 26](#_Toc93420781)

[**2.1.6.30** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 26](#_Toc93420782)

[**2.1.6.31** Use description 26](#_Toc93420783)

[**2.1.6.32** Use-specific instructions for use 27](#_Toc93420784)

[**2.1.6.33** Use-specific risk mitigation measures 27](#_Toc93420785)

[**2.1.6.34** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 27](#_Toc93420786)

[**2.1.6.35** Where specific to the use, the instructions for safe disposal of the product and its packaging 27](#_Toc93420787)

[**2.1.6.36** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 27](#_Toc93420788)

[2.1.7 General directions for use of the meta SPC 1 28](#_Toc93420789)

[**2.1.7.1** Instructions for use 28](#_Toc93420790)

[**2.1.7.2** Risk mitigation measures 28](#_Toc93420791)

[**2.1.7.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 28](#_Toc93420792)

[**2.1.7.4** Instructions for safe disposal of the product and its packaging 28](#_Toc93420793)

[**2.1.7.5** Conditions of storage and shelf-life of the product under normal conditions of storage 29](#_Toc93420794)

[2.1.8 Other information 29](#_Toc93420795)

[2.1.9 Trade name(s), authorisation number and specific composition of each individual product 29](#_Toc93420796)

[2.1.10 Meta SPC 2 administrative information 30](#_Toc93420797)

[**2.1.10.1** Meta SPC identifier 30](#_Toc93420798)

[**2.1.10.2** Suffix to the authorisation number 30](#_Toc93420799)

[**2.1.10.3** Product type(s) 30](#_Toc93420800)

[2.1.11 Meta SPC 2 composition 30](#_Toc93420801)

[**2.1.11.1** Qualitative and quantitative information on the composition of the meta SPC 2 30](#_Toc93420802)

[**2.1.11.2** Type(s) of formulation of the meta SPC 2 30](#_Toc93420803)

[2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2 30](#_Toc93420804)

[2.1.13 Authorised use(s) fort he META SPC 2 31](#_Toc93420805)

[**2.1.13.1** Use description 31](#_Toc93420806)

[**2.1.13.2** Use-specific instructions for use 32](#_Toc93420807)

[**2.1.13.3** Use-specific risk mitigation measures 32](#_Toc93420808)

[**2.1.13.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 32](#_Toc93420809)

[**2.1.13.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 32](#_Toc93420810)

[**2.1.13.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 32](#_Toc93420811)

[**2.1.13.7** Use description 32](#_Toc93420812)

[**2.1.13.8** Use-specific instructions for use 33](#_Toc93420813)

[**2.1.13.9** Use-specific risk mitigation measures 33](#_Toc93420814)

[**2.1.13.10** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 34](#_Toc93420815)

[**2.1.13.11** Where specific to the use, the instructions for safe disposal of the product and its packaging 34](#_Toc93420816)

[**2.1.13.12** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 34](#_Toc93420817)

[**2.1.13.13** Use description 34](#_Toc93420818)

[**2.1.13.14** Use-specific instructions for use 35](#_Toc93420819)

[**2.1.13.15** Use-specific risk mitigation measures 35](#_Toc93420820)

[**2.1.13.16** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 36](#_Toc93420821)

[**2.1.13.17** Where specific to the use, the instructions for safe disposal of the product and its packaging 36](#_Toc93420822)

[**2.1.13.18** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 36](#_Toc93420823)

[**2.1.13.19** Use description 36](#_Toc93420824)

[**2.1.13.20** Use-specific instructions for use 36](#_Toc93420825)

[**2.1.13.21** Use-specific risk mitigation measures 37](#_Toc93420826)

[**2.1.13.22** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 37](#_Toc93420827)

[**2.1.13.23** Where specific to the use, the instructions for safe disposal of the product and its packaging 37](#_Toc93420828)

[**2.1.13.24** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 38](#_Toc93420829)

[**2.1.13.25** Use description 38](#_Toc93420830)

[**2.1.13.26** Use-specific instructions for use 38](#_Toc93420831)

[**2.1.13.27** Use-specific risk mitigation measures 38](#_Toc93420832)

[**2.1.13.28** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 39](#_Toc93420833)

[**2.1.13.29** Where specific to the use, the instructions for safe disposal of the product and its packaging 39](#_Toc93420834)

[**2.1.13.30** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 39](#_Toc93420835)

[**2.1.13.31** Use description 39](#_Toc93420836)

[**2.1.13.32** Use-specific instructions for use 39](#_Toc93420837)

[**2.1.13.33** Use-specific risk mitigation measures 40](#_Toc93420838)

[**2.1.13.34** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 40](#_Toc93420839)

[**2.1.13.35** Where specific to the use, the instructions for safe disposal of the product and its packaging 40](#_Toc93420840)

[**2.1.13.36** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 40](#_Toc93420841)

[2.1.14 General directions for use of the meta SPC 2 41](#_Toc93420842)

[**2.1.14.1** Instructions for use 41](#_Toc93420843)

[**2.1.14.2** Risk mitigation measures 41](#_Toc93420844)

[**2.1.14.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 41](#_Toc93420845)

[**2.1.14.4** Instructions for safe disposal of the product and its packaging 41](#_Toc93420846)

[**2.1.14.5** Conditions of storage and shelf-life of the product under normal conditions of storage 42](#_Toc93420847)

[2.1.15 Other information 42](#_Toc93420848)

[2.1.16 Trade name(s), authorisation number and specific composition of each individual product 42](#_Toc93420849)

[2.1.17 Packaging of the biocidal product 43](#_Toc93420850)

[2.1.18 Documentation 43](#_Toc93420851)

[**2.1.18.1** Data submitted in relation to product application 43](#_Toc93420852)

[**2.1.18.2** Access to documentation 43](#_Toc93420853)

[2.2 Assessment of the biocidal product family 43](#_Toc93420854)

[2.2.1 Intended uses as applied for by the applicant 43](#_Toc93420855)

[2.2.2 Physical, chemical and technical properties 48](#_Toc93420856)

[2.2.3 Physical hazards and respective characteristics 62](#_Toc93420857)

[2.2.4 Methods for detection and identification 69](#_Toc93420858)

[2.2.5 Efficacy against target organisms 73](#_Toc93420859)

[**2.2.5.1** Function and field of use 73](#_Toc93420860)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 73](#_Toc93420861)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 73](#_Toc93420862)

[**2.2.5.4** Mode of action, including time delay 73](#_Toc93420863)

[**2.2.5.5** Efficacy data 74](#_Toc93420864)

[**2.2.5.6** Occurrence of resistance and resistance management 89](#_Toc93420865)

[**2.2.5.7** Known limitations 89](#_Toc93420866)

[**2.2.5.8** Evaluation of the label claims 89](#_Toc93420867)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 90](#_Toc93420868)

[2.2.6 Risk assessment for human health 91](#_Toc93420869)

[**2.2.6.1** Assessment of effects on Human Health 91](#_Toc93420870)

[**2.2.6.2** Exposure assessment 94](#_Toc93420871)

[**2.2.6.3** Risk characterisation for human health 139](#_Toc93420872)

[2.2.7 Risk assessment for animal health 162](#_Toc93420873)

[2.2.8 Risk assessment for the environment 162](#_Toc93420874)

[**2.2.8.1** Effects assessment on the environment 162](#_Toc93420875)

[**2.2.8.2** Exposure assessment 165](#_Toc93420876)

[**2.2.8.3** Risk characterisation 181](#_Toc93420877)

[*3* Annexes 185](#_Toc93420878)

[3.1 List of studies for the biocidal product (family) 185](#_Toc93420879)

[3.2 Output tables from exposure assessment tools 185](#_Toc93420880)

# CONCLUSION

MILK OF LIME, containing 12 to 45 % of calcium dihydroxide, is a PT2 and PT3 biocidal product family intended for professional for the disinfection of:

* sewage sludge (PT2), indoor or outdoor, against bacteria, yeast, fungi, virus and nematode eggs,
* indoor bedding materials and manure (PT3), walls of livestock buildings (PT3), indoor floor surfaces of animal accommodations and transportation (PT3) and outdoor floor of animal enclosures (PT3), against bacteria, yeast, fungi and virus.

The biocidal product family has been organised into two meta SPC:

* Meta SPC 1: products with active substance content range from 20 to 45% w/w;
* Meta SPC 2: products with active substance content range from 12 to 19.99% w/w.

**Physico chemical properties and analytical methods**

The biocidal products are 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.

The products are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties and they are not classified corrosive to metals.

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

**Efficacy**

The product family MILK OF LIME has shown a sufficient efficacy:

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

The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.

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

For virus, for the disinfection of sewage sludge, during the EFF WG-I-2022 of March 2022, the EFF WG concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control.

It has to be noted that for the large majority of cases, the sanitation process is based on addition of lime. 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 in some national regulations (less than 3 viable helminth eggs per 10 g of TS4)

Nevertheless, French legislation requires also microbiological controls of sanitised sludge prior soil spreading where quality indicators are defined on various pathogens, among which virus[[1]](#footnote-2). Recently, during the Coronavirus pandemic[[2]](#footnote-3), sanitation of all sewage sludge was recommended to prevent potentially contaminated sludge speading.

Then, even if eCA agree that efficacy critera are not strictly fulfilled in the efficacy study against virus according to the efficacy guidance (Vol II part B/C), eCA suggest that the SPC points out at section 6 that “lime has a virucidal activity and in case of spreading the treated sludge, the hygienized sludge must meet the microbiological quality indicators defined in the national regulations”. Thus, professional users disinfecting sludges comply with national regulation regarding virus.

* **For the disinfection of manure (PT3), against bacteria, virus and endoparasite (helminth eggs).**
* **For the disinfection of bedding materials (PT3), against bacteria and virus.**

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

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

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

* **For the disinfection of indoor floor surfaces of animal accommodations and transportation (PT3), against bacteria, yeast, fungi and virus at the application rate of 1 kg active substance/m².**
* **For the disinfection of animal accomodations; limewashing of walls against bacteria, yeast, fungi, viruses at the application rate of 800 g active substance /m²**
* **For the disinfection of livestock buildings walls (PT3) floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus at the application rate of 800 g active substance/m².**

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

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

**Resistance**

Literature searches have not revealed indication of resistance to lime.

**Human health**

**Disinfection of sewadge sludge and manures:**

The risk is considered as acceptable for all meta SPC if the following PPE/RPE are worn:

* automatic loading:
  + gloves,
  + coated coverall,
  + face shield.
  + cleaning of equipment:
* gloves,
* coated coverall,
* mask APF 40,
* goggles.
* rinsing of commercial packaging:
* gloves,
* coated coverall,
* face shield.

The following RMM are needed:

* Wear protective gloves and protection coverall during the manipulation of treated sewage sludge or manure.
* Minimisation of splashes and spills.
* The semi-automatic loading of the product in the blender must be carried out directly from the packaging.

Moreover, it is also likely that the addition of calcium dihydroxide to sewage leads to the production of ammonia gas, which may be of some concern. It is very difficult to predict the likely air concentrations that would prevail in treatment plants and whether they are likely to exceed such exposure limits.

Therefore, during the treatment of sewage sludge, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. During the cleaning step, the concentration of ammonia is considered be below than the one during the application step.

**Disinfection of floor surfaces:**

**Manual application :**

*High-pressure sprayer*

Meta SPC 1:

The risk is considered as unacceptable even if PPE are worn due to systemic and local effects of active susbtance.

Meta SCP 2:

The risk is considered acceptable considering systemic effects but unacceptable considering local effects of the active substance, even if a RPE is worn.

*Low-pressure sprayer*

Meta SPC 1:

The risk is considered as acceptable considering local effects of active substance but unacceptable considering systemic effects, even if PPE are worn.

Meta SPC 2:

The risk is considered as acceptable if the following PPE/RPE are worn during semi-automatic loading, manual application and cleaning of spray equipment:

* gloves,
* impermeable coverall,
* face shield.

and during rinsing of commercial packaging:

* gloves,
* coated coverall,
* face shield.

Moreover, the following RMM are needed:

* Minimisation of splashes and spills.
* The semi-automatic loading of the product in the sprayer must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.
* The application must be performed downwards with a low-pressure sprayer.
* During application, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas (only for use 4 disinfection of animal bedding materials).

**Semi-automatic application :**

The risk is considered acceptable if the following PPE/RPE are worn during:

* semi-automatic loading :
  + gloves,
  + impermeable coverall,
  + face shield.
* application :
* gloves,
* impermeable coverall,
* mask APF 40,
* goggles.
* rinsing of commercial packaging:
* gloves,
* coated coverall,
* face shield.

Moreover, the following RMM are needed:

* Minimisation of splashes and spills.
* The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.
* During application, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas (only for use 4 disinfection of animal bedding materials).

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

The risk is considered acceptable if the following PPE/RPE are worn during:

* semi-automatic loading :
  + gloves,
  + coated coverall,
  + face shield.
* application :
  + gloves,
  + coated coverall,
  + mask APF 4,
  + goggles.
* rinsing of commercial packaging:
  + gloves,
  + coated coverall,
  + face shield.

Moreover, the following RMM are needed:

* Minimisation of splashes and spills.
* Do not touch the treated wall the day of treatment.
* Do not touch the treated wall until complete drying of treated surfaces.
* The semi-automatic loading of the product in the buckets must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.

**Animal Health**

No exposure is expected for animals. The following instruction for use is proposed during application: “use only in the absence of animals*.”*

**Risk for consumers via residues in food**

Regarding the natural exposure and the toxicological properties of Ca2+, the dietary risk from consumer related to the intended uses is considered negligible.

**Risk for environment**

Acceptable risks for the environment are foreseen for the uses:

In PT2:

* disinfection of sewage sludge,

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

* disinfection of manure,
* disinfection of animal bedding material,
* disinfection of indoor walls of animal accommodations,
* disinfection of indoor floor of animal accommodations and transportation,

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

* disinfection of floors of outdoor animal enclosures.

**Authorized uses for MILK OF LIME:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Meta SPC** | **Users** | **Target organism** | **Application rate validated** | **Field of use** |
| 1 | Professional | Bacteria,  Endoparasites (helminth eggs) | Ready to use product : the pH must be above 12 | Disinfection of sewage sludge (PT2)  The product is mixed with the sewage sludge in a open mixer. The product must be loaded by a fully automated processes. |
| Professional | Bacteria,  Viruses,  Endoparasites (helminth eggs) | Ready to use product : the pH must be above 12 | Disinfection of manure indoor and outdoor livestock buildings (PT3)  The product is mixed with manure in an open blender. The product must be poured by a fully automated processes. |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :1 kg AS / m² | Disinfection of indoor floor surfaces of animal accomodations and transportation (PT3)  Spread onto the floors with a semi-automated spreader. |
| Professional | Bacteria,  Viruses | Ready to use product : the pH must be above 12 | Disinfection of animal bedding materials (straw, sawdust, woodchip) indoor livestock buildings (PT3)  Spread the product onto the bedding materials with a semi-automatic spreader. |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :  800 g AS / m² | Disinfection of animal accommodations walls (PT3).  The product is applied with a brush onto the walls of accomodations (poultry, cattle, sheep). |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :  800 g AS / m² | Disinfection of floors of outdoor animal enclosures (poultry) (PT3)  Spread onto the floors with a semi-automated spreader. |
| 2 | Professional | Bacteria,  Endoparasites (helminth eggs) | Ready to use product : the pH must be above 12 | Disinfection of sewage sludge (PT2)  The product is mixed with the sewage sludge in a open mixer. The product must be loaded by a fully automated processes. |
| Professional | Bacteria,  Viruses  Endoparasites (helminth eggs) | Ready to use product : the pH must be above 12 | Disinfection of manure indoor and outdoor livestock buildings (PT3)  The product is mixed with manure in an open blender. The product must be poured by a fully automated process. |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :1 kg AS / m² | Disinfection of indoor floor surfaces of animal accomodations and transportation (PT3)  Spread the product onto the floors manually (spraying downwards at low pressure) or using a semi-automatic spreader. |
| Professional | Bacteria,  Viruses | Ready to use product : the pH must be above 12 | Disinfection of animal bedding materials (straw, sawdust, woodchip) indoor livestock buildings (PT3)  Spread the product onto the bedding materials manually (spraying downwards at low pressure) or using a semi-automatic spreader. |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :  800 g AS / m² | Disinfection of animal accommodations walls (PT3).  The product is applied with a brush onto the walls of accomodations (poultry, cattle, sheep). |
| Professional | Bacteria,  Yeast,  Fungi,  Viruses | Ready to use product :  800 g AS / m² | Disinfection of floors of outdoor animal enclosures (poultry) (PT3)  Spread onto the floors manually (spraying downwards at low pressure) or using a semi-automatic spreader. |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[3]](#footnote-4)** | **Country (if relevant)** |
| --- | --- |
| Milk of lime | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Lhoist France Ouest |
| **Address** | 15 rue Henri Dagallier 38 100 Grenoble, France |
| **Authorisation number** | FR-2022-0052 | |
| **Date of the authorisation** | 22/06/2022 | |
| **Expiry date of the authorisation** | 21/06/2032 | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Lhoist France Ouest |
| **Address of manufacturer** | Lieu-dit Les Gaillards  36 800 Saint Gaultier, France |
| **Location of manufacturing sites** | Lieu-dit Les Gaillards  36 800 Saint Gaultier, France |

|  |  |
| --- | --- |
| **Name of manufacturer** | Lhoist France Ouest |
| **Address of manufacturer** | BP6  47 500 Sauveterre La Lémance, France |
| **Location of manufacturing sites** | Lieu-dit Le Martinet  47 500 Sauveterre La Lémance, France |

|  |  |
| --- | --- |
| **Name of manufacturer** | Lhoist France Ouest |
| **Address of manufacturer** | Lieu-dit Les Justices  24 120 Terrasson Lavilledieu, France |
| **Location of manufacturing sites** | Lieu-dit Les Justices  24 120 Terrasson Lavilledieu, France |

|  |  |
| --- | --- |
| **Name of manufacturer** | Lhoist France Ouest |
| **Address of manufacturer** | BP 0215 Neau  53 602 Evron Cedex, France |
| **Location of manufacturing sites** | Lieu-dit Geslin  53 150 Neau, France |

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

|  |  |
| --- | --- |
| **Active substance** | Calcium dihydroxide |
| **Name of manufacturer** | Lhoist France Ouest |
| **Address of manufacturer** | 15 rue Henri Dagallier 38 100 Grenoble, France |
| **Location of manufacturing sites** | 4 origins are used:  1/BP6 47500 Sauveterre La Lemance France  2/Les justices 24120 Terrasson Lavilledieu France  3/Les Gaillards 36800 Saint Gautier France  4/BP 0215 Neau 53602 Evron France |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substance

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

#### Candidate for substitution

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

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Calcium dihydroxide | Calcium  dihydroxide | Active substance | 1305-62-0 | 215-137-3 | 12.0 | 45.0 |

#### Information on technical equivalence

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

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

The biocidal product does not contain any substance of concern.

See confidential annex for details.

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

The biocidal product contains active substance calcium dihydroxide, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

See confidential annex for details.

#### Type of formulation

|  |
| --- |
| SD (concentrated suspension of calcium dihydroxide - ready to use) |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

| Number 1 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 and 3 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** |
| --- | --- | --- | --- | --- | --- |
| Calcium dihydroxide | Calcium dihydroxide | Active substance | 1305-62-0 | 215-137-3 | 20 - 45.0 |

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| SD (concentrated suspension of calcium dihydroxide - ready to use) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

### Authorised use(s) fort he META SPC 1

#### Use description

Table 1. Use # 1 – Disinfection of sewage sludge

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria and endoparasites (helminth eggs) |
| **Field of use** | Indoor, outdoor |
| **Application method(s)** | Direct and automated application  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. |
| **Application rate(s) and frequency** | Ready to use  The product is mixed with the sewage sludge  The application rate must be sufficient to maintain a pH >12 during the contact time.  Contact time: 24H to several weeks for helminth 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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * The application rate must be sufficient to maintain a pH >12 during the contact time. * Apply at 0.003 kg -30 kg of active substance (calcium hydroxide) per ton/m3 sludge. * The application dose should be set to achieve a rate of 20 - 50% of the dry solids weight of sludge. * The ratios may vary between applications and treatment plant designs. The user must ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The automatic loading of the product in the blender must be carried out directly from the packaging. * During the automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * During cleaning of equipment, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Wear protective gloves and protection coverall during the manipulation of treated sewage sludge. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 – Disinfection of manure

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, virus and endoparasites (helminth eggs) |
| **Field of use** | Application to manure inside or outside animal houses |
| **Application method(s)** | Direct and automated application by mix with manure  The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use. |
| **Application rate(s) and frequency** | Ready to use  The product is mixed with the manure  Contact time: 72 hours to several weeks for helminth 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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * The application rate must be sufficient to maintain a pH >12 during the contact time. * Application to manure outside animal houses: * 1. Remove the manure or litter from the animal house. * 2. Do not apply more than 30 kg lime /m3 of manure. * 3. Stockpile the lime treated manure. * 4. After the necessary contact time, dispose of the lime treated manure according to local legislation. * Application of lime to manure inside animal houses: * 1. Do not apply more than 30 kg lime /m3 of manure inside the animal house. * 2. Remove the lime/manure mixture from the animal house. * 3. Homogenise the manure or litter mixture. * 4. Stockpile the lime treated manure. * 5. After the necessary contact time, dispose the lime treated manure according to the local legislation. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The automatic loading of the product in the blender must be carried out directly from the packaging. * During the automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * During cleaning of equipment, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Wear protective gloves and protection coverall during the manipulation of treated sewage sludge. * Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant. |

#### 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

|  |
| --- |
| - |

#### Use description

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

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application with a semi-automated spreader  The product is spread directly onto the floors of animal accomodations (poultry, cattle, sheep) |
| **Application rate(s) and frequency** | Ready to use  1 kg active substance/m²  Contact time: 48H |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * The product is spread onto the floors of animal accommodations using a semi-automated spreader. * A. On concrete floors: * 1. Wash the installation with running water. * 2. Sprinkle approx.1 kg of active substance per m2 on the damp ground. * 3. Leave to act for at least 48 h. * B. On beaten-earth floors: * 1. Brush and wet the floor. * 2. Sprinkle approx.1 kg of active substance per m2 on the damp ground. * 3. Leave to act for at least 48 h. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant. * Forbid children’s access to treated floors.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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

|  |
| --- |
| - |

#### Use description

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

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application with a semi-automated spreader  The product is spread directly onto animal bedding materials (straw, sawdust, woodchip) |
| **Application rate(s) and frequency** | Ready-to-use  The application rate must be sufficient to maintain a pH >12 during the contact time.  Contact time: 72 h |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Cattle: Spread onto mulched or soiled bedding, do not apply lime alone to animal stalls. Use 1 to 1.5 kg of active substance per livestock unit per week in straw area. 200 to 300 g of active substance per stall once or twice a week. * Sheep/goats: 110 to 200 g of active substance/m2 per head/week. * Poultry: 100 to 200 g of active substance/m2 1-2 times per week. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant. * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * Forbid children’s access to treated floors.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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

|  |
| --- |
| - |

#### Use description

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

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application with a brush  The product is applied by brushing onto the walls of accomodations (poultry, cattle, sheep) |
| **Application rate(s) and frequency** | Ready to use product  800 g of AS/m²  Contact time: 48 hours |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Clean the surface with running water before the application of the product. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The semi-automatic loading of the product in buckets must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * Do not touch the walls the day of treatment. * Do not touch the treated wall until complete drying of treated surfaces. * Forbid children’s access to fresh and dried treated surfaces. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * During application, wear: * a respiratory mask at least APF 4 (respiratory mask type to be specified by the autorisation holder within the product information), * chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant. |

#### 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

|  |
| --- |
| - |

#### Use description

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

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Outdoor |
| **Application method(s)** | Direct application with a semi-automated spreader  The product is spread directly onto the surface of animal enclosures (poultry) |
| **Application rate(s) and frequency** | Ready to use  800 g of AS / m²  Contact time: 48 hours  2 applications/year at a maximum |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Brush and wet the floor before the application of the product. * At the beginning of a production cycle it is recommended to spread the product onto the ground and apply water to the soil. * Leave to act for at least 48 hours before bringing in poultry. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not exceed two applications per year. * Forbid children’s access to treated floors.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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 of the meta SPC 1

#### Instructions for use

|  |
| --- |
| * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). * Always read the label or leaflet before use and respect all the instructions provided. * 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. * Use only in the absence of animals. * 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. |

#### Risk mitigation measures

|  |
| --- |
| * Minimisation of splash and spills. * During rinsing of commercial packaging, wear: * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. |

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

|  |
| --- |
| * IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.   If symptoms: Call 112/ambulance for medical assistance.  If no symptoms: Call a POISON CENTRE or a doctor.   * IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. * IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. * Call 112/ambulance for medical assistance. |

#### 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

|  |
| --- |
| ***In France only:***  *Lime has a virucidal activity (see Anses opinion 2020-SA-0043 of the 27th of March 2020).*  *In case of spreading of the treated sludge, the hygienised sludge must meet the microbiological quality indicators defined in the national regulations. In France, the criteria are defined in the “arrêté du 8 janvier 1998”.* |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Basisec / NEUTRALAC® SLS 45 / NEUTRALAC® Calciflo Easylight** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content technical(%)** |
| Calcium dihydroxide | Calcium dihydroxide | Technical active substance | 1305-62-0 | 215-137-3 | 45.0 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **NEUTRALAC® SL30** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Calcium dihydroxide | Calcium dihydroxide | Technical active substance | 1305-62-0 | 215-137-3 | 30.0 |

**Part II - Second information level - meta SPC 2**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 2 |
| --- | --- |

#### Suffix to the authorisation number

| Number 2 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 and 3 |
| --- | --- |

### Meta SPC 2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** |
| --- | --- | --- | --- | --- | --- |
| Calcium dihydroxide | Calcium dihydroxide | Active substance | 1305-62-0 | 215-137-3 | 12.0 – 19.99 |

#### Type(s) of formulation of the meta SPC 2

|  |
| --- |
| SD (concentrated suspension of calcium dihydroxide - ready to use) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

| **Classification** | |
| --- | --- |
| Hazard category | Skin irritation, category 2  Serious eye damage, category 1 |
| Hazard statement | H315: Causes skin irritation  H318: Causes serious eye damage |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H315: Causes skin irritation  H318: Causes serious eye damage |
| Precautionary statements | P264: Wash … thoroughly after handling.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P302+P352: IF ON SKIN: Wash with plenty of soap and water.  P321: Specific treatment (see … on this label).  P332+P313: If skin irritation occurs: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash it before reuse.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTRE or doctor/physician. |
|  | |
| Note |  |

### Authorised use(s) fort he META SPC 2

#### Use description

Table 7. Use # 1 – Disinfection of sewage sludge

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria and endoparasite (helminth eggs) |
| **Field of use** | Indoor, outdoor |
| **Application method(s)** | Direct and automated application by mix with sewage sludge.  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. |
| **Application rate(s) and frequency** | Ready to use  The application rate must be sufficient to maintain a pH >12 during the contact time.  Contact time: 24H to several weeks for helminth 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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * The application rate must be sufficient to maintain a pH >12 during the contact time. * Apply at 0.003 kg -30 kg of active substance (calcium hydroxide) per ton/m3 sludge. * The application dose should be set to achieve a rate of 20 - 50% of the dry solids weight of sludge. * The ratios may vary between applications and treatment plant designs. The user must ensure that the treatment is effective through preliminary laboratory tests that guarantee efficacy according to the legislation applicable to each case. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The automatic loading of the product in the blender must be carried out directly from the packaging. * During the automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * During cleaning of equipment, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Wear protective gloves and protection coverall during the manipulation of treated sewage sludge. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 8. Use # 2 – Disinfection of manure

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, viruses and endoporasite (helminth eggs) |
| **Field of use** | Application to manure/litter inside or outside animal houses |
| **Application method(s)** | Direct and automated application by mix with manure  The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use. |
| **Application rate(s) and frequency** | Ready to use of product  The application rate must be sufficient to maintain a pH >12 during the contact time.  Contact time: 72 hours to 90 days for helminth 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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Application to manure/litter outside animal houses: * 1. Remove the manure or litter from the animal house. * 2. Do not apply more than 100 kg lime /m3 of litter or manure. * 3. Stockpile the lime treated manure. * 4. After te necessary contact time, dispose of the lime treated manure according to local legislation. * Application of lime to litter or manure inside animal houses: * 1. Do not apply more than 30 kg lime /m3 of litter or manure inside the animal house. * 2. Remove the lime/manure or lime/litter mixture from the animal house. * 3. Homogenise the lime/manure or litter mixture. * 4. Stockpile the lime treated manure. * 5. After the necessary contact time, dispose the lime treated manure according to the local legislation. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The automatic loading of the product in the blender must be carried out directly from the packaging. * During the automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * During cleaning of equipment, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Wear protective gloves and protection coverall during the manipulation of treated sewage sludge. * Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 9. Use # 3 – Disinfection of indoor floor surfaces of animal accomodations and transportation

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application manually (spraying downwards at low pressure) or with a semi-automated spreader  The product is spread directly onto the floors of animal accomodations (poultry, cattle, sheep) |
| **Application rate(s) and frequency** | Ready to use  1 kg active substance /m²  Contact time: 48 H |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * The product is spread onto the floors of animal accommodations using manual application (spraying downwards at low pressure) semi-automated spreader. * A. On concrete floors: * 1. Wash the installation with running water. * 2. Sprinkle approx.1 kg of active substance per m2 on the damp ground. * 3. Leave to act for at least 48 h. * B. On beaten-earth floors: * 1. Brush and wet the floor. * 2. Sprinkle approx.1 kg of active substance per m2 on the damp ground. * 3. Leave to act for at least 48 h. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant. * Forbid children’s access to treated floors.   **Manual application (low-pressure, downwards):**   * The semi-automatic loading of the product in the sprayer must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * The application must be performed downwards with a low-pressure sprayer. * During semi-automatic loading, application and cleaning of spray equipment, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 10. Use # 4 – Disinfection of animal bedding materials

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application manually (spraying downwards at low pressure) or with a semi-automated spreader  The product is spread directly onto animal bedding materials (straw, sawdust, woodchip) |
| **Application rate(s) and frequency** | Ready-to-use  The application rate must be sufficient to maintain a pH >12 during the contact time.  Contact time: 72 hours |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Cattle: Spread onto mulched or soiled bedding, do not apply lime alone to animal stalls. Use 1 to 1.5 kg of active substance per livestock unit per week in straw area. 200 to 300 g of active substance per stall once or twice a week. * Sheep/goats: 110 to 200 g of active substance/m2 per head/week. * Poultry: 100 - 200 g of active substance/m2 1-2 times per week. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. * Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant. * Forbid children’s access to treated floors.   **Manual application (low-pressure, downwards):**   * The semi-automatic loading of the product in the sprayer must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * The application must be performed downwards with a low-pressure sprayer * During semi-automatic loading, application and cleaning of spray equipment, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 11. Use # 5 – Disinfection of animal accommodations; limewashing of walls

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application with a brush  The product is applied by brushing onto the walls of accomodations (poultry, cattle, sheep) |
| **Application rate(s) and frequency** | Ready to use product  800 g AS/m²  Contact time: 48 hours |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Clean the surface with running water before the application of the product. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * The semi-automatic loading of the product in buckets must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. * During application, wear: * a respiratory mask at least APF 4 (respiratory mask type to be specified by the autorisation holder within the product information), * chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * goggles. * Do not touch the walls the day of treatment. * Do not touch the treated wall until complete drying of treated surfaces. * Forbid children’s access to fresh and dried treated surfaces. * Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 12. Use # 6 – Disinfection of floors of outdoor animal enclosures

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Outdoor |
| **Application method(s)** | Direct application manually (spraying downwards at low pressure) or with a semi-automated spreader  The product is spread directly onto the surface of animal enclosures (poultry) |
| **Application rate(s) and frequency** | Ready to use  800 g active substance/m²  Contact time 48H  2 applications/year at a maximum |
| **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 containers). |

#### Use-specific instructions for use

|  |
| --- |
| * Brush and wet the floor before the application of the product. * At the beginning of a production cycle it is recommended to spread the product onto the ground and apply water to the soil. * Leave to act for at least 48 hours before bringing in poultry. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not exceed two applications per year. * Forbid children’s access to treated floors.   **Manual application (low-pressure, downwards):**   * The semi-automatic loading of the product in the sprayer must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * The application must be performed downwards with a low-pressure sprayer * During semi-automatic loading, application and cleaning of spray equipment, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield.   **Semi-automatic process:**   * The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun. * During the semi-automatic loading of the product, wear : * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * face shield. * During application, wear: * a respiratory mask at least APF 40 (respiratory mask type to be specified by the autorisation holder within the product information), * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 4), * goggles. |

#### 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 of the meta SPC 2

#### Instructions for use

|  |
| --- |
| * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). * Always read the label or leaflet before use and respect all the instructions provided. * 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. * Use only in the absence of animals. * 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. |

#### Risk mitigation measures

|  |
| --- |
| * Minimisation of splash and spills. * During rinsing of commercial packaging, wear: * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * protective coverall (at least category III type 6), * face shield. |

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

|  |
| --- |
| * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. * IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. * Call 112/ambulance for medical assistance. |

#### 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

|  |
| --- |
| ***In France only****:*  *Lime has a virucidal activity (see Anses opinion 2020-SA-0043 of the 27th of March 2020).*  *In case of spreading of the treated sludge, the hygienised sludge must meet the microbiological quality indicators defined in the national regulations. In France, the criteria are defined in the “arrêté du 8 janvier 1998”.* |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **NEUTRALAC® SL12** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Calcium dihydroxide | Calcium dihydroxide | Technical active substance | 1305-62-0 | 215-137-3 | 12 |

### 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 made equipped with an electrical stirrer or with a recirculating pump | 1 m3 | HDPE | closed | Professional | Y |
| Container equipped with an electrical stirrer (IDRA containers). | Up to 25t | Stainless steel | closed | Professional | Y |

### Documentation

#### Data submitted in relation to product application

See Annex 3.1

#### Access to documentation

A letter of access from EulA (applicant supporting the active substance) to the applicant of the biocidal products family (Lhoist France Ouest) has been submitted and allow Lhoist France Ouest to refer to the calcium hydroxide active substance data set.

## Assessment of the biocidal product family

### Intended uses as applied for by the applicant

Table 7. Use # 1 – Disinfection of sewage sludge

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | The product is dosed into the sewage sludge and mixed by means of a blender. The treated sludge may have three destinations - agricultural use, incineration or landfill. |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses, nematode eggs |
| **Field of use** | Indoor, outdoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | The dry product is mixed with the sewage sludge in a open  mixer. The product can be loaded manually or using semi- or fully automated processes.  Apply at 0.003kg -30 kg of active substance per ton/m3 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 application. |
| **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 containers). |

Table 8. Use # 2 – Disinfection of manure

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** | The product is dosed into the manure and mixed by means of a blender. The treated manure is used for agricultural use. |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor, outdoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | Remove the manure or litter from the animal house.  1. For prevention: Add approximately 10 kg of active substance/m3 of  litter or manure.  2. For treatment: Add approx. 100 kg of active substance/m3 of litter  or manure  3. Stockpile the lime treated manure.  4. After at least 24h, dispose of the lime treated manure  according to local legislation.  Application of lime to litter or manure inside animal houses  1. For Prevention: Spread approx. 10 kg of active substance/m3 (2 kg of lime /m2 for 20 cm litter) on the litter or manure inside the poultry house  2. For treatment: Spread approx. 100 kg of active substance/m3 (20 kg of lime /m2 of 20 cm litter) on the litter or manure inside the animal house  3. Remove the lime/manure or lime/litter mixture from the animal house  4. Homogenise the lime/manure or litter mixture  5. Stockpile the lime treated manure  6. After at least 24 h, dispose the lime treated manure according to the local legislation |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | 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 containers). |

Table 9. Use # 3 – Disinfection of indoor floor surfaces of animal accomodations and transportation

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** | The product is spread directly onto the floors of animal accomodations (poultry, cattle, sheep) |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | Disinfection of indoor floor surfaces of animal accommodations and transportation. The product is spread onto the floors of animal accommodations using manual or automated techniques. Manual spreading using a shovel or  semi-automated using a low-impact spreader.  a. On concrete floors  1. Wash the installation with running water  2. Sprinkle sufficient product to  cover the damp ground (e.g. 1 kg of lime/m2)  3.  Leave to act for at least 2 h  B. On mud  floors  1. Brush the floor  2. Sprinkle approx.800 g of active substance per m2 on the damp  ground  3. Leave to act for at least 24 h |
| **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 containers). |

Table 10. Use # 4 – Disinfection of animal bedding materials

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** | The product is spread directly onto animal bedding materials (straw, sawdust, woodchip) |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | Cattle: Spread onto mulched or soiled bedding, do not apply alone to animal stalls. Use 1 to 1.5 kg of active substance per livestock unit per week in straw area. 200 to 300 g of active substance per stall once or twice  a week  Sheep/goats: 110 to 200 g/m2 of active substance per head/week  Poultry: 100 - 200 g/m2 of active substance 1-2 times per week |
| **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 containers). |

Table 11. Use # 5 – Disinfection of animal accommodations; limewashing of walls

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** | The product is diluted in water and the mixture painted onto the walls of accomodations (poultry, cattle, sheep) |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | Application rate: 600g of active substance to 1 m2 |
| **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 containers). |

Table 12. Use # 6 – Disinfection of floors of outdoor animal enclosures

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** | The product is spread directly onto the surface of animal enclosures (poultry) |
| **Target organism (including development stage)** | Bacteria, yeast, fungi, viruses |
| **Field of use** | Outdoor |
| **Application method(s)** | Direct application |
| **Application rate(s) and frequency** | At the beginning of a production cycle it is recommended to  spread 800 g of active substance /m2 of the product onto the ground and apply water to the soil.  At the end of the production cycle it is recommended to remove any remaining material from the soil.  Leave to act for at least 24 hours before bringing in poultry  When the flock is in place, reapply if the ground becomes muddy or unstable. |
| **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 containers). |

### Physical, chemical and technical properties

The products are ready to use. They are aqueous suspension of calcium dihydroxide. They can be applied manually or automated technics. All representative products in the CAR are DP formulation, so no extrapolation is possible to Milk of Lime.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **GLP** | **FR Ca 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 available  Ca. 94% w/w  NEUTRALAC® SL12 (Meta SCP 2)  NEUTRALAC® SL30 (Meta SPC 1)  NEUTRALAC® SLS45 (Meta SPC 1) | 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: 12.4  pH = 12.4  0.24 – 0.26 % w/w as NaOH  pH = 12.4  0.03 % w/w as NaOH  pH = 12.4  0.08 % w/w as NaOH  pH = 12.4  0.11 % w/w as NaOH | SDS/label  Merck Index  CAR  SDS/label  No reference  No reference  No reference | 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.  Additional information has been provided by the applicant and are considered sufficient. |
| Relative density / bulk density | / | Not available  NEUTRALAC® SL45 (meta SPC 1)  NEUTRALAC® SL12 (meta SPC 2)  NEUTRALAC® SL30 (meta SPC 1) | Density: 1.06-1.38 g/cm3 at 20°C  Additional information were reported in the IUCLID dossier by the applicant (no reference):  Suspension at 45%: 1.33 kg/dm3 at 15°C and 20°C  Suspension at 12%: 1.07 kg/dm3 at 15°C and 20°C  Suspension at 30%: 1.20 kg/dm3 at 15°C and 20°C | SDS “Mixture of calcium dihydroxide with water” 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 (meta SPC 1) 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 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; CB3.7/01  Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | Data from the CAR are not suitable for Milk of Lime.  Qualitative data on product NEUTRALAC® SL 30 has been submitted (viscosity, settling, appearance, resuspension, flowability, wet sieve test). Even if the report is not GLP and if methods used are not clearly reported, results show that a deposit is generally observed following storage.  The results confirm that the product should be kept under continuous agigation 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 products are 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 |  | 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. |  |  | 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 | Not reported | Experience indicates that paper bags lined with plastic (to prevent contact with moisture), plastic bags, steel, stainless steel and Aluminium do not react significantly with dry lime and so can be used as container material for this product. Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime based products (e.g. milk of lime) For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk transportation of wet lime products.  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 1200 mL 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: 0.72 mm/year for aluminium half immersed). Consequently, the corrosion rates are below the threshold limit of 6.25 mm/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). | Statement  CTL 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. |  |  | Considering the low solubility and suspensibility of Lime in aqueous solution, FR CA recommends an agitation before application and a 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® SL 30. | Milk of Lime meets the criteria of the wet sieving described in the standard EN 12518: w% refusal at 90 µm < 5.5, and at 600 µm < 0.1.  Wet sieve test before and after 28 day: 1.3-1.5% on a 90µm sieve and no residue on a 600µm sieve. | Wet sieving : UUID :  c890e7a8-5b80-40a4-aec0-abc102785750  Suivi stabilité: UUID : f57e5efe-b44c-49ae-a698-eda8cb927fcb |  | Acceptable.  Wet sieve test using a 90 µm sieve was performed in shelf life study. This study demonstrates that the product should be kept under agitation as residues can be formed on the bottom. |
| Emulsifiability, re-emulsifiability and emulsion stability | Waiver |  | The test is not appropriate for the use of lime products diluted in water for treatment of sewage sludge. |  |  | Not relevant |
| Disintegration time |  |  | Not applicable |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | EN 12485 (Laser diffraction) | NEUTRALAC® SL 30. | Laser diffraction   |  |  | | --- | --- | | 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 |  |  |  |  | No relevant as the product is a ready to use formulation. Additionally, there is no surfactant in the biocidal products. No foam is expected to be formed. |
| Flowability/Pourability/Dustability | not reported | NEUTRALAC® SL 30. | An assessment of the stability of 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 shaken 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 noticed due to low solubility of lime, the products should be kept under continuous agitation. |
| 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 1500 mPa.s for the 45% concentration and below 400 mPa.s for the below 30% concentration. | statement and  Suivi stabilité: UUID : 2ce0c51b-3df9-48f7-aac7-aeb70c1c7632 | / | Values on viscosity have been provided by the applicant. Even if a test according to standard method should have been provided, data are considered acceptable. |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The biocidal products are 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:** one 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. Additionally, as the product is a solution of an inorganic matter, flash point is not relevant according to CLP criteria. |
| 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 according to the assessment report, neither the formulant .Calcium dihydroxide is an inorganic substance, not classified as an oxidizing substance. Even if it contains oxygen, hydrated lime cannot yield dioxygen when it is diluted in water (calcium and hydroxide ions are formed in a certain quantity depending on the low solubility of lime in water) and oxygen is not directly bonded to calcium. Additionally, no heat is expected when milk of lime is diluted in water, in opposition to calcium oxide. On this basis, eCA considers that the products do not possess oxidizing properties. |
| Oxidising solids | Waiver |  | Not applicable |  |  | Not relevant |
| Organic peroxides | Waiver |  | Not applicable |  |  | Not relevant. |
| Corrosive to metals | Waiver |  | Experience indicates that paper bags lined with plastic (to prevent contact with moisture), plastic bags, steel, stainless steel and Aluminium do not react significantly with dry lime and so can be used as container material for this product. Aluminium and other materials sensitive to high pH are not suitable container materials for wet lime based products (e.g. milk of lime) For bulk transport of dry lime, steel, stainless steel and Aluminium can be used. Stainless steel is recommended, whereas Aluminium is unsuitable as container materials for bulk transportation of wet lime products.  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. eCa considers that the method is identical to the one described in Manuel RTDG (test C1). |
| Auto-ignition temperatures of products (liquids and gases) | Waiver |  | In Ca(OH)2, Calcium and Oxygen 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. |
| Relative self-ignition temperature for solids | Waiver |  | In Ca(OH)2, Calcium and Oxygen are in their respective preferred oxidation state.  Consequently, flammability can be excluded. |  |  | Not relevant for liquid formulation. |
| Dust explosion hazard |  |  | Not applicable. |  |  | Nor relevant for liquid formulation. |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The products are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties and they are not classified corrosive to metals. |

### Methods for detection and identification

The products are not the same as the active substance. However, analytical methods employed for the active substance are applicable. Justifications for non-submission of data for the active substance are appropriate for products.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Active substance*  *(CaO, MgO)* | Gravimetric,  Volumetric,  EDTA,  Pyrophosphate,  Insoluble  matter | N/A | N/A | N/A | See Table below | | | N/A | ASTM C25-99  (1999) |
| *Active substance*  *(Na, Mg)* | X-ray  spectrometric  analysis  Ca as % CaO  Mg as % MgO | 5 |  |  | 53.347  53.683  54.304  55.599  55.837  0.176  0.216  0.637  0.919  1.406 |  | 0.28 %  0.30 %  0.23 %  0.20 %  0.26 %  8.52 %  2.78 %  1.10 %  1.09 %  3.49 % |  | ASTM C1271-  99 (1999) |
| *Active substance*  *(calcium,*  *magnesium, oxide and hydroxide).* | ICP  AA | Duplicate |  |  |  |  |  |  | ASTM CC  1301 – 95  (1995)  (Reapproved  2001) |
| *Active substance* | Titration |  | N/A | Reproducibility:  12.64% |  |  | *2.30* |  | EN12945 |
| *Active substance* | AA (Mg) |  |  | Reproducibility:  0.25% |  |  | *0.21* |  | DIN EN  12946  DIN EN  12947  DIN EN  12048  DIN EN  14397-2 |

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

|  |
| --- |
| **Analytical methods for soil** |
| Relevant residues of Lime variants may be calcium, magnesium and hydroxide-ions. The determination of calcium and magnesium may be done e.g. with a complexometric method with EDTA or an Atomic Absorption method as described for the analysis of the active. Hydroxide-ions can be determined by acid-base titration or the measurement of pH-values. The main influences of Lime variants on soil are the change of the pH-value and the change of 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 – Agitation method””. However, given that these ions will occur naturally in soil and hydrated lime is commonly used for agricultural liming it would not be possible to determine the source of these ions as being from biocidal use. In addition, the biocidal use of hydrated lime allows for application of the treated sewage or manure to agricultural land (as a replacement for agricultural liming). Given this, the normal requirement for more detailed analysis of the active/residues in soil would seem unnecessary. |

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

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

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

|  |
| --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| Any analysis for the active/residues in food/feedstuffs would not be able to establish the origin of the ions as being naturally occurring, from liming or following use as a biocide. Established standard methods for the determination of Hydrated lime components (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 & the nature of the active/residues the requirement for more detailed analysis of the active/residues in food or feedstuffs would seem unnecessary. |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical methods for the active substance are applicable to the product. The ISO method for detection of the substance in air is applicable to monitor workplace exposures. 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

PT3: Veterinary hygiene

The products are suspension in water (milk), intended for use in the disinfection of sludge prior to spreading on the land or prior incineration (PT2) and applied on hard surfaces, bedding materials, manures, equipment and vehicles for veterinary applications such as livestock housing and the transportation of animals (PT3).

They are not intended to be used for direct contact with food or feeding stuffs.

The products are intended to be applied directly on surfaces beforehand wet.

In the case of bedding materials, manure and sewage sludge, this will likely be directly into the substrate.

The products are for professional users only.

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

Disinfectant products intended to control bacteria, yeast, fungi, viruses and endoparasites: helminth eggs in sewage sludge, manures, on surfaces, materials, equipment and vehicles in veterinary applications such as livestock housing and the transportation of animals.

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

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

The products are 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 developmental inhibition of endoparasites: helminth 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

Whatever the intended uses, efficacy tests have been performed with calcium oxide and/or calcium dihydroxide active substances. As the product MILK OF LIME is formulated with only calcium dihydroxide + solvent (water) without biocidal efficacy, read-accross is acceptable. Note that in the SPC, application rates are expressed in active substance, the user should implement the dose of product needed to achieve the efficient rate.

Both active substance and products may be referred to as “Lime”. Lime is a generic term, but by strict definition it only embraces manufactured forms of lime – quicklime (CaO) and hydrated lime (Ca(OH)2). 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 hydroxide in contact with water.

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

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

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

Simulated-use tests has been performed with lime (alone or suspended in water) in order to demonstrate efficacy of lime to disinfect sewage sludge.

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

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

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

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

It has to be noted that no negative control has been performed in the test.

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

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

It has to be noted that in the conditions tested, efficacy is related to the effects of pH and heat.

In the third study (6.7.03), the disinfectant effect of hydrated lime added to raw sewage sludge was investigated with special consideration of the influence on the following digestion process. In preliminary investigations in laboratory scale, the necessary pH-value and contact time of the sludge/lime mixture for a safe inactivation of salmonellas and coliforms 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* and coliforms were 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. Efficacy of calcium hydroxide has been shown against bacteria.

Based on these efficacy data, the efficacy of calcium hydroxide is demonstrated for the disinfection of sewage sludge, against bacteria and helminth eggs. Effective treatment is 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.

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

For virus, during the EFF WG-I-2022 of March 2022, in the frame of discussions for a similar product based on the same efficacy dataset, the EFF WG concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control in the first study.

It has to be noted that for the large majority of cases, the sanitation process is based on addition of lime. 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 in some national regulations (less than 3 viable helminth eggs per 10 g of TS4)

Nevertheless, French legislation requires also microbiological controls of sanitised sludge prior soil spreading where quality indicators are defined on various pathogens, among which virus[[4]](#footnote-5). Recently, during the Coronavirus pandemic[[5]](#footnote-6), sanitation of all sewage sludge was recommended to prevent potentially contaminated sludge speading.

Then, even if eCA agree that efficacy critera are not strictly fulfilled in the efficacy study against virus according to the efficacy guidance (Vol II part B/C), eCA suggest that the SPC points out at section 6 that “lime has a virucidal activity and in case of spreading the treated sludge, the hygienized sludge must meet the microbiological quality indicators defined in the national regulations”. Thus, professional users disinfecting sludges comply with national regulation regarding virus.

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

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

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

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

For calcium hydroxide, in liquid pig and cattle manure:

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

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

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

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

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

Based on these efficacy data, the efficacy of calcium dihydroxide is demonstrated for the disinfection of manure, against bacteria, virus and endoparasites: helminth eggs. Effective treatment is 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 dihydroxide, contact time is longer than the one with calcium oxide.

No data has been provided for yeast and fungi.

From the efficacy study, the quantity of lime to be applied should be enough to reach a pH>12 in all the cases. Two recommendations are presented by the applicant, one for routine application (10 kg lime/m3 of manure) and one in case of outbreak (30 kg lime/m3 of manure). Since application rate should be adapted the type of manure in order to achieve a pH>12, the SPC should only specify that 30 kg lime/m3 of manure should not be exceeded whatever the circonstancies of manure treatment.

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

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

eCA is of the opinion that the demonstration of efficacy for disinfection of bedding materials is covered by the efficacy data from disinfection of manure, considering that the conditions of uses encountered are less challenging for the product.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 study  Direct mixing of sewage sludge with the biocidal product  The test was applied on two different scales: one to simulate small scale use (mixers of 130 L and 145 L) and the second to simulate industrial scale treatment (cavity mixer-unknown volume).  For the small scale tests, burnt lime was homogeneously mixed into the substrates. The mixture was sampled at intervals to determine the numbers of viable bacteria, viruses or Ascaris eggs.  For the industrial scale test, the mix was pumped and piled for storage. Samples were taken from the stored material at intervals, to determine the numbers of viable bacteria, viruses or Ascaris eggs. | 0.7 kg CaO/kg total dried solids to 1.2 kg CaO/kg total dried solids  Contact time: 1-24 hours, until 8 weeks for *Ascaris suum*  temperatures and pH values were recorded over the time | 0.9 – 1.1 kg burnt lime / kg dried sludge  Small scale test :  pH>12.9    Industrial scale test:    Efficacy criteria achieved:  5 log reduction bacteria  4 log reduction viruses  3 log reduction nematode eggs | 6.7-01  R.I=2 supporting data in the absence of negative control |
| Disinfectant for sewage sludge | PT2 – Use 1 | Milk of lime (Ca(OH)2 suspension in water  Dry hydrated lime (Ca(OH)2  Burnt lime (CaO) | Nematodes  *Ascaris suum* eggs  (Sludge from pig slaughter houses)  Sludge A:  924 ± 295 eggs per 10 g solid  Total solids: 33%  Sludge B  132 ± 108 eggs per 10 g solid  Total solids: 15% | Simulated-use tests:  1), Artificially contaminated milk  of lime was heated to 50°C, 55°C and 60°C.  2) Naturally contaminated sewage sludges were treated with slaked lime (40% weight slaked  lime per weight of sludge dry solids) and afterwards heated to either 50°C or 60°C.  3) Naturally contaminated sewage sludge was treated with  quick lime at a predetermined dose in order to reach 50°C, 55°C and 60°C.  4) Sewage  sludge was treated at full scale with a predetermined dose of quick lime in order to reach temperatures  ranging from 50°C to 60°C and stockpiled. When the stockpile target temperature was reached, bags containing Ascaris eggs were inserted in it. | Contact time : 5-160 minutes  pH ≥12 | Inactivation threshold: duration required to reach a level of inactivation at which no viable egg was detected per g of solid sludge (TS)  Inactivation threshold is:  - in milk of lime and heat, is equal to 70, 5 and 2 min, respectively at 50°C, 55°C and 60°C  - with quick lime, is equal to 120 min at 50°C, to 45 min at 55°C, and 5 min at around 60°C  - with slaked lime and heat, is higher than 128 min at 50°C, and ranges between 4 and 8 min at 60°C  - is equal to 75 min at 55°C and 5 min at 60°C in the industrial situation (quicklime)  => This study has demonstrated that in the four investigated situations, either 75 min at 55°C or 8 min at 60°C will lead to a negligible level of viable Ascaris eggs | 6.7-02  RI=2  No test condition without heat |
| 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 logs  Step 4: in Digester 1, Salmonella and coliforms are detected, while in Digested 2 (treated for the first time), total germs decreased of 3 log. | 6.7-03  RI=2 |
| Disinfectant for manure | PT 3 – Use 2 | Calcium dihydroxide  (liquid manure)  Calcium oxide (solid manure) | Bacteria (lab collection)  *Salmonella senftenberg*  *Enteroccoccus faecium*  For each bacteria: 5.108 CFU/ml,  Virus  *Bovine Parvovirus*  The virus host cells were MDCK cells  Nematodes  *Ascaris suum* eggs (recovered from adult female worms)  2 ml egg suspension in gaze-bags (200000 eggs) | Simulated test  Direct mixing of manure with the biocidal product  Suspension of bacteria was added to liquid manure (100 ml) and filled into the steel pipe, or added to 500 g lime-treated solid manure  Virus:  Sandwich-germ-carrier technique was used (viral suspension was given on an electropositive charged membrane, and exposed to liquid or solid waste)    Nematodes:  Stockpiled lime treated manure and contaminated with gaze-bags of eggs  At the end of the trial the treated aliquots were compared to untreated (unlimed) controls and log reduction calculated | Liquid manure:  Bacteria and viruses: 72H and 96 hours contact time without heating  (except for A. suum eggs – 60 min with heated manure at 60°C)  Solid manure  60 and 120 min contact time  Temperature : 60 and 70°C  pH >12 | Liquid pig and cattle manure (Ca(OH)2) at 72H contact time:  Virus: > 5 log reduction  Bacteria: > 7 log reduction  *Ascaris suum* eggs: 100% development inhibition at 60 min exposure time (manure heated à 60°C)  Solid pig manure and poultry manure (CaO), at 60° C (CT of 60 and 120 min) and at 70°C (CT of 30 and 60 min) :  Virus: > 5 log reduction  Bacteria: > 7 log reduction  *Ascaris suum* eggs: 100% development inhibition | 6.7-06  RI=2 |
| Disinfectant for manures | PT3 – Use 2 | Calcium dihydroxide | Nematodes  *Ascaris suum* eggs (recovered from adult female worms)  2 ml egg suspension in gaze-bags (200000 eggs) | Simulated test  Direct mixing of manure with the biocidal product  Stockpiled lime treated manure and contaminated with gaze-bags of eggs  At the end of the trial the treated aliquots were compared to untreated (unlimed) controls and log reduction calculated | Liquid manure:  Contact time: 30/60/90 days without heating | Contact time: 90 days  liquid pig manure: 100 % development inhibition  liquid cattle manure: 98 % development inhibition | 6.7-13  RI = 2 |

* **Uses 3/5/6 surface disinfection (PT3)**

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

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

Therefore eCA agreed with the following approach to demonstrate the efficacy of lime:

* Laboratory suspension tests (phase 2, step 1 tests) have been withdrawn, as not valid for an insoluble active substance applied as a dry powder or as a thick slurry.
* Laboratory surface tests (phase 2, step 2 tests) according to EN 14349 and EN 16437 have been provided with some deviations from the standard methodology (test coupons are larger, test procedure adapted). Efficacy criteria and experimental conditions (temperature, contact time, interfering substances and test organisms) met the requirements of the norms.
* Bactericidal activity is demonstrated on non-porous surfaces, according to EN 14349, at 10°C, with a contact time of 30 min, in clean (3 g/L BSA) and dirty conditions (10 g/L BSA and 10 g/L yeast extract), in clean conditions (3 g/l BSA) with Calcium dihydroxide-based product at the application rate of 800 g as/m².
* Bactericidal activity is not demonstrated on porous surfaces, according to EN 16437, at 10 °C, with a contact time of 60 min, in clean conditions (3 g/L BSA), with Calcium dihydroxide-based product at the application rate of 800 g as/m².

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

In order to solve these methodology issues and demonstrate the efficacy of lime products for all the activities claimed, the applicant performed both simulated-use tests and field tests:

* Simulated-use tests on a larger scale have been carried out, following a methodology inspired from the French norm NF T 72 281 (for the test procedure and validation parameters) to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice (mosaic tile as stone carriers is then used). Efficacy criteria and experimental conditions (temperature, contact time, interfering substances and test organisms) met the requirements of the surface norms for vet areas.
* Bactericidal activity (4 Log reduction according to EN 14349) and yeasticidal activity (3 Log reduction according to EN 16438) are demonstrated, at 15-22°C, with a contact time of 24 hours, in dirty conditions (10 g/L BSA and 10 g/L yeast extract), with Calcium dihydroxide-based product, used as ready to use, at the application rate of 800 g as/m².

In these conditions, fungicidal activity is not proven (< 3 log reduction).

* Fungicidal activity (3 log reduction according to EN 16438) is demonstrated, at 15-22°C, with a contact time of 24 hours, in clean conditions (3 g/L BSA) with Calcium hydroxide-based product, used as ready to use, at respectively the application rate of 800 g as/m².
* Virucidal activity (3 log reduction according to prEN 17122) is demonstrated, at 15-22°C, with a contact time of 2 hours, in clean conditions (3 g/L BSA), with Calcium hydroxide-based product, used as ready to use, at respectively the application rate of 800 g sa/m².

To complete results from laboratory and simulated-use tests, field tests have been performed in poultry farms during 2 years (in France), in 2018 (summer season) and 2019 (in March), in order to study the biocidal efficacy of lime for use in surface treatment during crawl space. The crawlspace was disinfected between inhabitation by the breeding populations.

The quicklime used in these tests was provided at the dose of 800 g CaO / m² of floor (2018) and 600 g/m² CaO /m² (2019).

This study was conducted in two phases:

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

The second phase consisted in evaluating the effectiveness of CaO under real conditions of disinfectant treatment during sanitary vacuum, on order to demonstrate the effectiveness of the product to be tested. The building is cleaned beforehand with a water pressure washer. The product is then applied directly to wet soil in the area.

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

=> Salmonella and staphylococci are not detected on the floor of the building, either before or after the technical operations (washing, biocidal treatment or not) of the crawl space. Indeed, many precautions are implemented in poultry farms to avoid the presence of salmonella on these sites.

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

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

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

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

=>As a result, a slight mortality of microorganisms in untreated area due to the cleaning the water pressure washer was noticed. Reduction of the order or more than 2/3 logs is obtained for aerobic microorganisms, Pseudomonas sp., yeast and moulds. Abatement is less for other microorganisms since populations in untreated areas are present in small quantities (E. coli, *Clostridium perfringens*, intestinal enterococci). The applied dose of 600 g as/m² gives similar results to 800 g as /m².

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | *Pseudomonas aeruginosa* ATCC 15442,  *Staphylococcus aureus* ATCC 6538  *Enterococcus hirae* ATCC 10541  *Proteus vulgaris* ATCC 13315 | EN 14349 modified  Test coupons: 3.14 cm² with 251 mg of powder applied  To obtain an application rate: equivalent to 800 g/m2 product mixed with 2000 ml/m2 water | 3 g/L BSA)  T°C : 10°C  TC : 30 min  800 g as /m² | Pass  >4 log reduction | 6.7-09  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | *Pseudomonas aeruginosa* ATCC 15442,  *Staphylococcus aureus* ATCC 6538  *Enterococcus hirae* ATCC 10541  *Proteus vulgaris* ATCC 13315 | EN 14349 modified  Test coupons: 3.14 cm² with 251 mg of powder applied to obtain an application rate: equivalent to 800 g/m2 product mixed with 2000 ml/m2 water | Dirty conditions (10 g/L BSA + 10 g/L yeast extract)  T°C : 10°C  TC : 30 min  800 g as/m² | Fail  >4 log reduction sur *P.aeruginosa*, *E.hirae* and *P.vulgaris*  <4 log reduction sur *S.aureus* | 6.7-10  RI = 3 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | *Pseudomonas aeruginosa* ATCC 15442,  *Staphylococcus aureus* ATCC 6538  *Enterococcus hirae* ATCC 10541  *Proteus vulgaris* ATCC 13315 | EN 16437 modified  Test coupons: 2 cm² with 160 mg of powder applied to obtain an application rate: equivalent to 800 g/m2 product mixed with 2000 ml/m2 water | 3 g/L BSA)  T°C : 10°C  TC : 60 min  800 g as/m² | FAIL  *P.aeruginosa* and *P.vulgaris* =>4log reduction  *S.aureus* and *E. hirae* <4log reduction | 6.7-12  RI = 3 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | *Enterococcus hirae* CIP 58.55  *Pseudomonas aeruginosa* DSM 939  *Stapylococcus aureus* DSM 799  *Candida albicans* ATCC 10231  *Aspergillus brasiliensis* ATCC 16404  Strains have been chosen in accordance with those used in the standard EN tests: EN16437, EN16438  Test suspensions prepared in accordance with NF T 72-281 | Simulated test  The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms.  The organisms are placed on carriers (mosaic tiles) and air-dried.  The tiles are placed in the test room and 0.25 L/m2 water added (no pressure);  The test material was applied and another aliquot of water as above to give total water of  0.5L/m2  Survivors counted in accordance with NF T-72-281  Log reduction calculated by comparison between test carriers and control carriers  Efficacy criteria:  Bacteria 3 log reduction  Yeasts/fungi: 3 log reduction | Dirty conditions (10 g/L BSA + 10 g/L yeast extract)  T°C : 15-22°C  Contact time: 2h  *Pseudomonas aeruginosa*  *Candida albicans*  Contact time: 24 h  Remaining organisms  Test material:  Ca(OH) 2:800g as /m2 | Calcium Hydroxide  PASS Bactericidal (> 4 log reduction):  *Pseudomonas aeruginosa*  2 hours contact time  PASS Bactericidal (> 4 log reduction):  *Enterococcus hirae*  *Stapylococcus aureus*  24 hours contact time  PASS Yeasticidal (> 3 log reduction):  *Candida albicans*  2 hours contact time  FAIL: Not Fungicidal (<1 log reduction)  *Aspergillus brasiliensis* | 6.7-15  RE-1143/0419  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | *Aspergillus brasiliensis* DSM 1988  Strain has been chosen in accordance with those used in the standard EN test: EN16438 | Simulated test  The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms.  The organisms are placed on carriers (ceramic tiles) and air-dried.  The tiles are placed in the test room and 0.25 L/m2 water added (no pressure);  The test material was applied and another aliquot of water as above to give total water of  0.5L/m2  Survivors counted in accordance with NF T-72-281  Log reduction calculated by comparison between test carriers and control carriers  Veterinary LowLevel Soil conditions (3.0 g/L bovine albumin)  Efficacy criteria:  Fungi: 3 log reduction | Clean conditions (3 g/L BSA)  T°C : 15-22°C  Contact time: 24h  *Aspergillus brasiliensis*  Test suspensions prepared in accordance with NF T 72-281  Test material:  Ca(OH) 2:800 g as/m2 | PASS  Fungicidal (>3 log reduction) | 6.7-15A  RE-1303/0919/A  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium dihydroxide | Porcine parvovirus  Strain has been chosen in accordance with those used in the standard EN test: prEN17122. | Simulated test  The study is designed to mimic the PT 3 EN surface tests on a larger scale to enable effective quantities of the material, as typically used in practice, to come into contact with the test organisms.  The organisms are placed on carriers (ceramic tiles) and air-dried.  The tiles are placed in the test room and 0.25L/m2 water added (no pressure);  The test material was applied and another aliquot of water as above to give total water of  0.5L/m2  Survivors counted in accordance with NF T-72-281  Log reduction calculated by comparison between test carriers and control carriers  Veterinary High Level Soil conditions  Efficacy criteria:  Virus; 3 log reduction | Dirty conditions (10 g/L BSA+ 10 g/L yeast extract)  T°C : 15-22°C  Contact time: 2h  Porcine parvovirus  Test suspensions prepared in accordance with NF T 72-281  Test material:  Ca(OH) 2:800 g as/m2 | PASS: Virucidal (>3 log reduction)  Porcine parvovirus | 6.7-15B  RE-1298/0819  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium oxide | Organisms monitored:  Aerobic microorganisms at 30°C  Escherichia coli B glucuronidase positive at 44 °C  Clostridium Perfringens  intestinal enterococci  enterobacteria at 30°C  Pseudomonas spp  Aspergillus  Salmonella  Staphylococci Coagulase  Yeasts  Moulds  Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods | Field Trial (poultry farm in France)  The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in poultry farming (indoor floor disinfection).  Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.  Samples are taken on delimited areas of 1x1 m.  Each modality is represented by 6 repetitions, ie 6 zones of 1x1 m  For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.  2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored | Phase 1 control  Standard treatment  Phase 2:  800 g of CaO / m² of soil  Contact time: 48 h  Temp: ambient (max 31.4 deg C) | 100% CaO at 800 g/m2 (48h contact time):  > Log 4 reduction for all organisms analysed  Reduction greater than 4 Log for microorganisms monitored with high initial concentrations (greater than 4 Log10). | 6.7-16  RITTMO 18-445R  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium oxide | Organisms monitored:  Escherichia coli B glucuronidase at 44 °C  Clostridium Perfringens  intestinal enterococci  enterobacteria at 30°C  Pseudomonas spp  Aspergillus  Salmonella  Staphylococci Coagulase  Yeasts  Moulds  Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods | Field Trial (Poultry farm in France)  The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in poultry farming (indoor floor disinfection)  Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.  Samples are taken on delimited areas of 1x1 m. Each modality is represented by 6 repetitions, i.e. 6 zones of 1x1 m  For an area of 1x1 m zone, the microorganisms are removed using sampling cloths. The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.  2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored | 600 g of CaO / m² of soil  Contact time: 48 h  Temp: ambient (Feb 2019: max 7.6 deg C). The increase of the soil temperature is + 3.1 ° between the start of the test and the end of the quicklime intake  pH = 11 after 48H exposure and after hydration.  The soil temperature is increased by 3.1 °C between the start of the test and the end of the quicklime intake.  traces of ammonium (NH3) were measured in the breeding room (between 2 and 6ppm) during product treatment | 100% CaO at 600 g/m2 (48h contact time):  Pathogen concentration has declined sharply to reach values close to the detection limit for these pathogens (< 10 cfu/m²).  Populations of aerobic microorganisms, intestinal enterococci and Pseudomonas have a reduction of more than 3 Log.  Staphylococci are not detected  Initial level s of organisms low with some less than Log3. | 6.7-17  RITTMO 19415R  RI = 2 |
| Surface disinfectant | PT3– Uses 3/5/6 | Calcium oxide | Organisms monitored:  Escherichia coli B glucuronidase  Clostridium Perfringens  intestinal enterococci  enterobacteria  Pseudomonas spp  Aspergillus  Salmonella  Staphylococci Coagulase  Yeasts  Moulds  Analysis performed by Laon Analysis and Research Laboratory (LDAR) using validated standard methods | Field Trial (pig farm in France)  The objective of this test is to study the biocidal efficacy of quicklime (CaO) for use in wetted surface treatment during crawl space in pig farms (indoor floor disinfection)  Monitoring of the presence and concentration of microorganisms before and after treatment in order to evaluate the microbial abatement following the application of the product.  Three treatments were studied: an untreated housing unit, a housing unit treated with 600 g / m² of product, and a last housing unit treated with 800 g / m² of product.  Concrete floor and/or gratings  12 housing of equivalent sizes (4, 5x2 m) – 3 per treatment  Samples are taken on delimited areas of 1x1 m. For an area of 1x1 m zone, the microorganisms are removed using sampling cloths 4 per zone (1/4 surface/wipe). The lime crust is removed from the soil using a shovel rinsed in ethanol and air-dried.  2 wipes are used for the counting of Salmonella spp (the extraction method is different from other microorganisms), and 2 other wipes are used for enumeration of the other microorganisms monitored | 600 or 800g of CaO / m² of soil  Contact time: 40 h  Temp: ambient (ave 8.5 deg C), the temperature rise associated with the hydration of quicklime is limited (max 1.1 °C)  pH = 11 after 40H exposure and after hydration  Follow up of the emissions of ammoniac (NH3): increase emissions of NH3 in the box treated, even they remain very low (max 22 ppm) | 100% CaO at 600 g as/m2 (40h contact time):  >2/3 Log for aerobic microorganisms, Pseudomonas spp, yeast and moulds  Less reduction for the other microorganisms (small level of initial population)  No significant difference between 600 and 800 g as/m2 application in terms of reduction. | 6.7-18  RITTMO 19-431R  RI = 2 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| The product family MILK OF LIME has shown a sufficient efficacy:   * For the disinfection of sewage sludge (PT 2) against bacteria and endoparasites (helminth eggs).   The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time. The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.  No data has been provided for yeast and fungi for the disinfection of sewage sludge.  For virus, for the disinfection of sewage sludge, during the EFF WG-I-2022 of March 2022, the EFF WG concluded that efficacy data submitted for virus were not sufficiently robust, due to the lack of negative control.  It has to be noted that for the large majority of cases, the sanitation process is based on addition of lime. 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 in some national regulations (less than 3 viable helminth eggs per 10 g of TS4)  Nevertheless, French legislation requires also microbiological controls of sanitised sludge prior soil spreading where quality indicators are defined on various pathogens, among which virus[[6]](#footnote-7). Recently, during the Coronavirus pandemic[[7]](#footnote-8), sanitation of all sewage sludge was recommended to prevent potentially contaminated sludge speading.  Then, even if eCA agree that efficacy critera are not strictly fulfilled in the efficacy study against virus according to the efficacy guidance (Vol II part B/C), eCA suggest that the SPC points out at section 6 that “lime has a virucidal activity and in case of spreading the treated sludge, the hygienized sludge must meet the microbiological quality indicators defined in the national regulations”. Thus, professional users disinfecting sludges comply with national regulation regarding virus.   * For the disinfection of manure (PT3), against bacteria, virus and endoparasite (helminth eggs). * For the disinfection of bedding materials (PT3), against bacteria and virus.   The effective final use concentration and contact time are variable. pH should be > 12 during the exposure time.  The proper amount of active substance has to be added to the substrate in order to reach the required pH. It should be calculated by the users with regard to the dry weight of the substrate.  No data has been provided for yeast and fungi for the disinfection of manure.   * For the disinfection of indoor floor surfaces of animal accommodations and transportation (PT3), against bacteria, yeast, fungi and virus at the application rate of 1 kg active substance/m². * For the disinfection of animal accomodations; limewashing of walls against bacteria, yeast, fungi, viruses at the application rate of 800 g active substance /m² * For the disinfection of livestock buildings walls (PT3) floors of outdoor animal enclosures (PT3), against bacteria, yeast, fungi and virus at the application rate of 800 g active substance/m².   The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).  To ensure a satisfactory level of efficacy and avoid the development of resistance, the provisions 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

Please refer to the SPC

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

Not applicable

### Risk assessment for human health

In order to avoid unnecessary animal experiment, no study was conducted. Classification is determined following the CAR 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***

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The biocidal family product is considered irritant to the skin. |
| Justification for the value/conclusion | The product is an aqueous suspension of the active substance.  Considering the content in active substance in the meta SPC 1 and meta SPC 2 superior or equal to 10%, 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 | Classification Skin irritation, category 2 - H315: Causes skin irritation is required. |

***Eye irritation***

*Meta SPC 1-2*

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

***Respiratory tract irritation***

*Meta SPC 1*

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | No new data on irritation in the respiratory tract was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content in active substance in the biocidal product family superiror or equal to 20%, a classification STOT SE 3 H335 is needed. |
| Classification of the product according to CLP and DSD | Classification STOT SE 3 H335: May cause respiratory irritation is required. |

*Meta SPC 2*

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | No new data on irritation in the respiratory tract was performed. The classification is determined using the calculation method of CLP Regulation. Considering the maximum content in active substance in the biocidal product family inferior to 20%, no classification is required. |
| Classification of the product according to CLP and DSD | No classification for respiratory tract irritation is required. |

***Skin sensitization***

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **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 performed. Therefore, the classification is determined according to the CLP Regulation.  No classification for skin sensitisation is required. |
| Classification of the product according to CLP and DSD | No classification for skin sensitisation is required. |

***Respiratory sensitization (ADS)***

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for respiratory sensitisation. |
| Classification of the product according to CLP and DSD | No classification for respiratory sensitisation is required. |

***Acute toxicity***

*Acute toxicity by oral route*

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **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. |
| Classification of the product according to CLP and DSD | No classification for acute oral toxicity is required. |

*Acute toxicity by inhalation*

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **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. |
| Classification of the product according to CLP and DSD | No classification for acute inhalation toxicity is required. |

*Acute toxicity by dermal route*

*Meta SPC 1-2*

|  |  |
| --- | --- |
| **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. |
| Classification of the product according to CLP and DSD | No classification for acute dermal toxicity is required. |

***Information on dermal absorption***

*Meta SPC 1-2*

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

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

*Meta SPC 1-2*

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.

#### Exposure assessment

MILK OF LIME is used by professionals for:

* disinfection of sewage sludge (PT2) and manures (PT3),
* disinfection of floors surfaces (animal accomodation and transportation, animal beddings materials and outdoor enclosure) (PT3),
* disinfection of walls animal accomodation using a brush (PT3).

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

**Calcium and magnesium contents**

The main contents of the lime variants are calcium, magnesium and their oxides and hydroxides. According to the CAR, the assessments of calcium dihydroxide, **calcium and magnesium** exposure are proposed.

The following contents are considered for exposure:

Meta SPC 1

|  |  |
| --- | --- |
| **Calcium and magnesium contents** | |
| Ca(OH)2 (max.) | 45% |
| **Ca (equivalent) (max.)** | **24.3%** |
| **Mg (equivalent) (max.)** | 1.0% |

Meta SPC 2

|  |  |
| --- | --- |
| **Calcium and magnesium contents** | |
| Ca(OH)2 (max.) | 19.99%\* |
| **Ca (equivalent) (max.)** | **10.8%** |
| **Mg (equivalent) (max.)** | 0.46% |

\* For sake of simplicity, the concentration of active substance (Ca(OH)2) has been rounded to 20% for exposure assessment.

**Ammonia**

It is likely that the addition of calcium dihydroxide to sewage sludge/manure/animal beddings leads to the production of ammonia gas, which may be of some concern. Please refer to ammonia assessment (PAR 2.2.6.3).

**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 | Nr | Yes | Nr | n.a. | No | No | No |
| Dermal | Nr | Yes | Nr | n.a. | Yes | Yes | No |
| Oral | Nr | No | Nr | n.a. | No | Yes | No |

First of all, the exposure assessment has been performed at the active substance concentration of 45%, corresponding to the maximum concentration of the products pertaining to the family MILK OF LIME, and consequently to the meta SPC 1.

If the systemic and/or local risk assessment leads to an unacceptable risk at 45% of a.s for some uses, the exposure assessment has been completed with the maximum concentration of meta SPC 2 (20%) to ascertain if the risk is acceptable or unacceptable for these uses.

***List of scenarios***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: scenarios** | | | |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| **Disinfection of sewage sludge and manures** | | | |
| 1. | Automatic loading | Primary  Automatic loading of product to system of sewage sludge and manures | Professionals |
| 2. | Cleaning and maintenance | Primary  Manual cleaning of equipment. | Professionals |
| **Disinfection of floor surfaces** | | | |
| Manual application | | | |
| 3. | Semi-automatic loading | Primary  Semi-automatic loading of the product from packaging (IBC 1m3 or container up to 25t) to the low-pressure sprayer | Professionals |
| 4. | Manual application with low-pressure sprayer (downward application) | Primary  Manual application of product with a manual sprayer equipment (low-pressure).  Downward application | Professionals |
| 5. | Manual application with high-pressure sprayer (loading included) | Primary  Manual application of product with a manual sprayer equipment (high-pressure). The exposure modelling covers also loading of the product from the packaging to the spray equipment | Professionals |
| 6. | Cleaning of equipment | Primary  Manual cleaning of equipment (system application: manual sprayer) | Professionals |
| Semi-automatic application | | | |
| 7. | Semi-automatic loading | Primary  Semi-automatic loading of the product from packaging (IBC 1m3 or container up to 25t) to the tank of tractor sprayer | Professionals |
| 8. | Semi-automatic application | Primary  Semi-automatic application with vehicle-mounted (downward spraying) | Professionals |
| **Disinfection of animal accommodation walls using a brush** | | | |
| 9. | Semi-automatic loading | Primary  Semi-automatic loading of the product from packaging (IBC 1m3 or container up to 25t) to buckets | Professionals |
| 10. | Manual application on walls | Primary  Manual application by brush | Professionals |
| 11. | Cleaning of the brush | Primary  Cleaning of the brush equipment | Professionals |
| 12. | Professional touching freshly-painted or dry surfaces of walls | Secondary  After application, secondary dermal exposure may occur during the contact with the treated surfaces (wet or dried) | Professionals |
| 13. | Toddler touching freshly-painted or dry surfaces of walls and hand-to-mouth transfer | Secondary  After brushing on surfaces, secondary dermal exposure may occur during the contact with the treated surfaces (wet or dried) | General public (Toddler) |

***Professional exposure***

*Scenario [1] Automatic loading of product to system of sewage sludge and manures*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| MILK OF LIME is a suspension packed in containers up to 25t or IBC tanker of 1m3.  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 worker 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 dermal exposure, RISKOFDERM Toolkit Connecting lines Model is used (HEEG opinion 1).  A duration of 10 minutes is taken into consideration (CAR hydrated lime). | | | |
|  | Parameters1 | Value | Reference |
|  | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Duration (min) | 10 | CAR |
| Dermal exposure – Hands only (mg p.b /min) | 0.92 | RISKOFDERM Toolkit Connecting Lines (HEEG Opinion 1) |
| Dermal absorption | 100% | Default value, CAR |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |

***Calculations for Scenario [1]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 1 – automatic application to system | Tier 1/ no PPE | negligible | 3.73E-02 | 3.73E-02 |

**Systemic exposure - magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 1 – automatic application to system | Tier 1/ no PPE | negligible | 1.53E-03 | 1.53E-03 |

*Scenario [2] Cleaning and maintenance- Manual cleaning of 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 MILK OF LIME 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 hydrated lime 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 maximal predicted air concentration for manual loading of bags of powder of 23.2 mg/m3 (see EuLA study presentend in the CAR).  The task duration is 30 min according to the CAR. | | | |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Density | 1.33 |  |
| Duration (min) | 30 | CAR |
| Dermal exposure – Hand (µl b.p/min) | 35.87 | BEAT |
| Dermal exposure – Body (µl b.p/min) | 19.28 | BEAT |
| Inhalation (mg b.p/m3) | 23.2 | CAR (INTERPRETATION REPORT No. KSP1401-0272-001\_1, 1403-0232-001, 1405-0047-001\_1, Evaluation of Exposure to Lime Dust, 06/05/2014° |
| Inhalation absorption | 100% | Default value, CAR |
| Dermal absorption | 100% | Default value, CAR |
| Inhalation rate (m3/h) | 1.25 | Ag Hoc Recommendation 1 (2017) |
| Body weight (kg) | 60 | Ag Hoc Recommendation 1 (2017) |
| Tier 2 for systemic effects | Gloves | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2 for local effects | RPE | APF 40 | HEEG Opinion 9 (2010) |

***Calculations for Scenario [2]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 2 – cleaning of equipment | Tier 1/no PPE | 5.87E-02 | 8.91 | 8.97 |
| Tier 2/gloves | 5.87E-02 | 3.70 | 3.75 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 2 – cleaning of equipment | Tier 1/no PPE | 2.42E-03 | 3.67E-01 | 3.69E-01 |

**Local exposure – calcium dihydroxide**

| **Summary table: local exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated calcium dihydroxide inhalation uptake (mg/m3)** |
| **META SPC 1** | | |
| Scenario 2  cleaning of equipment | Tier 1/no RPE | 10.44 |
| Tier 2/RPE (APF **40**) | 0.26 |

*Combined scenarios (scenario 1 + 2)*

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 1+2 | Tier 1/no PPE | 5.87E-02 | 8.95 | 9.01 |
| Tier 2/gloves for cleaning | 5.87E-02 | 3.73 | 3.79 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 1+2 | Tier 1/no PPE | 2.42E-03 | 3.68E-01 | 3.71E-01 |

*Scenario [3] Semi-automatic loading of the product from IBC/IDRA container to the low-pressure sprayer*

| **Description of Scenario [3]** | | | | |
| --- | --- | --- | --- | --- |
| The 1m³ IBCs are fitted with a drain valve, which can be fitted with a drain spout, or dispensing gun (see pictures below), and raised, which allows loading the product by gravity into buckets. Therefore, semi-automatic loading is expected.  AUER Packaging Conteneurs IBC avec palette plastique IBC 1000 K 150.50Bec de vidange Ø 40 mm Sotralentz + écrou 2" S60x6Kit Vidange Cuve IBC à cames 2" S60X6 + 4 m tuyau + Pistolet blanc (Joint FPM)  Calcium dihydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected during this task.  To determine dermal exposure during the semi-automatic loading, RISKOFDERM Toolkit for loading liquid, partly automated, has been used (HEEG Opinion 1).  A duration of 10 minutes is taken into consideration. | | | | |
|  | Parameters | | Value | Reference |
|  | Ca(OH)2 concentration | Meta SPC 1  Meta SPC 2 | 45%  20% |  |
| Assumed calcium fraction | Meta SPC 1  Meta SPC 2 | 24.3%  10.8% |  |
| Assumed magnesium fraction | Meta SPC 1  Meta SPC 2 | 1%  0.46% |  |
| Duration (min) | | 10 |  |
| Dermal exposure – Hands (mg p.b /min) | | 2.8 | RISKOFDERM Toolkit Loading Liquid, partly automated (HEEG Opinion 1) |
| Dermal exposure – Body (mg p.b /min) | | 8.7 | RISKOFDERM Toolkit Loading Liquid, partly automated (HEEG Opinion 1) |
| Dermal absorption | | 100% | Default value, CAR |
| Body weight (kg) | | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2a for systemic effects | Gloves | | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Coated coverall | | 10% penetration  20% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves  Impermeable coverall | | 10% penetration  5% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [3]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | n.a | 4.66E-01 | 4.66E-01 |
| Tier 2a/gloves | n.a | 3.64E-01 | 3.64E-01 |
| Tier 2b/gloves + coated coverall | n.a | 8.18E-02 | 8.18E-02 |
| Tier 2c/gloves + impermeable coverall | n.a | 2.90E-02 | 2.90E-02 |
| **META SPC 2** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | n.a | 2.07E-01 | 2.07E-01 |
| Tier 2a/gloves | n.a | 1.62E-01 | 1.62E-01 |
| Tier 2b/gloves + coated coverall | n.a | 3.64E-02 | 3.64E-02 |
| Tier 2c/gloves + impermeable coverall | n.a | 1.29E-02 | 1.29E-02 |

**Systemic exposure - magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/ no PPE | n.a | 1.92E-02 | 1.92E-02 |
| Tier 2a/ gloves | n.a | 1.50E-02 | 1.50E-02 |
| Tier 2b/ gloves + coated coverall | n.a | 3.37E-03 | 3.37E-03 |
| Tier 2b/ gloves + impermeable coverall | n.a | 1.19E-03 | 1.19E-03 |
| **META SPC 2** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | n.a | 8.82E-03 | 8.82E-03 |
| Tier 2a/ gloves | n.a | 6.88E-03 | 6.88E-03 |
| Tier 2b/ gloves + coated coverall | n.a | 1.55E-03 | 1.55E-03 |

*Scenario [4] - Manual application with a low-pressure sprayer*

| **Description of Scenario [4]** | | | | |
| --- | --- | --- | --- | --- |
| According to applicant’s data, the biocidal product can be loaded in a low-pressure sprayer as a coarse or medium spray and then applied with the manual sprayer downwards (floors).  According to the Ad Hoc Recommendation 3, considering that the application is performed downwards with a low-pressure sprayer, dermal exposure is determined with RISKOFDERM model and inhalation exposure with ART model (instead of Spraying Model 1).  An exposure duration of 120 minutes is taken into consideration. This choice of value is reinforced by the value proposed in the Excel spreadsheet PT3 for spraying in the BHHEM, 2015.  Remark: these models do not cover the loading of the product from the packaging (IBC 1m3 or container up to 25t) to the manual spraying equipment. | | | | |
|  | Parameters | | Value | References |
| Tier 1 | Ca(OH)2 concentration | Meta SPC 1  Meta SPC 2 | 45%  20% |  |
| Assumed calcium fraction | Meta SPC 1  Meta SPC 2 | 24.3%  10.8% |  |
| Assumed magnesium fraction | Meta SPC 1  Meta SPC 2 | 1%  0.46% |  |
| Density (g/cm3) | Meta SPC 1  Meta SPC 2 | 1.33  1.13 |  |
| Duration (min) | | 120 | BHEEM, 2015 |
| Dermal exposure – Hands (µl b.p/min) | | 56.2 (75th percentile) | RISKOFDERM model |
| Dermal exposure – Body (µl b.p/min) | | 354 (75th percentile) | RISKOFDERM model |
| Inhalation (mg b.p/m3) | | 1.3 (75th percentile) | ART model |
| Inhalation absorption | | 100% | Default value, CAR |
| Dermal absorption | | 100% | Default value, CAR |
| Inhalation rate (m3/h) | | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2 for local effects | RPE for meta SPC 1 | | APF 4 | HEEG Opinion 9 (2010) |
| Tier 2a for systemic effects | Gloves | | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Coated coverall | | 10% penetration  10% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves  Impermeable coverall | | 10% penetration  5% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [4]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 4 – manual spraying with low-pressure sprayer | Tier 1/no PPE | 1.32E-02 | 265 | 265 |
| Tier 2a/gloves | 1.32E-02 | 232 | 232 |
| Tier 2b/gloves + coated coverall | 1.32E-02 | 26.5 | 26.5 |
| Tier 2c/gloves + impermeable coverall | 1.32E-02 | 15.1 | 15.1 |
| **META SPC 2** | | | | |
| Scenario 4 – manual spraying with low-pressure sprayer | Tier 1/no PPE | 5.85E-03 | 100 | 100 |
| Tier 2a/gloves | 5.85E-03 | 87.8 | 87.8 |
| Tier 2b/gloves + coated coverall | 5.85E-03 | 10.0 | 10.0 |
| Tier 2c/gloves + impermeable coverall | 5.85E-03 | 5.69 | 5.69 |

**Systemic exposure – magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 4 – manual spraying with low-pressure sprayer | Tier 1/no PPE | 5.42E-04 | 10.9 | 10.9 |
| Tier 2a/gloves | 5.42E-04 | 9.57 | 9.57 |
| Tier 2b/gloves + coated coverall | 5.42E-04 | 1.09 | 1.09 |
| Tier 2b/gloves + impermeable coverall | 5.42E-04 | 6.20 | 6.21E-01 |
| **META SPC 2** | | | | |
| Scenario 4 – manual spraying with low-pressure sprayer | Tier 1/no PPE | 2.49E-04 | 4.26 | 4.26 |
| Tier 2a/gloves | 2.49E-04 | 3.74 | 3.74 |
| Tier 2b/gloves + coated coverall | 2.49E-04 | 4.26E-01 | 4.27E-01 |

**Local exposure – calcium dihydroxide**

| **Summary table: local exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated calcium dihydroxide inhalation uptake (mg/m3)** |
| **META SPC 1** | | |
| Scenario 4  manual spraying with low-pressure sprayer | Tier 1/no RPE | 0.6 |
| Tier 2/RPE (APF **4**) | 0.15 |
| **META SPC 2** | | |
| Scenario 4  manual spraying with low-pressure sprayer | Tier 1/no RPE | 0.26 |

*Scenario [5] - Manual application with a high-pressure sprayer*

| **Description of Scenario [5]** | | | | |
| --- | --- | --- | --- | --- |
| According to applicant’s data, the biocidal product can also be loaded in a powered spray at 4 to 7 bar pressure as a coarse or medium spray and then applied with the manual sprayer.  An exposure duration of 120 minutes is taken into consideration. This choice of value is reinforced by the value proposed in the Excel spreadsheet PT3 for spraying in the BHHEM, 2015.  To determine dermal and inhalation exposure, Spraying Model 2 is used (BHEEM, 2015).  This model covers the loading of the product from the packaging (IBC 1m3 or container up to 25t) to the manual spraying equipment1. | | | | |
|  | Parameters | | Value | References |
| Tier 1 | Ca(OH)2 concentration | Meta SPC 1  Meta SPC 2 | 45%  20% |  |
| Assumed calcium fraction | Meta SPC 1  Meta SPC 2 | 24.3%  10.8% |  |
| Assumed magnesium fraction | Meta SPC 1  Meta SPC 2 | 1%  0.46% |  |
| Duration (min) | | 120 | BHEEM, 2015 |
| Dermal exposure – Hand (mg b.p/min) | | 273 (75th percentile) | Spraying Model 2 (BHEEM, 2015) |
| Dermal exposure – Body (mg b.p/min) | | 222 (75th percentile) | Spraying Model 2 (BHEEM, 2015) |
| Inhalation (mg b.p/m3) | | 76 (75th percentile) | Spraying Model 2 (BHEEM, 2015) |
| Inhalation absorption | | 100% | Default value, CAR |
| Dermal absorption | | 100% | Default value, CAR |
| Inhalation rate (m3/h) | | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2 for local effects | RPE for meta SPC 1-2 | | APF 40 | HEEG Opinion 9 (2010) |
| Tier 2a for systemic effects | Gloves in the model:  mg b.p/min | | 7.8 | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves in the model  Coated coverall penetration factor | | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves in the model  Impermeable coverall penetration factor  RPE | | 5% penetration  APF 40 | HEEG Opinion 9 (2010) |

1 conservative assessment because loading included in the Spraying Model 2 is a manual loading. However, for this product, applicant data indicate that a semi-automatic loading is expected. Indeed, the 1m³ IBCs are fitted with a drain valve, which can be fitted with a drain spout, or dispensing gun (see pictures below), and raised, which allows loading the product by gravity to portable sprayers. For container up to 25t, a transfer peristaltic pump is also expected to fill the tank of portable sprayers.



***Calculations for Scenario [5]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 5 – manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 7.70E-01 | 241 | 241 |
| Tier 2a/gloves | 7.70E-01 | 112 | 112 |
| Tier 2b/gloves + coated coverall | 7.70E-01 | 14.6 | 15.3 |
| Tier 2c/gloves + impermeable coverall + RPE APF40 | 1.92E-02 | 9.19 | 9.20 |
| **Meta SPC 2** | | | | |
| Scenario 5 – manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 3.42E-01 | 107 | 107 |
| Tier 2a/gloves | 3.42E-01 | 49.6 | 50.0 |
| Tier 2b/gloves + coated coverall | 3.42E-01 | 6.48 | 6.82 |
| Tier 2c/gloves + impermeable coverall | 3.42E-01 | 4.08 | 4.42 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 5 – manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 3.17E-02 | 9.90 | 9.93 |
| Tier 2a/gloves | 3.17E-02 | 4.60 | 4.63 |
| Tier 2b/gloves + coated coverall | 3.17E-02 | 6.00E-01 | 6.32E-01 |
| Tier 2c/gloves + impermeable coverall | 3.17E-02 | 3.78E-01 | 4.10E-01 |
| **Meta SPC 2** | | | | |
| Scenario 5 – manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 1.46E-02 | 4.55 | 4.57 |
| Tier 2a/gloves | 1.46E-02 | 2.11 | 2.13 |
| Tier 2b/gloves + coated coverall | 1.46E-02 | 2.76E-01 | 2.91E-01 |
| Tier 2c/gloves + impermeable coverall | 1.46E-02 | 1.74E-02 | 1.88E-01 |

**Local exposure – calcium dihydroxide**

| **Summary table: local exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated calcium dihydroxide inhalation uptake (mg/m3)** |
| **META SPC 1** | | |
| Scenario 5  manual spraying with a high-pressure sprayer (loading included) | Tier 1/no RPE | 34.2 |
| Tier 2/RPE (APF **40**) | 0.86 |
| **META SPC 2** | | |
| Scenario 5  manual spraying with a high-pressure sprayer (loading included) | Tier 1/no RPE | 15.2 |
| Tier 2/RPE (APF **40**) | 0.38 |

*Scenario [6] Cleaning - Manual cleaning of spray equipment*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [6]** | | | | |
| Cleaning of equipment is modelled according to BEAT scenario “*Cleaning of the spray equipment*” from TNsG (2007). The task duration is 10 min. Considering the low volatility of active substance, inhalation exposure is negligible. | | | | |
|  | Parameters | | Value | References |
|  | Ca(OH)2 concentration | Meta SPC 1  Meta SPC 2 | 45%  20% |  |
| Assumed calcium fraction | Meta SPC 1  Meta SPC 2 | 24.3%  10.8% |  |
| Assumed magnesium fraction | Meta SPC 1  Meta SPC 2 | 1%  0.46% |  |
| Density | Meta SPC 1  Meta SPC 2 | 1.33  1.13 |  |
| Duration (min) | | 10 | expert judgement |
| Dermal exposure – Hand (µL b.p/min) | | 35.87 | BEAT |
| Dermal exposure – Body (µl b.p/min) | | 19.28 | BEAT |
| Dermal absorption | | 100% | Default value, CAR |
| Body weight (kg) | | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2a for systemic effects | Gloves | | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Coated coverall | | 10% penetration 20% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves  Impermeable coverall | | 10% penetration 5% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [6]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 6 – cleaning of spray equipment | Tier 1/no PPE | n.r. | 2.97 | 2.97 |
| Tier 2a/gloves | n.r | 1.23 | 1.23 |
| Tier 2b/gloves + coated coverall | n.r | 4.01E-01 | 4.01E-01 |
| Tier 2c/gloves + impermeable coverall | n.r | 2.45E-01 | 2.45E-01 |
| **Meta SPC 2** | | | | |
| Scenario 6 – cleaning of spray equipment | Tier 1/no PPE | n.r. | 1.12 | 1.12 |
| Tier 2a/gloves | n.r | 4.65E-01 | 4.65E-01 |
| Tier 2b/gloves + coated coverall | n.r | 1.51E-01 | 1.51E-01 |
| Tier 2c/gloves + impermeable coverall | n.r | 9.26E-02 | 9.26E-02 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 6 – cleaning of spray equipment | Tier 1/no PPE | n.r. | 1.22E-01 | 1.22E-01 |
| Tier 2a/gloves | n.r | 5.07E-02 | 5.07E-02 |
| Tier 2b/gloves + coated coverall | n.r | 1.65E-02 | 1.65E-02 |
| Tier 2b/gloves + impermeable coverall | n.r | 1.01E-02 | 1.01E-02 |
| **Meta SPC 2** | | | | |
| Scenario 6 – cleaning of spray equipment | Tier 1/no PPE | n.r | 4,78E-02 | 4,78E-02 |
| Tier 2a/gloves | n.r | 1.98E-02 | 1.98E-02 |
| Tier 2b/gloves + coated coverall | n.r | 6.54E-03 | 6.54E-03 |

***Combined scenarios (3+4+6 for low-pressure spraying, 5+6 for high-pressure spraying)***

**Systemic exposure – calcium**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | | 1.32E-02 | 269 | 269 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | | 1.32E-02 | 234 | 234 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | | 1.32E-02 | 27 | 27 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | | 1.32E-02 | 15.3 | 15.4 |
| Scenario 5+6 (loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 7.70E-01 | | 244 | 244 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 7.70E-01 | | 113 | 114 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 7.70E-01 | | 15 | 15.8 |
| Tier 2c/gloves + impermeable coverall + RPE APF 40 during semi-automatic loading and application gloves + impermeable coverall during cleaning | 1.92E-02 | | 9.43 | 9.45 |
| **Meta SPC 2** | | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 5.85E-03 | | 101 | 101 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 5.85E-03 | | 88.4 | 88.4 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 5.85E-03 | | 10.2 | 10.2 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | 5.85E-03 | | 5.8 | 5.8 |
| Scenario 5+6 (loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 3.42E-01 | | 108 | 108 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 3.42E-01 | | 50.1 | 50.4 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 3.42E-01 | | 6.63 | 6.97 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading and application gloves + coated coverall during cleaning | 3.42E-01 | | 4.23 | 4.58 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 5.42E-04 | 11.1 | 11.1 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 5.42E-04 | 9.63 | 9.63 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 5.42E-04 | 1.11 | 1.11 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | 5.42E-04 | 6.32E-01 | 6.32E-01 |
| Scenario 5+6 (semi-automatic loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 3.17E-02 | 10 | 10.1 |
| Tier 2a/gloves during loading, application and cleaning | 3.17E-02 | 4.65 | 4.68 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 3.17E-02 | 6.16E-01 | 6.48E-01 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading and application gloves + coated coverall during cleaning | 3.17E-02 | 3.94E-01 | 4.26E-01 |
| **Meta SPC 2** | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 2.49E-04 | 4.32 | 4.32 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 2.49E-04 | 3.77 | 3.77 |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 2.49E-04 | 0.43 | 0.44 |
| Scenario 5+6 (semi-automatic loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 1.46E-02 | 4.60 | 4.62 |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 1.46E-02 | 2.13 | 2.15 |
| Tier 2b/gloves + coated coverall during semi-automatic loading and application | 1.46E-02 | 3.24E-01 | 3.38E-01 |

*Scenario [7] – Semi-automatic loading of the product from IBC/IDRA container to the tank of sprayer (tractor)*

| **Description of Scenario [7]** | | | |
| --- | --- | --- | --- |
| The 1m³ IBCs are fitted with a drain valve, which can be fitted with a drain spout, or dispensing gun (see pictures below), and raised, which allows loading the product by gravity to the tank of tractor sprayer. For container up to 25t, a transfer peristaltic pump is also expected to fill the tank of tractor sprayer. Therefore, semi-automatic loading is expected.  AUER Packaging Conteneurs IBC avec palette plastique IBC 1000 K 150.50Bec de vidange Ø 40 mm Sotralentz + écrou 2" S60x6Kit Vidange Cuve IBC à cames 2" S60X6 + 4 m tuyau + Pistolet blanc (Joint FPM)  Calcium dihydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected during this task.  To determine dermal exposure during the semi-automatic loading, RISKOFDERM Toolkit for loading liquid, partly automated, has been used (HEEG Opinion 1).  A duration of 10 minutes is taken into consideration. | | | |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Duration (min) | 10 | BHHEM, 2015 |
| Dermal exposure – Hands (mg b.p/min) | 2.8 | HEEG Opinion 1 (2008) |
| Dermal exposure – Body (mg b.p/min) | 8.7 | HEEG Opinion 1 (2008) |
| Dermal absorption | 100% | Default value, CAR |
| Body weight (kg) | 60 | Ag Hoc Recommendation 1 (2017) |
| Tier 2a for systemic effects | Gloves | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Coated coverall | 10% penetration  20% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves  Impermeable coverall | 10% penetration  5% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [7]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 7 – Semi-automatic loading of the sprayer tank (tractor) | Tier 1/no PPE | n.a | 4.66E-01 | 4.66E-01 |
| Tier 2a/gloves | n.a | 3.64E-01 | 3.64E-01 |
| Tier 2b/gloves + coated coverall | n.a | 8.18E-02 | 8.18E-02 |
| Tier 2c/gloves + impermeable coverall | n.a | 2.90E-02 | 2.90E-02 |

**Systemic exposure - magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 7 – Semi-automatic loading of the sprayer tank (tractor) | Tier 1/no PPE | n.a | 1.92E-02 | 1.92E-02 |
| Tier 2a/gloves | n.a | 1.50E-02 | 1.50E-02 |
| Tier 2b/gloves + coated coverall | n.a | 3.37E-03 | 3.37E-03 |
| Tier 2b/gloves + impermeable coverall | n.a | 1.19E-03 | 1.19E-03 |

*Scenario [8] – Semi-automatic application of product with vehicle-mounted*

| **Description of Scenario [8]** | | | |
| --- | --- | --- | --- |
| Professional exposure may also occur during semi-automatic application of the product with a micro-tractor or a quad with a boom sprayer.  There is no readily available model to predict exposure for this scenario in the Biocides Human Health Exposure Methodology (2015).  To assess dermal and inhalation exposure during this task, the German Model BBA model used in the context of phytopharmaceutical produt has been considered.  The closest application method compared to this task ***“tractor-mounted/trailed boom sprayer : hydraulic nozzles”*** has been selected. The exposure during mixing and loading in this model has been deliberately ignored due to its inclusion in the scenario 5.  As the worst-case maximum treated floor surface, 3330 m2 (ESD PT3 for turkey sheds) is considered .  The BBA model considers that for the selected application method, it takes 5 hours to treat 4 ha. A duration of 25 min (0.333 ha × 300 min) / 4 ha = 25 min) is thus needed to treat this surface. | | | |
|  | Parameters | Value | References |
| Tier 1 | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Density | 1.33 |  |
| Dose (l/ha) | 17000 | Applicant’s data |
| Surface treated area (ha) | 0.333 | ESD PT3 (turkey sheds) |
| Inhalation absorption | 100% | Default value, CAR |
| Dermal absorption | 100% | Default value, CAR |
| Body weight (kg) | 60 | Recommendation 14 (2017) |
| Tier 2 for local effects | RPE | APF 40 | HEEG Opinion 9 (2010) |
| Tier 2a for systemic effects | Gloves | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Impermeable coverall | 10% penetration  5% penetration | HEEG Opinion 9 (2010) |
| Tier 2c for systemic effects | Gloves  Impermeable coverall  RPE | 10% penetration  5% penetration  APF 40 | HEEG Opinion 9 (2010) |

***Calculations for Scenario [8]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 8  – semi-automatic application | Tier 1/no PPE | 3.05E-02 | 62.2 | 62.2 |
| Tier 2a/gloves | 3.05E-02 | 51.8 | 51.8 |
| Tier 2b/gloves + impermeable coverall | 3.05E-02 | 5.43 | 5.46 |
| Tier 2c/gloves + impermeable coverall + APF 40 | 7.62E-04 | 5.43 | 5.43 |

**Systemic exposure – magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 8 – semi-automatic application | Tier 1/no PPE | 1.25E-03 | 2.56 | 2.56 |
| Tier 2a/gloves | 1.25E-03 | 2.13 | 2.13 |
| Tier 2b/gloves + coated coverall | 1.25E-03 | 0.53 | 0.53 |

**Local exposure – calcium dihydroxide**

| **Summary table: local exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated calcium dihydroxide inhalation uptake (mg/m3)** |
| **META SPC1** | | |
| Scenario 8 – semi-automatic application | Tier 1/no RPE | 6.51 |
| Tier 2/RPE (APF **40**) | 0.16 |

***Combined exposure (scenario 7-8)***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 7+8 (semi-automatic loading + semi-automatic application) | Tier 1/no PPE | 3.05E-02 | 62.7 | 62.7 |
| Tier 2a/gloves during semi-automatic loading and application | 3.05E-02 | 52.1 | 52.2 |
| Tier 2b/gloves + coated coverall during semi-automatic loading  gloves + impermeable coverall during application | 3.05E-02 | 5.51 | 5.54 |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading  gloves + impermeable coverall + RPE APF 40 during application | 7.62E-04 | 5.46 | 5.46 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 7+8 (semi-automatic loading + semi-automatic application) | Tier 1/no PPE | 1.25E-03 | 2.58 | 2.58 |
| Tier 2a/gloves during loading and application | 1.25E-03 | 2.15 | 2.15 |
| Tier 2b/gloves + coated coverall during application | 1.25E-03 | 0.54 | 0.55 |

*Scenario [9] – Semi-automatic loading of the product from IBC/IDRA container to buckets*

| **Description of Scenario [9]** | | | |
| --- | --- | --- | --- |
| The 1m³ IBCs are fitted with a drain valve, which can be fitted with a drain spout, or dispensing gun (see pictures below), and raised, which allows loading the product by gravity into buckets. Therefore, semi-automatic loading is expected.  AUER Packaging Conteneurs IBC avec palette plastique IBC 1000 K 150.50Bec de vidange Ø 40 mm Sotralentz + écrou 2" S60x6Kit Vidange Cuve IBC à cames 2" S60X6 + 4 m tuyau + Pistolet blanc (Joint FPM)  Calcium dihydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected during this task.  To determine dermal exposure during the semi-automatic loading, RISKOFDERM Toolkit for loading liquid, partly automated, has been used (HEEG Opinion 1).  Considering the active substance dose of 0.8 kg/m2 for application and the concentration of active susbtance in the product, the product dose have been calculated taking into account the density:   * Meta SPC 1: (100% × 0.8) / 45%) / 1.33 = 1.4 L/m2   Considering the dose for each meta SPC and the worst-case wall area for turkeys sheds of 1320 m2 (ESD document for PT3), the worst-case volume of product to be painted on walls is:   * Meta SPC 1: 1848 L (1.4 L/m2 × 1320 m2 = 1848 L)   Considering the time spent for each loading of bucket of 0.5 min, an assumed volume bucket of 20L (expert judgment) and the worst-case volume of product to be painted calculated above, the duration of exposure have been considered for each meta SPC:   * **Meta SPC 1: 46 min** ((1848 L/20 L) × 0.5 min = 46 min) | | | |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Duration (min) | 46 |  |
| Dermal exposure – Hands (mg b.p/min) | 2.8 | HEEG Opinion 1 (2008) |
| Dermal exposure – Body (mg b.p/min) | 8.7 | HEEG Opinion 1 (2008) |
| Dermal absorption | 100% | Default value, CAR |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2a for systemic effects | Gloves | 10% penetration | HEEG Opinion 9 (2010) |
| Tier 2b for systemic effects | Gloves  Coated coverall | 10% penetration  20% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [9]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 9 – Semi-automatic loading of buckets | Tier 1/no PPE | n.a | 2.14 | 2.14 |
| Tier 2a/gloves | n.a | 1.67 | 1.67 |
| Tier 2b/gloves + coated coverall | n.a | 0.38 | 0.38 |

**Systemic exposure - magnesium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 9 – Semi-automatic loading of buckets | Tier 1/no PPE | n.a | 8.82E-02 | 8.82E-02 |
| Tier 2a/gloves | n.a | 6.88E-02 | 6.88E-02 |
| Tier 2b/gloves + coated coverall | n.a | 1.55E-02 | 1.55E-02 |

*Scenario [10] – Manual application on walls using a brush*

| **Description of Scenario [10]** | | | |
| --- | --- | --- | --- |
| Exposure of the professionnal to the product may occur during painting on walls using a brush.  Dermal exposure and inhalation exposure (splashes and aerosols) are expected during this task.  According to Ad Hoc Recommendation 10 (2016), dermal exposure is evaluated using Austrian/BfR study results and inhalation exposure using Consumer Product Painting Model 3.  Considering the worst-case wall surface to brush (1320 m2 for turkey sheds), an exposure duration of 6 hours has been considered according to expert judgment and duration of application by brush mentioned by Excel spreadsheet for PT2-6-7-10-18 for brushing liquid in the Biocides Human Health Exposure Methodoly (BHHEM, 2015).  Considering MILK OF LIME is a water-based product and hydrated lime is low-volatile, the indicative exposure value from the model are as follows:   * Body: 1.7 μL/min * Hands: 4.07 μL/min * Inhalation: 1.63 mg/m3 | | | |
|  | Parameters | Value | References |
|  | Ca(OH)2 concentration | 45% |  |
| Assumed calcium fraction | 24.3% |  |
| Assumed magnesium fraction | 1% |  |
| Duration (min) | 360 | BHEEM, 2015 |
| Density | 1.33 | Applicant’s data |
| Dermal exposure – Hand (µl b.p/min) | 4.07 | Ad Hoc Recommendation 10 (2016) |
| Dermal exposure – Body (µl b.p/min) | 1.7 | Ad Hoc Recommendation 10 (2016) |
| Inhalation (mg b.p/m3) | 1.63 mg/m3 | Ad Hoc Recommendation 10 (2016) |
| Inhalation absorption | 100% | Default value, CAR |
| Dermal absorption | 100% | Default value, CAR |
| Inhalation rate (m3/h) | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2 for local effects | RPE | APF 4 | HEEG Opinion 9 (2010) |
| Tier 2a for systemic effects | Gloves | 10% penetration | HEEG Opinion 9 (2010) |

***Calculations for Scenario [10]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 10 – manual application using a brush | Tier 1/no PPE | 9.17E-02 | 11.2 | 11.3 |
| Tier 2/gloves | 9.17E-02 | 4.09 | 4.18 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 10 – manual application using a brush | Tier 1/no PPE | 2.04E-03 | 4.60E-01 | 4.62E-01 |
| Tier 2/gloves | 2.04E-03 | 1.68E-01 | 1.70E-01 |

**Local exposure – calcium dihydroxide**

| **Summary table: local exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated calcium dihydroxide inhalation uptake (mg/m3)** |
| **META SPC 1** | | |
| Scenario 10 – manual application using a brush | Tier 1/no RPE | 0.73 |
| Tier 2/RPE (APF **4**) | 0.18 |

*Scenario [11] – Cleaning of the brush equipment*

According to the HEEG Opinion 11, it is expected that for water-based paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands. MILK OF LIME product family being a water-based product, no exposure during cleaning of the brush equipment is expected.

***Combined scenarios (scenario 9-10)***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 9-10 (semi-automatic loading + manual brush) | Tier 1/no PPE | 9.17E-02 | 13.3 | 13.4 |
| Tier 2a/gloves during semi-automatic loading and application | 9.17E-02 | 5.76 | 5.85 |
| Tier 2b/gloves + coated coverall during semi-automatic loading  gloves during application | 9.17E-02 | 4.46 | 4.55 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 9-10 (semi-automatic loading + manual brush) | Tier 1/no PPE | 2.04E-03 | 0.55 | 0.55 |
| Tier 2/gloves during application | 2.04E-03 | 0.26 | 0.26 |

*Scenario [12] – Professional touching freshly-painted or dry surfaces of walls*

| **Description of Scenario [12]** |
| --- |
| Secondary dermal exposure of the professional who touches after application the treated wall with its hands (wet and dry surfaces) can occur. This scenario covers the exposure of an adult (general public) who touches the treated wall after the application.  Calcium dihydroxide has a low vapour pressure (below 10-5 Pa), therefore no exposure by inhalation is expected during this task. Only dermal exposure is expected.  MILK OF LIME is expected to have a similar viscosity compared to paints, as antifouling paints. Therefore, for this scenario, some exposure parameters have been used according to the paramaters agreed in Ad Hoc Recommendation 5:   * Proportion of palm hands in contact with milk of lime : 100% for wet paint / 40% for dried paint * Transfer coefficient of paint from treated surface to hand: 50% for wet paint / 3% for dried paint  |  |  |  |  | | --- | --- | --- | --- | |  | Parameters | Value | References | | Tier 1 | Ca(OH)2 concentration | 45% | Applicant’s data | | Assumed calcium fraction | 24.3% | Applicant’s data | | Assumed magnesium fraction | 1% | Applicant’s data | | Product application rate | 1800 g/m2 | Applicant’s data | | Dermal absorption | 100% | Default value, CAR | | Body weight (kg) | 60 | Ad Hoc Recommendation 14 | | Area of hands – palms only of both hands | 410 cm2 | | Proportion of palm hands in contact with wet paint | 100% | Ad Hoc Recommendation 5 | | Transfer coefficient of paint from treated surface to hand | 50% | | Tier 2 | Proportion of palm hands in contact with wet paint | 40% | | Transfer coefficient of paint from treated surface to hand | 3% | |

***Calculations for Scenario [12]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 12 | Tier 1/wet paint | n.a | 149 | 149 |
| Tier 2/dried paint | n.a | 3.59 | 3.59 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 12 | Tier 1/wet paint | n.a | 6.15 | 6.15 |
| Tier 2/dried paint | n.a | 0.15 | 0.15 |

***Non-professional exposure***

Not relevant.

***Exposure of the general public***

*Scenario [13] – Toddler touching freshly-painted or dried surfaces of walls with hand-to-mouth transfer*

| **Description of Scenario [13]** |
| --- |
| Secondary dermal exposure of toddler who touches after application the treated wall with its hands (wet and dry surfaces) can occur. Hand-to-mouth transfer is also expected.  Inhalation of volatilised residues after application is considered to be negligible due to the low volatile properties of the active substance. Therefore, only dermal exposure is expected.  MILK OF LIME is expected to have a similar viscosity compared to paints, as antifouling paintss. Therefore, for this scenario, some exposure parameters have been used according to the paramaters agreed in Ad Hoc Recommendation 5:   * Proportion of palm hands in contact with milk of lime : 100% for wet paint / 40% for dried paint * Transfer coefficient of paint from treated surface to hand: 50% for wet paint / 3% for dried paint  |  |  |  |  | | --- | --- | --- | --- | |  | Parameters | Value | References | | Tier 1 | Ca(OH)2 concentration | 45% | Applicant’s data | | Assumed calcium fraction | 24.3% | Applicant’s data | | Assumed magnesium fraction | 1% | Applicant’s data | | Product application rate | 1800 g/m2 | Applicant’s data | | Dermal absorption | 100% | Default value, CAR | | Body weight (kg) | 10 | Ad Hoc Recommendation 14 | | Area of hands – palms only of both hands | 115.2 cm2 | | Proportion of palm hands in contact with wet paint | 100% | Ad Hoc Recommendation 5 | | Transfer coefficient of paint from treated surface to hand | 50% | | Transfer coefficient of wet paint from hands to mouth | 10% | | Tier 2 | Proportion of palm hands in contact with wet paint | 40% | | Transfer coefficient of paint from treated surface to hand | 3% | |  | Transfer coefficient of dried paint from hands to mouth | 50% |  | |

***Calculations for Scenario [13]***

**Systemic exposure – calcium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 13 | Tier 1/wet paint | 25.2 | 227 | 252 |
| Tier 2/dried paint | 3.02 | 3.02 | 6.05 |

**Systemic exposure – magnésium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| **META SPC 1** | | | | |
| Scenario 13 | Tier 1/wet paint | 1.04 | 9.33 | 10.4 |
| Tier 2/dried paint | 1.24E-01 | 1.24E-01 | 2.49-01 |

***Monitoring data***

None*.*

***Dietary exposure***

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

Regarding intended uses on floors and walls surface indoor in livestock accommodations or transportations (TP3 use#3 and use#5) and uses on floors of outdoor animal enclosures (TP3 use#6), no dietary exposure is expected considering the instructions of use (Use only in the absence of animals).

Regarding intended uses on bedding materials (TP3 use#4), the animals may be in direct contact with the active substance. Therefore, an indirect exposure via food of animal origin might be expected for these uses. eCA has asked the applicant to compare the quantities of active substance as a biocides, to those of already authorized uses in the plant protection framework, including fertilisers. Following this request, the applicant provided an assessment of animal exposure.

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

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

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

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

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

Residue definitions

When dissolved in water, calcium hydroxide dissociates into 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.  Default MRL of 0.01\* mg/kg for calcium oxide |
| 2. | Fertiliser | Application to agricultural soils | - |
| 3. | Veterinary medicinal products | All food producing species | No MRL required |
| 4. | Food additives | Added to some food categories | « Quantum satis » |
| 5. | Food supplements | Mineral added to food | Calcium UL = 2500 mg/d for adults |

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

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

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

Considering that the active substance is composed of Ca2+ , whichis an essential element of the body and an ubiquitous compound used in high amounts as fertilizer, livestock are already exposed to Ca2+ via daily consumption of current feed. Hence, potential exposure of livestock from the intended uses is expected to be regulated by the animal metabolism. Therefore, human dietary exposure calculations via products of animal origin related to the intended uses is not considered to be relevant.

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

Only professional uses are intended in this dossier.

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation (systemic risk) – **calcium hydroxide**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 |
| UL calcium | - | - | - | - | 42 mg/kg bw/day |
| ARfD | Not applicable | | | | |
| ADI | Not applicable | | | | |

Reference values to be used in Risk Characterisation (systemic risk) – **magnesium**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| 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***

No exposure is foreseen.

***Risk for professional users***

Systemic effects **(calcium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)**\* |
| **META SPC 1** | | | | |
| Scenario 1 – Automatic application to system | Tier 1/no PPE | 42 | 3.73E-02 | 0.09 |
| Scenario 2  Cleaning and maintenance- Manual cleaning of equipment | Tier 1/no PPE | 42 | 8.97 | **21.4** |
| Tier 1/gloves | 42 | 3.75 | 8.94 |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | 42 | 4.66E-01 | 1.1 |
| Tier 2a/gloves | 3.64E-01 | 0.9 |
| Tier 2b/gloves + coated coverall | 8.18E-02 | 0.2 |
| Tier 2c/gloves + impermeable coverall | 2.90E-02 | 0.1 |
| Scenario 4 – Manual spraying with low-pressure sprayer | Tier 1/no PPE | 42 | 265 | **631** |
| Tier 2a/gloves | 232 | **553** |
| Tier 2b/gloves + coated coverall | 26.5 | **63.1** |
| Tier 2c/gloves + impermeable coverall | 15.1 | **35.9** |
| Scenario 5 – Manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 42 | 241 | **575** |
| Tier 2a/gloves | 42 | 112 | **268** |
| Tier 2b/gloves + coated coverall | 42 | 15.3 | **37** |
| Tier 2c/gloves + impermeable coverall + RPE APF 40 | 42 | 9.20 | **22** |
| Scenario 6  Cleaning of spray equipment | Tier 1/no PPE | 42 | 2.97 | 7.1 |
| Tier 2a/gloves | 42 | 1.23 | 2.9 |
| Tier 2b/gloves + coated coverall | 42 | 4.01E-01 | 0.95 |
| Tier 2c/gloves + impermeable coverall | 42 | 2.45E-01 | 0.58 |
| Scenario 7 – Semi-automatic loading of the sprayer tank (tractor) | Tier 1/no PPE | 42 | 4.66E-01 | 1.1 |
| Tier 2a/gloves | 42 | 3.64E-01 | 0.9 |
| Tier 2b/gloves + coated coverall | 42 | 8.18E-02 | 0.14 |
| Tier 2c/gloves + impermeable coverall | 42 | 2.90E-02 | 0.07 |
| Scenario 8 – Semi-automatic application | Tier 1/no PPE | 42 | 62.2 | **148** |
| Tier 2a/gloves | 42 | 51.8 | **123** |
| Tier 2b/gloves + impermeable coverall | 42 | 5.46 | 12.99 |
| Tier 2c/gloves + impermeable coverall + APF 40 | 42 | 5.43 | 12.93 |
| Scenario 9 – Semi-automatic loading of buckets | Tier 1/no PPE | 42 | 2.14 | 5.1 |
| Tier 2a/gloves | 42 | 1.67 | 4.0 |
| Tier 2b/gloves + coated coverall | 42 | 0.38 | 0.9 |
| Scenario 10  Manual application using a brush | Tier 1/no PPE | 42 | 11.3 | **26.9** |
| Tier 2/gloves | 42 | 4.18 | 9.95 |
| Scenario 12 Professional touching freshly-painted or dried surfaces of walls | Tier 1/wet paint | 42 | 149 | **356** |
| Tier 2/dried paint | 42 | 3.59 | 8.5 |
| **Meta SPC 2** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | 42 | 2.07E-01 | 0.5 |
| Tier 2a/gloves | 1.62E-01 | 0.4 |
| Tier 2b/gloves + coated coverall | 3.64E-02 | 0.1 |
| Tier 2c/gloves + impermeable coverall | 1.29E-02 | 0.03 |
| Scenario 4 – Manual spraying with low-pressure sprayer | Tier 1/no PPE | 42 | 100 | **238** |
| Tier 2a/gloves | 87.8 | **209** |
| Tier 2b/gloves + coated coverall | 10.0 | **23.8** |
| Tier 2c/gloves + impermeable coverall | 5.69 | 13.6 |
| Scenario 5 – Manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 42 | 107 | **255** |
| Tier 2a/gloves | 50.0 | **119** |
| Tier 2b/gloves + coated coverall | 6.82 | **16.2** |
| Tier 2c/gloves + impermeable coverall | 4.42 | 10.5 |
| Scenario 6 – Cleaning of spray equipement | Tier 1/no PPE | 42 | 1.12 | 2.7 |
| Tier 2a/gloves | 4.65E-01 | 1.1 |
| Tier 2b/gloves + coated coverall | 1.51E-01 | 0.36 |

*\*According to the CAR, exposure to calcium is acceptable when expressed as a percentage of the UL it should be less than 13%.*

**Combined scenarios (calcium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)**\* |
| **META SPC 1** | | | | |
| Scenario 1+2 (automatic loading + cleaning of equipment) | 1/no PPE | 42 | 9.01 | **21.5** |
| 2/gloves during cleaning | 42 | 3.79 | 9.0 |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 42 | 269 | **640** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 42 | 234 | **557** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 42 | 27 | **64.3** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | 42 | 15.4 | **36.6** |
| Scenario 5+6 (loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 42 | 244 | **582** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 42 | 114 | **271** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 42 | 15.8 | **37.5** |
| Tier 2c/gloves + impermeable coverall + RPE APF 40 during semi-automatic loading and application gloves + impermeable coverall during cleaning | 42 | 9.45 | **22.5** |
| Scenario 7+8 (semi-automatic loading + semi-automatic application) | Tier 1/no PPE | 42 | 62.7 | **149** |
| Tier 2a/gloves during semi-automatic loading and application | 42 | 52.2 | **124** |
| Tier 2b/gloves + coated coverall during semi-automatic loading  gloves + impermeable coverall during application | 42 | 5.54 | **13.2** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading  gloves + impermeable coverall + RPE APF 40 during application | 42 | 5.46 | 12.99 |
| Scenario 9-10 (semi-automatic loading + manual brush) | Tier 1/no PPE | 42 | 13.4 | **32** |
| Tier 2a/gloves during semi-automatic loading and application | 42 | 5.85 | **14** |
| Tier 2b/gloves + coated coverall during semi-automatic loading  gloves during application | 42 | 4.55 | 10.8 |
| **META SPC 2** | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 42 | 101 | **242** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 88.4 | **211** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 10.2 | **24** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | 5.8 | 13.8 |
| Scenario 5+6 (loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 42 | 108 | **258** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 42 | 50.4 | **120** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 42 | 6.97 | **17** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading and application gloves + coated coverall during cleaning | 42 | 4.58 | 10.9 |

*\*According to the CAR, exposure to calcium is acceptable when expressed as a percentage of the UL it should be less than 13%.*

**For disinfection of sewage sludge and manure**

The combined exposure is inferior to 13% of UL considering that gloves are worn during the cleaning.

**For disinfection of floor**

* **Manual application** (low-pressure sprayer, downwards)

Meta SPC 1

The combined exposure is superior to 13% of UL (36.6%) even if PPE (gloves and impermeable coverall) are worn during semi-automatic loading, application and cleaning of spray equipment.

Meta SPC 2

The combined exposure is slightly superior to 13% of UL considering that gloves and impermeable coverall are worn during semi-automatic loading, application and cleaning of spray equipment but relatively close to the 13% of the UL of calcium (13.8%) to be considered as acceptable.

* **Manual application** (high-pressure sprayer)

Meta SPC 1

The combined exposure is superior to 13% of UL (22.5%) even if PPE (gloves, impermeable coverall and APF 40) are worn during semi-automatic loading and application and gloves and impermeable coverall during cleaning.

Meta SPC 2

The combined exposure is inferior to 13% of UL (10.9%) if gloves/impermeable coverall are worn during semi-automatic loading/application and gloves/coated coverall are worn during cleaning of spray equipment.

* **Semi-automatic application:**

The combined exposure is inferior to 13% of UL (12.99%) if gloves/impermeable coverall are worn during semi-automatic loading and gloves/impermeable coverall/mask APF 40 during semi-automatic application.

**For disinfection of wall:**

*Primary exposure*

The combined exposure is inferior to 13% of UL (10.8%) if gloves/coated coverall are worn during semi-automatic loading and gloves during application.

*Secondary exposure*

For professional touching freshly-painted of walls, the exposure is superior to 13% of UL (356%). For professional touching dried surfaces, the exposure is inferior to 13% of UL (8.5%).

Therefore, a RMM must be added in order to avoid professional dermal contact with wet treated surfaces.

Moreover, since each exposure for primary and secondary exposure is close to 13% of UL, professional must not touch the treated surface the day of the application.

Systemic effects **(magnésium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)**\* |
| **META SPC 1** | | | | |
| Scenario 1 – automatic application to system | Tier 1/no PPE | 4.2 | 1.53E-03 | 0.04 |
| Scenario 2  Cleaning and maintenance - Manual cleaning of equipment | Tier 1/no PPE | 4.2 | 3.69E-01 | 8.8 |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/ no PPE | 4.2 | 1.92E-02 | 0.46 |
| Tier 2a/ gloves | 4.2 | 1.50E-02 | 0.36 |
| Tier 2b/ gloves + coated coverall | 4.2 | 3.37E-03 | 0.08 |
| Tier 2b/ gloves + impermeable coverall | 4.2 | 1.19E-03 | 0.03 |
| Scenario 4 – Manual spraying with low-pressure sprayer | Tier 1/no PPE | 4.2 | 10.9 | **260** |
| Tier 2a/gloves | 4.2 | 9.57 | **228** |
| Tier 2b/gloves + coated coverall | 4.2 | 1.09 | **26** |
| Tier 2b/gloves + impermeable coverall | 4.2 | 6.21E-01 | **15** |
| Scenario 5 – Manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 4.2 | 9.93 | **236** |
| Tier 2a/gloves | 4.2 | 4.63 | **110** |
| Tier 2b/gloves + coated coverall | 4.2 | 6.32E-01 | **15** |
| Tier 2c/gloves + impermeable coverall | 4.2 | 4.10E-01 | 9.8 |
| Scenario 6 – Cleaning of spray equipment | Tier 1/no PPE | 4.2 | 1.22E-01 | 2.9 |
| Tier 2a/gloves | 4.2 | 5.07E-02 | 1.21 |
| Tier 2b/gloves + coated coverall | 4.2 | 1.65E-02 | 0.39 |
| Tier 2b/gloves + impermeable coverall | 4.2 | 1.01E-02 | 0.24 |
| Scenario 7 – Semi-automatic loading of the sprayer tank (tractor) | Tier 1/no PPE | 4.2 | 1.92E-02 | 0.46 |
| Tier 2a/gloves | 4.2 | 1.50E-02 | 0.36 |
| Tier 2b/gloves + coated coverall | 4.2 | 3.37E-03 | 0.08 |
| Tier 2b/gloves + impermeable coverall | 4.2 | 1.19E-03 | 0.03 |
| Scenario 8 – Semi-automatic application | Tier 1/no PPE | 4.2 | 2.56 | **61** |
| Tier 2a/gloves | 4.2 | 2.13 | **51** |
| Tier 2b/gloves + coated coverall | 4.2 | 0.53 | 12.5 |
| Scenario 9 – Semi-automatic loading of buckets | Tier 1/ no PPE | 4.2 | 8.82E-02 | 2.1 |
| Tier 2a/ gloves | 4.2 | 6.88E-02 | 1.6 |
| Tier 2b/ gloves + coated coverall | 4.2 | 1.55E-02 | 0.4 |
| Scenario 10  Manual application using a brush | Tier 1/no PPE | 4.2 | 4.62E-01 | 11 |
| Tier 2a/gloves | 4.2 | 1.70E-01 | 4.1 |
| Scenario 12 Professional touching freshly-painted or dried surfaces of walls | Tier 1/wet paint | 4.2 | 6.15 | **146** |
| Tier 2/dried paint | 4.2 | 1.48E-01 | 3.5 |
| **Meta SPC 2** | | | | |
| Scenario 3 – Semi-automatic loading of the low-pressure sprayer | Tier 1/no PPE | 4.2 | 8.82E-03 | 0.21 |
| Tier 2a/gloves | 6.88E-03 | 0.16 |
| Tier 2b/gloves + coated coverall | 1.55E-03 | 0.04 |
| Scenario 4 – manual spraying with low-pressure sprayer | Tier 1/no PPE | 4.2 | 4.26 | **102** |
| Tier 2a/gloves | 3.74 | **89** |
| Tier 2b/gloves + coated coverall | 4.27E-01 | 10 |
| Scenario 5 – manual spraying with a high-pressure sprayer (loading included) | Tier 1/no PPE | 4.2 | 4.57 | **109** |
| Tier 2a/gloves | 2.13 | **51** |
| Tier 2b/gloves + coated coverall | 2.91E-01 | 6.9 |
| Tier 2c/gloves + impermeable coverall | 1.88E-01 | 4.5 |
| Scenario 6 – Cleaning of spray equipment | Tier 1/no PPE | 4.2 | 4.78E-02 | 1.1 |
| Tier 2a/gloves | 1.98E-02 | 0.5 |
| Tier 2b/gloves + coated coverall | 6.54E-03 | 0.15 |

*\*According to the CAR, exposure to calcium is acceptable when expressed as a percentage of the UL it should be less than 13%.*

**Combined scenarios (magnésium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)**\* |
| **META SPC 1** | | | | |
| Scenario 1+2 (automatic loading + cleaning of equipment) | 1/no PPE | 4.2 | 3.71E-01 | 8.8 |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 4.2 | 11.1 | **263** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 9.63 | **229** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 1.11 | **26** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading, application and cleaning | 6.32E-01 | **15** |
| Scenario 5+6 (semi-automatic loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 4.2 | 10.1 | **239** |
| Tier 2a/gloves during loading, application and cleaning | 4.2 | 4.68 | **111** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 4.2 | 6.48E-01 | **15.4** |
| Tier 2c/gloves + impermeable coverall during semi-automatic loading and application gloves + coated coverall during cleaning | 4.2 | 4.26E-01 | 10.2 |
| Scenario 7+8 (semi-automatic loading + semi-automatic application) | Tier 1/no PPE | 4.2 | 2.58 | **61** |
| Tier 2a/gloves during loading and application | 2.15 | **51** |
| Tier 2b/gloves + coated coverall during application | 0.55 | 12.98 |
| Scenario 9-10 (semi-automatic loading + manual brush) | Tier 1/no PPE | 4.2 | 0.55 | **13.1** |
| Tier 2/gloves for application | 4.2 | 0.26 | 6.2 |
| **META SPC 2** | | | | |
| Scenario 3+4+6 (semi-automatic loading + application with a **low-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 4.2 | 4.32 | **103** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 3.77 | **89.7** |
| Tier 2b/gloves + coated coverall during semi-automatic loading, application and cleaning | 0.44 | 10.4 |
| Scenario 5+6 (semi-automatic loading + application with a **high-pressure** sprayer + cleaning of equipment) | Tier 1/no PPE | 4.2 | 4.62 | **110** |
| Tier 2a/gloves during semi-automatic loading, application and cleaning | 4.2 | 2.15 | **51** |
| Tier 2b/gloves + coated coverall during semi-automatic loading and application | 4.2 | 3.38E-01 | 8.1 |

*\*According to the CAR, exposure to calcium is acceptable when expressed as a percentage of the UL it has to be less than 13%.*

**For disinfection of sewage sludge and manure**

The combined exposure is inferior to 13% of UL. No PPE are required.

**For disinfection of floor**

* **Manual application** (low-pressure sprayer, downwards)

Meta SPC 1

The combined exposure is slightly superior to 13% of UL (15%) considering that gloves and impermeable coverall are worn during semi-automatic loading, application and cleaning of spray equipment.

Meta SPC 2

The combined exposure is inferior to 13% of UL (10.4%) considering that gloves/coated coverall are worn during semi-automatic loading, application and cleaning of spray equipment.

* **Manual application** (high-pressure sprayer)

The combined exposure is inferior to 13% of UL (10.2%) if gloves/impermeable coverall are worn during semi-automatic loading/application and gloves/coated coverall are worn during cleaning of spray equipment.

* **Semi-automatic application:**

The combined exposure is inferior to 13% of UL (12.98%) if gloves/coated coverall are worn during semi-automatic application.

**For disinfection of wall:**

*Primary exposure*

The combined exposure is inferior to 13% of UL (6.2%) if gloves are worn during manual application.

*Secondary exposure*

For professional touching freshly-painted of walls, the exposure is superior to 13% of UL (146%). For professional touching dried surfaces, the exposure is inferior to 13% of UL (3.5%).

Therefore, a RMM must be added in order to avoid professional dermal contact with wet treated surfaces.

Moreover, since each exposure for primary and secondary exposure is close to 13% of UL, professional must not touch the treated surface the day of the application.

**Local effects – calcium dihydroxide**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario number** | **Tier/RPE** | **AEC (mg/m3)** | **Estimated calcium dihydroxide inhalation uptake**  **(mg/m3)** | **Estimated uptake/AEC**  **(%)** |
| **META SPC 1** | | | | |
| Scenario 2  Manual cleaning of equipment | Tier 1/no RPE | 0.3 | 10.44 | **3480** |
| Tier 2/RPE (APF **40**) | 0.3 | 0.26 | 87 |
| Scenario 4 -  Manual spraying with low-pressure sprayer | Tier 1/no RPE | 0.3 | 0.6 | **195** |
| Tier 2/RPE (APF **4**) | 0.3 | 0.15 | 49 |
| Scenario 5 -  Manual spraying with a high-pressure sprayer (loading included) | Tier 1/no RPE | 0.3 | 34.2 | **11400** |
| Tier 2/RPE (APF **40**) | 0.3 | 0.86 | **285** |
| Scenario 8  Semi-automatic application | Tier 1/no RPE | 0.3 | 6.51 | **2168** |
| Tier 2/RPE (APF **40**) | 0.3 | 0.16 | 54 |
| Scenario 10  Manual application using a brush | Tier 1/no RPE | 0.3 | 0.73 | **245** |
| Tier 2/RPE (APF **4**) | 0.3 | 0.18 | 61 |
| **META SPC 2** | | | | |
| Scenario 4 -  Manual spraying with low-pressure sprayer | Tier 1/no RPE | 0.3 | 0.26 | 87 |
| Scenario 5 - Manual spraying with a high-pressure sprayer (loading included) | Tier 1/no RPE | 0.3 | 15.2 | **5067** |
| Tier 2/RPE (APF **40**) | 0.3 | 0.38 | **127** |

**For disinfection of sewage sludge and manure**

During the cleaning of equipment, the local exposure is inferior to AEC if mask APF 40 is worn.

**For disinfection of floor**

* **Manual application (low-pressure sprayer):**

For meta SPC 1, during manual spraying with a low-pressure sprayer, the local exposure is inferior to AEC if mask APF 4 is worn.

For meta SPC 2, during manual spraying with a low-pressure sprayer, the local exposure is inferior to AEC witout RPE.

* **Manual application (high-pressure sprayer):**

For meta SPC 1-2, the local exposure is superior to AEC even if RPE is worn.

* **Semi-automatic application:**

During the semi-automatic application, the local exposure is inferior to AEC if mask APF 40 is worn during application.

**For disinfection of wall:**

The local exposure is inferior to AEC if mask APF 4 is worn during application by brushing.

**Local effects (hydrated lime)**

According to the guidance on the BPR for human health, a qualitative local risk assessment is performed, since meta SPC 1 is classified H315/H318/H335 and meta SPC 2 is classified H315/H319.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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* |
| **Disinfection of sewage sludge and manures** – Uses #1-2 | | | | | | | | | |
| Meta SPC 1 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 2-3 | Professional | 1: (semi-)automatic loading  2: 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1:  - face shield  - substance/task appropriate gloves  - protection coverall  For task 2:  - goggles  - protection coverall  - substance/task appropriate gloves |
| Very high | Eye Dam.1, H318 | - | 2-3 | Professional | 1: (semi-)automatic loading  2: cleaning | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1:   * face shield   For task 2:   * goggles |
| Low | STOT RE 3, H335 | - | 2-3 | Professional | Cleaning | Inhalation | 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 RPE during cleaning:  - Substance/task appropriate respirator |
| Meta SPC 2 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 2-3 | Professional | 1: (semi-)automatic loading  2: 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following RPE:  - face shield  - substance/task appropriate gloves  - protection coverall |
| Very high | Eye Dam.1, H318 | - | 2-3 | Professional | 1: (semi-)automatic loading  2: cleaning | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:   * face shield |
| **Disinfection of floor surfaces** – Uses #3-4-6 | | | | | | | | | |
| Meta SPC 1 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 3 | Professional | 1: semi-automatic loading  2: manual or semi-automatic application  3: cleaning of manual sprayer | 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1-3:  - face shield  - substance/task appropriate gloves  - protection coverall  For task 2:  - goggles  - substance/task appropriate gloves  - protection coverall |
| Very high | Eye Dam.1, H318 | - | 3 | Professional | 1: semi-automatic loading  2: manual  3:semi-automatic application  3: cleaning of manual sprayer | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1-3:   * face shield   For task 2:   * goggles |
| Low | STOT RE 3, H335 | - | 3 | Professional | Manual or semi-automatic application | Inhalation | 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 RPE during application:  - Substance/task appropriate respirator |
| Meta SPC 2 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 3 | Professional | 1: semi-automatic loading  2: manual or semi-automatic application  3: cleaning of manual sprayer | 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following RPE:  - face shield  - substance/task appropriate gloves  - protection coverall |
| Very high | Eye Dam.1, H318 | - | 3 | Professional | 1: semi-automatic loading  2: manual or semi-automatic application  3: cleaning of manual sprayer | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:   * face shield |
| **Disinfection of animal accommodation walls by brush** – Use #5 | | | | | | | | | |
| Meta SPC 1 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 3 | Professional | 1: semi-automatic loading of buckets  2: application by brush | 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1:  - face shield  - substance/task appropriate gloves  - protection coverall  For task 2:  - goggles  - substance/task appropriate gloves  - protection coverall |
| Very high | Eye Dam.1, H318 | - | 3 | Professional | 1: semi-automatic loading of buckets  2: application by brush | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  For task 1:   * face shield   For task 2:   * goggles |
| Low | STOT RE 3, H335 | - | 3 | Professional | Application by brush | Inhalation | 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 RPE during application:  - Substance/task appropriate respirator |
| Meta SPC 2 | | | | | | | | | |
| High | Skin Irrit.2, H315 | - | 3 | Professional | 1: semi-automatic loading of buckets  2: application by brush | 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:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:  - face shield  - substance/task appropriate gloves  - protection coverall |
| Very high | Eye Dam.1, H318 | - | 3 | Professional | 1: semi-automatic loading of buckets  2: application by brush | Ocular | Few minutes per  day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | Considering that the product will be applied by a professional, technic and organizational RMM are followed:   * Minimisation of splashes and spills   The risk is acceptable considering the following PPE:   * face shield |

A rinsing of commercial packaging with water can performed by professionals after use. Considering that exposure during this task is the same than those during cleaning of manual spray equipment, the same PPE deriving from the local qualitative risk assessment are proposed:

* gloves
* coated coverall
* face shield

**Conclusion**

**Disinfection of sewadge sludge and manures:**

The risk is considered as acceptable for all meta SPC if the following PPE/RPE are worn:

* automatic loading:
  + gloves
  + coated coverall
  + face shield
  + cleaning of equipment
* gloves
* coated coverall
* mask APF 40
* goggles
* rinsing of commercial packaging
* gloves
* coated coverall
* face shield

The following RMM are needed:

* Wear protective gloves and protection coverall during the manipulation of treated sewage sludge or manure.
* Minimisation of splashes and spills.
* The semi-automatic loading of the product in the blender must be carried out directly from the packaging.

Moreover, it is also likely that the addition of calcium dihydroxide to sewage leads to the production of ammonia gas, which may be of some concern. It is very difficult to predict the likely air concentrations that would prevail in treatment plants and whether they are likely to exceed such exposure limits.

Therefore, during the treatment of sewage sludge, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas. During the cleaning step, the concentration of ammonia is considered be below than the one during the application step.

**Disinfection of floor surfaces:**

**Manual application :**

*High-pressure sprayer*

Meta SPC 1:

The risk is considered as unacceptable .

Meta SCP 2:

The risk is considered as unacceptable.

*Low-pressure sprayer*

Meta SPC 1:

The risk is considered as unacceptable .

Meta SPC 2:

The risk is considered as acceptable if the following PPE/RPE are worn during semi-automatic loading, manual application and cleaning of spray equipment:

* gloves
* impermeable coverall
* face shield

and during rinsing of commercial packaging:

* + gloves
  + coated coverall
  + face shield

Moreover, the following RMM are needed:

* Minimisation of splashes and spills.
* The semi-automatic loading of the product in the sprayer must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.
* The application must be performed downwards with a low-pressure sprayer
* During application, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas (only for use 4 disinfection of animal bedding materials).

**Semi-automatic application :**

The risk is considered acceptable if the following PPE/RPE are worn during:

* semi-automatic loading :
  + gloves
  + impermeable coverall
  + face shield
* application :
* gloves
* impermeable coverall
* mask APF 40
* goggles
* rinsing of commercial packaging:
  + gloves
  + coated coverall
  + face shield

Moreover, the following RMM are needed:

* Minimisation of splashes and spills
* The semi-automatic loading of the product in the spraying systems must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.
* During application, the wear of air fed or canister RPE specific for ammonia gas is recommended in absence of collective management measures to estimate and prevent an exposure greater than the EUOEL of 14 mg/m3 for this gas (only for use 4 disinfection of animal bedding materials).

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

The risk is considered acceptable if the following PPE/RPE are worn during:

* semi-automatic loading :
  + gloves
  + coated coverall
  + face shield
* application :
  + gloves
  + coated coverall
  + mask APF 4
  + goggles
* rinsing of commercial packaging:
  + gloves
  + coated coverall
  + face shield

Moreover, the following RMM are needed:

* Minimisation of splashes and spills.
* Do not touch the treated wall until complete drying of treated surfaces.
* Do not touch the treated wall the day of treatment
* The semi-automatic loading of the product in the buckets must be carried out directly from the packaging. During loading, the IBC must be fitted with a drain spout or a dispensing gun.

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

Not relevant.

***Risk for the general public***

Systemic effects **(calcium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **META SPC 1** | | | | |
| Scenario 13- Toddler touching freshly-painted or dried surfaces of walls with hand-to-mouth transfer | Tier 1/wet paint | 42 | 252 | **600** |
| Tier 2/dried paint | 42 | 6.05 | **14** |

For toddler touching freshly-painted or dried surfaces of walls with hand-to-mouth transfer, the exposure is superior to 13% of UL. A RMM must be added in order to prevent children from accessing treated areas.

Systemic effects **(magnesium)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **META SPC 1** | | | | |
| Scenario 13- Toddler touching freshly-painted or dried surfaces of walls with hand-to-mouth transfer | Tier 1/wet paint | 4.2 | 10.4 | **247** |
| Tier 2/dried paint | 4.2 | 2.49-01 | 5.9 |

For toddler touching freshly-painted or dried surfaces of walls with hand-to-mouth transfer, the exposure is superior to 13% of UL.

**Conclusion**

The following RMM is needed:

* Forbid children’s access to fresh or dried treated surfaces.

To avoid dermal exposure of children by crawling on treated floors (uses #3-4-6), the following RMM is required:

* Forbid children’s access to treated floors

Moreover, for general public who manipulate treated sludge or manure, the following RMM is required:

* Wear protective gloves and protection coverall during the manipulation of treated sewage sludge or manure.

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

Considering that the active substance is composed from Ca2+, whichis an essential element of the body and an ubiquitous compound used in high amounts as fertilizer, the general public dietary exposure related to the intended uses is not considered to be relevant.

**Conclusion**

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

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

Regarding intended uses on bedding materials (TP3 use#4), the animals may be in direct contact with the active substance. Therefore, an indirect exposure via food of animal origin might be expected for these uses. Nevertheless, regarding the natural exposure and the toxicological properties of the compound under consideration, Ca2+, RMS considered that the dietary risk from consumer related to the intended uses is negligible.

### Risk assessment for animal health

No exposure is expected for animals. The following risk mitigation measure is proposed during application: “use only in the absence of animals.”

### Risk assessment for the environment

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

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

The products are a blend of the active substance (at a concentration of 12 to 45%) and water. This active substance is a naturally occurring inorganic salt.

No environmental SoCs were identified for the MILK OF LIME 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 and 3: Veterinary hygiene, RMS UK, May 2016).

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

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 MILK OF LIME are not available. Therefore, all data pertaining to the active substance are derived from the Calcium dihydroxide, Hydrated lime CAR (2016).

***Further Ecotoxicological studies***

No data required.

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

No data available.

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

No data available.

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

No data available.

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

Further information on the secondary ecological effect is not required.

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

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

Direct routes:

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

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

No data available.

***Leaching behaviour (ADS)***

No data available.

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

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

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

**Distribution**

Hydrated lime would simply dissociate to its respective ion constituents (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 MILK OF LIME.

***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 MILK OF LIME.

***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 the European level, a qualitative assessment will be conducted. For the terrestrial compartment, it involves the calculation of lime emissions on arable land due to the biocidal claimed uses and the comparison with routine agricultural use of lime to control soil pH. According to EU wide good agricultural practices, the guideline recommends application rates to neutralise agricultural soil up to 16 tons/ha per year (as CaO) in lime deficient soils.

#### Exposure assessment

MILK OF LIME is a PT2 and PT3 product family (divided in 3 products) containing calcium dihydroxide, Hydrated lime (CAS 1305-78-8) with a maximum concentration of 45% of active substance. Considering that for each use, the same active substance dose is required for each product (only the product dose and the product concentration are different), all products are evaluated with one calculation based on active substance dose.

**General information**

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

|  |  |
| --- | --- |
| Assessed PT | PT 3 |
| Assessed scenarios | Scenario 2.1: Application to manure,  Scenario 2.2: Application on animal bedding materials,  Scenario 2.3: Application on indoor walls of animal accommodations,  Scenario 2.4: Application on indoor floor of animal accommodations,  Scenario 3: Application on indoor floor of animal transportation,  Scenario 4: Application on floors of outdoor animal enclosures (poultry). |
| ESD(s) used | Scenario 2.1:   * ESDTP3, Veterinary hygiene biocidal products, 2011 * ESDTP18, Emission scenario document for Insecticides for stables and manure storage systems, 2006   Scenario 2.2, 2.3, 2.4 and 3:   * ESDTP3, Veterinary hygiene biocidal products, 2011   Scenario 4: Not applicable |
| Approach | Semi-qualitative assessment is performed in accordance with the approach used in the active substance CAR. |
| Distribution in the environment |  |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 2, 3, 4:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks |  |

***Emission estimation***

###### Scenario 1 (PT2): disinfection of sewage sludge in an open mixer

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

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

This use has been assessed in the CAR of the active substance Hydrated Lime PT2, with the following application rate in comparison with the product MILK OF LIME:

|  |  |  |
| --- | --- | --- |
| **Application rate of active substance in sewage sludge** | | |
|  | **Representative product of the CAR Hydrated Lime, 2016** | **MILK OF LIME products** |
|  | | |
| Application rate of the a.s (in % of dry solid weight of sludge) | 50 | 3 |

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 MILK OF LIME (see table below).

|  |  |  |
| --- | --- | --- |
| **Application rate of active substance in agricultural fields** | | |
|  | **Representative product of the CAR Hydrated lime, 2016** | **MILK OF LIME product** |
| **Input** |  |  |
| Application rate of the a.s for the use described in the CAR | 50% of dry solid weight of sludge | 3% of dry solid weight of sludge |
| Maximum 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 | 150 kg |
| Total dry weight of treated sludge after the treatment | 7500 kg | 5150 kg |
| Application of a.s per ha per year due to the final 5000 kg of actual sludge landed in agricultural field | 5000/7500 \* 2500 = 1.7 t/ha/year | 5000/5150\*150 = 0.146 t/ha/year |

As the use of MILK OF LIME will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME 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.

###### Scenario 2 (PT3): disinfection of animal accomodations:

For the four following uses:

- 2.1: disinfection of manure,

- 2.2: disinfection of animal bedding materials,

- 2.3: disinfection of walls of indoor animal accommodations and

- 2.4: disinfection of indoor floor of animal accommodations,

the product is mixed or released in manure after application. The mix hydrated lime/manure is removed when accommodations are cleaned and sent to manure storage for use in fields or for incineration. The applicant said that the product will not be released to drain as the type of waste makes it physically impossible to send to STP/drain. Nevertheless, a risk mitigation measure preventing the releases to STP will be added:

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

The manure could be spread on fields, therefore the soil compartment is directly exposed to the active substance.

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

* For cattle: veal calves emissions,
* For poultry: turkeys emissions.

*Scenario 2.1: disinfection of manure*

The product is mixed with a manure, litter or manure/litter mixture, outdoor in a manure storage silo/pit (for any type of animal accommodations) or is gathered in a specific area inside the animal house and treated inside (for poultry only).

It can be demonstrated that this use generates applications of lime in agricultural soil lower than 16t/ha/year.

In order to estimate this, the following parameters are calculated:

1. **The concentration of a.s in manure** after the application of the product.

Then,

1. **The maximum application rate of manure in grassland and arable land**, based on the nitrogen immission standard. The concentration of nitrogen in manure are calculated according to ESDTP3 and ESDTP18 for stables adapted parameters.

Finally,

1. **The maximum application rate of substance in agricultural soil**, considering the concentration of a.s in manure after the application, and the maximum application rate of manure.

The concentration rate of active substance in manure is calculated as follow:

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Concentration of a.s in manure after the application of product** | | | |
|  | **Symbol** | **Value** | **Unit** |
|  | **MILK OF LIME products**  **Scenario 2.1** |  |
|  | | | |
| **Concentration of a.s in manure after the application of product** | **-** | **30** | [kg/m3 of manure] |

As no scenario exists for this use, some parameters from ESDTP3, (2011) and ESDTP18 for stables (2006) were adapted to calculate the maximal application rate of manure in agricultural soil.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **Application rate of manure in arable and grassland** | | | | | | |
| **Parameters** | **Symbol from ESDTP3/18** | **Value** | | **Unit** | **Remarks** |
| **Input** | | | | | |
|  |  | **Scenario 2.1 - Manure** | |  |  |
| **Veal calves** | **Turkey** |
| Amount of nitrogen produced per animal per day | Qnitrogi1 | 0.02382 | 0.00482 | [kg/day/animal] | ESDTP3, 2011 |
| Amount of manure produced per animal per day | - | 0.007 | 0.00036 | [m3/animal/d] | ESDTP18, 2006  Table in Appendix 5 with conversion of L to m3 |
| Maximum emission standard for nitrogen on grassland | Qn, grassland | 170 | | [kg/ha/year] | ESDTP3, 2011 |
| Maximum emission standard for nitrogen on arable land | Qn, arable land | 170 | | [kg/ha/year] | ESDTP3, 2011 |
| **Intermediate Calculations** | | | | | |
| Concentration of nitrogen in the manure | - | 3.40 | 13.39 | [kg/m3] | Concentration of nitrogen in the manure =  Amount of nitrogen produced per animal per day / Amount of manure produced per animal per day |
| **Output** | | | | | |
| **Maximum application rate of manure on grassland** | - | **49.96** | **12.69** | [m3/year/ha soil] | Maximum application rate of manure on grassland or arable land =  Maximum emission standard for nitrogen on grassland or arable land / Concentration of nitrogen in the manure |
| **Maximum application rate of manure on arable land** | - | **49.96** | **12.69** | [m3/year/ha soil] |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Application rate of active substance in arable land and grassland** | | | | |
| **Input** | | | | |
| **Parameters** | **Value** | | **Unit** |
|  | **Scenario 2.1 - Manure** | |  |
| **Veal calves** | **Turkey** |
| Concentration of a.s in manure | 30 | 30 | [kg/m3 of wet manure] |
| Maximum application rate of manure on grassland and arable land | 49.96 | 12.69 | [m3/year/ha soil] |
| **Output** | | | |
| **3) Maximum application rate of active substance on grassland or arable land per year per hectare** | **1.50** | **0.38** | [T/year/ha] |

As the use of MILK OF LIME products will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME products 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 manure application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

*Scenario 2.2: disinfection of animal bedding materials*

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

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

For poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

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

Therefore, for treatment in:

* Veal caves accommodations, the surface of bedding material is 160+20 = 180 m².
* Turkeys accommodations, the surface of wall is 3330+60 = 3390 m².

Concerning the application rate:

* For veal calves, 1.5 kg of a.s/animal are considered. Therefore, 80 x 1.5 = 120 kg of active substance are needed to treat the bedding material of 80 animals distributed over 180 m².
* For turkeys, the value given by the applicant is 0.2 kg active substance/m² at a maximum.

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

| **Concentration of a.s in manure after the last application** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
| **Input** | | | |  |  |
| Type of House | cat-subcat (i1) | Veal calves | Turkey in free range – litter floor | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | Disinfectant | [-] | D |
| Emission to STP | Elocalwastewater | Not relevant | Not relevant | [-] | O |
| Amount of a.s prescribed to be used per m² | Qa.s m² | Not relevant | 0.2 | [kg/m²] | S |
| a.s | Qa.s ani | 1.5 | Not relevant | [kg/animal] | S |
|  |  |  |  |  |  |
| Area of the housing for application (bedding material surfaces only) | AREAi1 | 180 | 3390 | [m2] | D |
| Amount of active ingredient to be used for one  application | Qai-prescri1,i2,i3 | 120 | 678 | [kg] | O |
| Number of disinfectant applications in one year | Napp-bioc | 52**\*** | 104**\*** | [-] | D |
| Biocide application interval | Tbioc-int | 7**\*** | 3**\*** | [d] | D/O |
| Number of manure applications - grassland | Nlapp-grass | 4 | 4 | [-] | D |
| Number of manure applications - arable land | Nlapp-arab | 1 | 1 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | 53 | [d] | D |
| Manure application time interval for arable land | Tar-int | 212 | 212 | [d] | D |
| Number of animals | Nanimal i1 | 80 | 10000 | [-] | D |
| Amount of nitrogen per animal | Qnitrog i1 | 0.02382 | 0.00482 | [kg/d] | D |
| **if nitrogen immission standards are applied** | | | | | |
| Nitrogen immission standard for one year - grassland | QN,grassland | 170 | 170 | [kg.ha-1] | D |
| Nitrogen immission standard for one year - arable land | QN,arable\_land | 170 | 170 | [kg.ha-1] | D |
| **Intermediate Calculations** | | | | | |
| Fraction of a.s released to slurry/manure | Fslurry/manure | 0.5 | 0.2+0.3=0.5 | [-] |  |
| Number of biocide applications – grassland / arable land | Napp-manure grassland and arable land | 1**\*** | 1**\*** | [-] | O |
| Amount of active ingredient in manure - grassland / arable land | Qai-grass/arabi1,i2,i3,i4 | 60 | 339 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 101 | 2555 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of  animal/housing i1 and application to arable land | Qnitrog-arabi1,i4 | 404 | 10218 | [kg] | O |
| **Outputs** | | | | | |
| ***Soil exposure via manure spreading*** | | | | | |
| Annual application rate per hectare (arable land) | - | 25.2 | 5.64 | [kg/yr/ha] | O |
| Annual application rate per hectare (grassland) | - | 101**\*\*** | 22.6**\*\*** | [kg/yr/ha] | O |

\*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manuregr and Napp-manurear = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emission.

\*\* Worst-case used in the risk assessment.

As the use of MILK OF LIME products will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME products 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 manure application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

*Scenario 2.3: disinfection of indoor walls of animal accommodations*

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

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

For poultry bedding material treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

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

Therefore, for treatment in:

* Veal caves accommodations, the surface of walls is 330-160 = 170 m².
* Turkeys accommodations, the surface of walls is 4650-3330 = 1320 m².

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

| **Concentration of a.s in manure after the last application** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
| **Input** | | | |  |  |
| Type of House | cat-subcat (i1) | Veal calves | Turkey in free range – litter floor | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | Disinfectant | [-] | D |
| Emission to STP | Elocalwastewater | Not relevant | Not relevant | [-] | O |
| Amount of a.s prescribed to be used per m² | Qprod | 0.8 | 0.8 | [kg/m²] |  |
| Area of the housing for application (walls only) | AREAi1 | 170 | 1320 | [m2] | D |
| Amount of active ingredient to be used for one  application | Qai-prescri1,i2,i3 | 136 | 1060 | [kg] | O |
| Number of disinfectant applications in one year | Napp-bioc | 1**\*** | 1**\*** | [-] | D |
| Biocide application interval | Tbioc-int | 365**\*** | 365**\*** | [d] | D/O |
| Number of manure applications - grassland | Nlapp-grass | 4 | 4 | [-] | D |
| Number of manure applications - arable land | Nlapp-arab | 1 | 1 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | 53 | [d] | D |
| Manure application time interval for arable land | Tar-int | 212 | 212 | [d] | D |
| Number of animals | Nanimal i1 | 80 | 10000 | [-] | D |
| Amount of nitrogen per animal | Qnitrog i1 | 0.02382 | 0.00482 | [kg/d] | D |
| **if nitrogen immission standards are applied** | | | | | |
| Nitrogen immission standard for one year - grassland | QN,grassland | 170 | 170 | [kg.ha-1] | D |
| Nitrogen immission standard for one year - arable land | QN,arable\_land | 170 | 170 | [kg.ha-1] | D |
| **Intermediate Calculations** | | | | | |
| Fraction of a.s released to slurry/manure | Fslurry/manure | 0.5 | 0.2+0.3=0.5 | [-] |  |
| Number of biocide applications – grassland / arable land | Napp-manure grassland and arable land | 1**\*** | 1**\*** | [-] | O |
| Amount of active ingredient in manure - grassland / arable land | Qai-grass/arabi1,i2,i3,i4 | 68 | 528 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 101 | 2555 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of  animal/housing i1 and application to arable land | Qnitrog-arabi1,i4 | 404 | 10218 | [kg] | O |
| **Outputs** | | | | | |
| ***Soil exposure via manure spreading*** | | | | | |
| Annual application rate per hectare (arable land) | - | 28.6 | 8.78 | [kg/yr/ha] | O |
| Annual application rate per hectare (grassland) | - | 114**\*\*** | 35.1**\*\*** | [kg/yr/ha] | O |

\*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manuregr and Napp-manurear = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emission.

\*\* Worst-case used in the risk assessment.

As the use of MILK OF LIME products will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME products 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 manure application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

*Scenario 2.4: disinfection of indoor floor of animal accommodations*

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

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

For poultry floor treatment, no emissions to the STP compartment is considered and the fraction of release to STP was added to the fraction of release to manure/slurry (20%+30% = 50%).

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

| **Concentration of a.s in manure after the last application** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | | **Unit** | **S/D/O** |
| **Input** | | | |  |  |
| Type of House | cat-subcat (i1) | Veal calves | Turkey in free range – litter floor | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | Disinfectant | [-] | D |
| Emission to STP | Elocalwastewater | Not relevant | Not relevant | [-] | O |
|  |  |  |  |  |  |
| Amount of a.s prescribed to be used per m² | Qa.s | 1 | 1 | [kg/m²] |  |
|  |  |  |  |  |  |
| Area of the housing for application (floor only) | AREAi1 | 160 | 3330 | [m2] | D |
| Amount of active ingredient to be used for one  application | Qai-prescri1,i2,i3 | 160 | 3300 | [kg] | O |
| Number of disinfectant applications in one year | Napp-bioc | 4**\*** | 2**\*** | [-] | D |
| Biocide application interval | Tbioc-int | 91**\*** | 182**\*** | [d] | D/O |
| Number of manure applications - grassland | Nlapp-grass | 4 | 4 | [-] | D |
| Number of manure applications - arable land | Nlapp-arab | 1 | 1 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | 53 | [d] | D |
| Manure application time interval for arable land | Tar-int | 212 | 212 | [d] | D |
| Number of animals | Nanimal i1 | 80 | 10000 | [-] | D |
| Amount of nitrogen per animal | Qnitrog i1 | 0.02382 | 0.00482 | [kg/d] | D |
| **if nitrogen immission standards are applied** | | | | | |
| Nitrogen immission standard for one year - grassland | QN,grassland | 170 | 170 | [kg.ha-1] | D |
| Nitrogen immission standard for one year - arable land | QN,arable\_land | 170 | 170 | [kg.ha-1] | D |
| **Intermediate Calculations** | | | | | |
| Fraction of a.s released to slurry/manure | Fslurry/manure | 0.5 | 0.2+0.3=0.5 | [-] |  |
| Number of biocide applications – grassland / arable land | Napp-manure grassland and arable land | 1**\*** | 1**\*** | [-] | O |
| Amount of active ingredient in manure - grassland / arable land | Qai-grass/arabi1,i2,i3,i4 | 80 | 1665 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 101 | 2555 | [kg] | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of  animal/housing i1 and application to arable land | Qnitrog-arabi1,i4 | 404 | 10218 | [kg] | O |
| **Outputs** | | | | | |
| ***Soil exposure via manure spreading*** | | | | | |
| Annual application rate per hectare (arable land) | - | 33.7 | 27.7 | [kg/yr/ha] | O |
| Annual application rate per hectare (grassland) | - | 135**\*\*** | 111**\*\*** | [kg/yr/ha] | O |

\*As only the last application of biocide is considered, one application of biocide during storage is applied in the calculations (Napp-manuregr and Napp-manurear = 1). Therefore, the number of disinfectant applications in one year (Napp-bioc) and the biocide application interval (Tbioc-int) of the ESD are presented for information only and not taken into account in the calculations of the emission.

\*\* Worst-case used in the risk assessment.

As the use of MILK OF LIME products will generate application of lime in agricultural soil lower than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME products 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 manure application is foreseen. Therefore, no emissions to aquatic compartments (STP, surface water or sediment) are expected and considered in the risk assessment.

###### Scenario 3: disinfection of indoor floor of animal transportation

The product is applied on floor inside of vehicle every day after every transport.

In ESDTP3 of 2011, the main emission pathway is emission to the wastewater, but also emission to air may take place. Based on a low vapour pressure (<<1.0E-05 Pa), negligible exposure via air is expected and therefore not further assessed.

To calculate the emissions to the STP of active substances such as lime is difficult because of the nature of the substance and the lack of data about their behavior in the STP, as this pathway was not assessed at the approval stage.

The doc IIA of the CAR (2016) specifies that adding lime up to 1000 mg/L in activated sludge test media causes high rises in pH (>12) which reduces to pH 10.6 after 3h. Other studies in different water media conducted with the same dose conclude that the reduction of the pH to background values can last up to 7 days. Such pH changes in the STP over such times (3h as much as 7 days) would result in the elimination of microorganisms and disruption of its functioning.

Although a complete quantitative risk assessment is not possible due to a lack of data, the Elocalwastewater is calculated to estimate a PECSTP and compare it with doses used in the activated sludge test of the CAR.

The calculation of the Elocalwastewater is done according to the ESDTP3, 2011, and presented in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Emissions and PEC calculations for of indoor floor of animal transportation** | | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Area of trucks (mammal transports) | AREAmam | 4546 | [m²] | ESDTP03, 2011 |
| Area of trucks (poultry transports) | AREApoul | 1120 | [m²] | ESDTP03, 2011 |
| Area of containers (poultry transports) | AREAcont | 3355 | [m²] | ESDTP03, 2011 |
|  |  |  |  |  |
| Amount of a.s prescribed to be used per m² | Qa.si2,i3 | 1 | [kg/m²] | S |
|  |  |  |  |  |
| Dilution factor (for preparation of the working solution from the formulation | Fdil | 1 | [-] | ESDTP03, 2011 |
| Fraction released to waste water | Fstpi2i3i4 | 0.9 | [-] | ESDTP03, 2011 |
| Number of disinfectant applications in one year | Napp-bioc | 365 | [-] | ESDTP03, 2011 |
| **Output** | | | | |
| **Emission from one application to a standard STP or an on-site waste water treatment plant (mammal)** | **Elocal wastewateri2i3i4 mammal** | **4091** | [kg/d] |  |
| **Emission from one application to a standard STP or an on-site waste water treatment plant (poultry)** | **Elocal wastewateri2i3i4 poultry** | **4028** | [kg/d] |  |
| **PECSTP calculation** | | | | |
| **Input** | | | | |
| Fraction of release to water from the STP | Fwater | 1**\*** | [-] |  |
| Effluent discharge rate of STP | EFFLUENTstp | 2000000 | [L/d] | Vol IV Part B+C; 2017 |
| **Output** | | | | |
| **PECSTP resulting of one application to a standard STP or an on-site waste water treatment plant (mammal)** | **PECSTP mammal** | **2.05** | [g/L] |  |
| **PECSTP resulting of one application to a standard STP or an on-site waste water treatment plant (poultry)** | **PECSTP poultry** | **2.01** | [g/L] |  |

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

As both PECSTP are higher than the doses assessed in the CAR (and more than 500 times higher than the PNECSTP  of 3.004 mg/L), high rises of the pH in the STP are expected. Therefore a release to the STP of the product after its use for animal transport disinfection leads to non-acceptable risks.

According to the applicant, a common practice to remove the lime consists in brushing the resulting dry waste before starting new transport to recycle them as agricultural liming material.

To prevent any releases to the STP from the disinfection of animal transport, the following RMM is applied:

“Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant”.

###### Scenario 4: disinfection of floor of outdoor animal enclosures

According to the applicant, the dry product is applied on the ground of poultry enclosures before each production cycle, every two weeks.

However, it has to be considering that as for manure and sludge spreading, 16 tons/ha /year of a.s is the maximum amount of lime that can be spread on soil. An application rate of 0.8 kg a.s/m² of soil corresponds to an application rate of 8. tons of a.s/ha. Therefore, only 2 applications per year at a maximum should be authorised. Higher application frequencies would lead to non-acceptable risks.

Moreover, in accordance with a French opinion[[8]](#footnote-9), the disinfection of the rangeland using such biocidal active substances is only carried out when the farms have been detected infected. Expert considers that an at least 6 weeks of fallowing is mandatory after the treatment. In routine, zootechnical measures are recommended.

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| Use | | Scenario | Fresh-water | Freshwater sediment | STP | Air | Soil | Groundwater |
| TP2 | Disinfection of sewage sludge | Scenario 1 | No | No | No | No | Yes | Yes |
| TP3 | Disinfection of manure | Scenario 2.1 | No | No | No | No | Yes | Yes |
| Disinfection of bedding material | Scenario 2.2 | No | No | No | No | Yes | Yes |
| disinfection of walls of indoor animal accommodations | Scenario 2.3 | No | No | No | No | Yes | Yes |
| Disinfection of indoor floor surfaces of animal accommodations | Scenario 2.4 | No | No | No | No | Yes | Yes |
| Disinfection of animal transportation area | Scenario 3 | Yes | Yes | Yes | No | Yes | Yes |
| Disinfection of floors of outdoor animal enclosures | Scenario 4 | No | No | No | No | Yes | Yes |

|  |  |  |  |
| --- | --- | --- | --- |
| **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) | 0.752h | 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***

For uses assessed in scenarios:

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

As all the uses generate lower emissions than the routine agricultural use of lime used to amend soil pH and maintain soil fertility, no further calculations are necessary to assess the impact of the use of MILK OF LIME on soil. A qualitative assessment is deemed sufficient as proposed during the assessment of the active substance at the European level.

For use assessed in scenario 3 (treatment of vehicle for animal transport), only PECSTP is calculated (see [Emission estimation](#_Scenario_3:_disinfection) section):

* For mammals: PECSTP = 2.05 g/L
* For poultry: PECSTP = 2.01 g/L

***Primary and secondary poisoning***

Primary poisoning

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

Secondary poisoning

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

For uses assessed in scenarios:

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

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

For use assessed in scenario 3 (treatment of indoor floor of animal transportation), a risk assessment for the STP compartment is conducted for mammal and poultry:

|  |  |  |  |
| --- | --- | --- | --- |
| **Uses** | **PECSTP (mg/L)** | **PNECSTP (mg/L)** | **PEC/PNEC** |
| Scenario 3 – indoor floor of animal transportation - Mammals | **2050** | 3.004 | **681** |
| Scenario 3 – indoor floor of animal transportation - Poultry | **2010** | 3.004 | **670** |

Thus, unacceptable risks are foreseen for the STP compartment for this use of all products.

The following RMM will be included to prevent any releases to the STP:

“Do not apply the product if releases from animal transport disinfection areas can be directed to a sewage treatment plant”.

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

All the uses of MILK OF LIME products that lead to emissions to soil will generate application rate of lime on agricultural soil lower than the routine agricultural use of lime spread to correct soil pH and maintain soil fertility (16T/ha/year, see table below).

|  |  |  |
| --- | --- | --- |
| **Uses** | **Emissions to soil (agricultural land, in T/ha/year)** | |
| **PT2** | | |
| 1 – Disinfection of sewage sludge | 0.146 | |
|  | | |
| **PT3** | Veal calves | Turkeys |
| 2.1 – Disinfection of manure | 1.50 | 0.38 |
| 2.2 - Disinfection of bedding material | 0.10 | 0.02 |
| 2.3 - Disinfection of indoor walls of animal accommodations | 0.11 | 0.04 |
| 2.4 - Disinfection of indoor floor surfaces of animal accommodations | 0.14 | 0.11 |
| 3 - Disinfection of animal transportation area | n.r. | n.r. |
| 4 - Disinfection of floor of outdoor animal enclosures | n.r. | 16 |

Therefore, the use of MILK OF LIME products 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 further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions will simply form part of existing chemical cycles in the natural environment.

In terms of the groundwater compartment, 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 groundwater.

##### ***Primary and secondary poisoning***

Primary poisoning

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

Secondary poisoning

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

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



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

No aggregated exposure is relevant for this dossier. However, an aggregated risk assessment leads to acceptable risks when all the uses are considered.

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

It is considered that this verification is part of good spreading/amendments practices. For example, in France several norms and regulation ensure the correct spreading of lime treated materials on agricultural fields, including soil pH monitorings. Hence eCA considers that such RMM is not necessary nor relevant in the SPC of the biocidal product MILK OF LIME.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Acceptable risks for the environment are foreseen for the uses:  In PT2:   * disinfection of sewage sludge,   In PT3, considering the following RMM “Do not apply the product if releases from animal housings, manure/slurry storage areas, or animal transportation disinfection areas can be directed to a sewage treatment plant”:   * disinfection of manure, * disinfection of animal bedding material, * disinfection of indoor walls of animal accommodations, * disinfection of indoor floor of animal accommodations and transportation,   In PT3, and considering the following RMM “Do not exceed two applications per year.”   * disinfection of floors of outdoor animal enclosures. |

# Annexes[[9]](#footnote-10)

## List of studies for the biocidal product (family)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Ownsby R.K, Krantz B. D. | 2012 | Corrosion testing per OSHA Regulations CFR 1910.1200 Appendix B | NO | PUB |
| Rückert. J, Höpfner. W | 2000 | CTL REF 29392-1R, 2012  & BAM evaluation metal corrosivity of Milk of Lime 11 Jan 2000 | NO | PUB |
| Schirm V. et al  6.7-01 | 2003 | Development of a safe method to hygienise bio-waste with lime.  Forschungsgemainschaft Kalk, 1/03/ C 023 Jan 2003  Report no. 336-0201 | NO | PUB |
| Author: Capizzi-Banas S.  6.7-02 | 2004 | Liming as an advanced treatment for sludge sanitisation: helminth eggs elimination - Ascaris as a model  Water Research 38: 3251-3258: Doc. No. 392-024, Year: 2004. | NO | PUB |
| Pfuderer G  6.7-03 | 1984 | Hygenic aspects related to treatment and use of sewage sludge  Ed P. L’Hermite, Elsevier, pp 85-97; Doc No 392-035, Year: 1984 | NO | PUB |
| Prof. Dr. A. Daugshies  6.7-06 | 2008 | Evaluation of limingin liquid and solid manure  Feb 6, 2008 | YES | EuLA Brussels Belgium |
| Crane D., Burney C.  6.7-09 | 2018 | Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action (Phase 2 Step 2) Calcium Hydroxide, clean conditions  J000714-1 | YES | EuLA Brussels Belgium |
| Crane D., Burney C.  6.7-10 | 2018 | Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on non porous surfaces without mechanical action, Calcium hydroxide dirty conditions (Phase 2 Step 2) | YES | EuLA Brussels Belgium |
| Crane D., Burney C.  6.7-12 | 2018 | Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants used in the veterinary area on non porous surfaces without  J000714-2 | YES | EuLA Brussels Belgium |
| : Prof. Dr. Daugschies  6.7-13 | 2008 | Evaluation of the effect of liming in liquid pig and cattle manure on Ascaris suum eggs | YES | EuLA Brussels Belgium |
| A. Carré  P. Strohl  6.7-15 | 2019 | Determination of microbicide activity of 2 powders: hydra-lime and oxi-lime according a methodology issued to NF T 72-281  RE-1143-0419 | YES | EuLA Brussels Belgium |
| A. Carré  P. Strohl  6.7-15A | 2019 | Determination of microbicide activity of Eula hydralime 23 according a methodology issued to NF T 72-281  Test on Aspergillus brasiliensis ATCC 16404 in low level soiling conditions for veterinary area  RE-1303-0919/A | YES | EuLA Brussels Belgium |
| A. Carré  P. Strohl  6.7-15B | 2019 | Determination of microbicide activity of Eula hydralime 23 according a methodology issued to NF T 72-281  Test on Porcine parvovirus ATCC VR-742 in high level soiling conditions for veterinary area  RE-1298/0819 | YES | EuLA Brussels Belgium |
| Nassar N et al  6.7-16 | 2019 | Effectiveness study of a biocide product for treatment of poultry (farm trial)  Company study number: 18-445R | YES | Lhoist on behalf of EuLA |
| NassarN et al  6.7-17 | 2019 | Efficacy Study Of A Biocidal Product For The Treatment Of Poultry Housing.  Company study number: 19-415R | YES | Lhoist on behalf of EuLA |
| Nassr N et al  6.7-18 | 2019 | EFFICACY STUDY OF A BIOCIDAL PRODUCT Treatment of swine husbandry building  Company study number: 19-413R | YES | Lhoist on behalf of EuLA |

## Output tables from exposure assessment tools



1. Arrêté du 8 janvier 1998 fixant les prescriptions techniques applicables aux épandages de boues sur les sols agricoles pris en application du décret n° 97-1133 du 8 décembre 1997 relatif à l'épandage des boues issues du traitement des eaux usées [↑](#footnote-ref-2)
2. <https://www.anses.fr/fr/system/files/MFSC2020SA0043.pdf> [↑](#footnote-ref-3)
3. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-4)
4. Arrêté du 8 janvier 1998 fixant les prescriptions techniques applicables aux épandages de boues sur les sols agricoles pris en application du décret n° 97-1133 du 8 décembre 1997 relatif à l'épandage des boues issues du traitement des eaux usées [↑](#footnote-ref-5)
5. <https://www.anses.fr/fr/system/files/MFSC2020SA0043.pdf> [↑](#footnote-ref-6)
6. Arrêté du 8 janvier 1998 fixant les prescriptions techniques applicables aux épandages de boues sur les sols agricoles pris en application du décret n° 97-1133 du 8 décembre 1997 relatif à l'épandage des boues issues du traitement des eaux usées [↑](#footnote-ref-7)
7. <https://www.anses.fr/fr/system/files/MFSC2020SA0043.pdf> [↑](#footnote-ref-8)
8. AVIS du 14/10/16 révisé le 08/03/17\* de l’Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail (ANSES) relatif aux « procédés efficaces de désinfection des parcours en exploitations de volailles » [↑](#footnote-ref-9)
9. 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-10)