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

Evaluation of active substances

Assessment Report

Hydrated Lime

Product Type 2

(Disinfectants and algaecides not intended for direct application to humans or animals)

May 2016

UK

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance hydrated lime as Product Type 2 (private area and public health area disinfectants), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Hydrated lime (CAS no. 1305-62-0) was notified as an existing active substance, by the European Lime Association (EuLA), hereafter referred to as the applicant, in Product Type 2.

Commission Regulation (EC) No 1062/2014 of 4 August 2014[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

On 27/02/2006 the UK Competent Authority received a dossier from EuLA. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 08/08/2006.

On 19/09/2011, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the "Agency" (ECHA). Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of hydrated lime for Product Type 2, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency website, shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

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[1] COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014, p. 1

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the active substance

2.1.1. Identity, physico-chemical properties & methods of analysis

The main identification characteristics and the physico-chemical properties of hydrated lime are given in Appendix I to this document. The active substance must be technically equivalent to the specification given.

There are a number of common analytical techniques available to quantify the four supported lime variants (burnt lime, burnt dolomitic lime, hydrated dolomitic lime, hydrated lime) as manufactured. All impurities, except water, are natural constituents of limestone and will vary depending on the local environment during the formation of the limestone. The impurities are analytically determined as elements but calculated and expressed as oxides. A specification has been provided, along with sample Certificates of Analysis (CoA). All Members of the EuLA who have not already done so will provide CoA six months before product Authorisation.

2.1.2. Intended uses and efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

Hydrated lime is used as a disinfectant for the treatment of sewage sludge (PT 2). The function of hydrated lime is to kill viruses, bacteria and parasites present in the media to which it is applied. In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and labelling of the active substance

Hydrated lime is not currently included in Annex VI of Regulation EC/1272/2008 (Classification, Labelling and Packaging Regulation). The proposed classification and labelling of the active substance hydrated lime according to CLP Regulation is shown in Table 2.1.

Table 2.1 Proposed classification of hydrated lime based on CLP Regulation

Pictogram	Signal Word	Hazard Class and Category	Hazard Statement
GHS05	Danger	Skin Irrit. 2 Eye Dam. 1 STOT SE 3	H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation

2.2. Summary of the risk assessment

2.2.1. Human health risk assessment

2.2.1.1. Hazard identification and effects assessment

<u>Introduction</u>

The active substance, hydrated lime, is practically identical to the biocidal products Schaefer Precal 50S and Schaefer Precal 50N. Hydrated lime is used as a disinfectant for the treatment of sewage sludge (PT 2). The function of hydrated lime is to kill viruses, bacteria and parasites present in the media to which it is applied. This is achieved through an increase in alkalinity and temperature and a decrease in water availability. Disinfectant products based on hydrated lime are used only by professional workers in specific treatment areas.

There are four structurally related lime compounds under review. These are: hydrated lime, burnt lime, hydrated dolomitic lime and burnt dolomitic lime. As they all share similar toxicological properties, in the risk assessment, where appropriate, they have been considered together. As explained below, the toxicological local effects of hydrated lime are driven by the presence or release (when reacting with moisture on the external surfaces of the human body) of the hydroxide ion.

Burnt lime (calcium oxide) forms slightly more hydroxide ions per unit mass than those liberated from calcium hydroxide (hydrated lime) and develops heat by reaction with water (which leads to desiccation of the exposed tissues over and above the pH-related effects caused by the hydroxide ions). Therefore, burnt lime is predicted to be more potent than hydrated lime. With regard to the dolomitic variants, as they contain only 2/3 (67 %) of calcium oxide/hydroxide, with 1/3 (33 %) being the insoluble, unreactive and undissociable magnesium oxide/hydroxide, they produce less severe effects than the non-dolomitic variants.

Overall, therefore, in relation to local effects, of the four active substances under review, burnt lime represents the worst-case. With regard to exposure, the intended uses of the four substances and their physico-chemical similarity are such that equivalent exposure estimates can be predicted for all four active substances. However, similarly to the hazard side, as burnt lime is the dustiest of the four substances, higher exposures may occur for burnt lime. Hence, a local risk assessment performed with the hazard and exposure data of burnt lime will represent the worst-case and encompass all 4 lime variants under review. The risk characterisation for local effects follows the principles agreed by the Biocides Technical Meeting and described in the Technical Guidance Document for Risk Characterisation of Local Effects. A local risk assessment is conducted by comparing external exposure concentrations with the derived Acceptable Exposure Concentration (AEC) = N(L)OAEC/overall assessment factor (AF). Risks are considered acceptable if the external exposure concentration is < AEC.

As indicated below, the toxicological systemic effects of hydrated lime are driven by its calcium content. Calcium is a natural constituent of the body and an essential element of the human diet. A Tolerable Upper oral intake Level (UL) for calcium has been established by the EU Scientific Committee on Food (SCF). This is 2500 mg calcium/person/day (SCF, 2003), which corresponds to 42 mg calcium/kg bw/day for a 60 kg person. Hence, for the systemic risk assessment of hydrated lime, the calcium fraction of the exposure estimate will be compared with the calcium UL. If the exposure estimates give rise to calcium body burdens significantly lower than the respective UL, then there are no risks of systemic effects from exposure to hydrated lime. It is important to ensure that the calcium body burden arising from exposure to hydrated lime contributes minimally to the overall calcium UL, as a significant part of the UL depends on other sources of exposure to calcium, mainly through the diet. For calcium, as there is an important contribution to the total body burden from dietary intake, the BPC Meeting agreed to set a cut-off value of 13 % of the UL, since this was the highest level that at Tier I generated acceptable risk. Therefore, only risks from the use of lime as a biocidal active substance below 87 % of the UL will be considered acceptable. This figure should still only be used with caution because dietary intakes of calcium vary greatly across the EU.

Toxicology Hazard Summary

The toxicological properties of hydrated lime have been evaluated on the basis of human data and animal studies conducted with some of the four lime variants under review and with soluble calcium salts and with other hydroxides. Where data on hydrated lime were not available, read-across from data on the other lime variants and calcium salts or other hydroxides, has been performed (see chapter 3 of Document IIA for more details). Only very few animal and *in vitro* studies carried out with the four lime variants under review were conducted to GLP and internationally accepted guidelines. The majority of the available animal studies were completed before the introduction of specific guidelines or GLP practices. However, the human database (especially that on calcium salts) is extensive and of high scientific quality. Overall, therefore, the available information is sufficient and of a standard acceptable for the purpose of this review. Where data were poor, inadequate or lacking, worst-case defaults were adopted.

The rationale for the read-across from data on other lime variants, calcium and/or other hydroxides is outlined below.

Hydrated lime (calcium hydroxide) is a solid, which is slightly soluble in water and moderately alkaline. When dissolved in water, as occurs on the external surfaces of the body, hydrated lime dissociates into Ca^{2+} and OH^-. The dissociation products Ca^{2+} and OH^- are chemically and biologically not further degradable because they constitute simple basic structures. Therefore the toxicological properties (local and systemic effects) of hydrated lime are equivalent to those of its dissociation products.

Burnt lime (calcium oxide) is a solid, which is slightly soluble in water and moderately alkaline. When dissolved in water, as occurs on the external surfaces of the body, burnt lime is converted through an exothermic reaction to calcium hydroxide (hydrated lime) which dissociates into Ca^{2+} and OH^-. Burnt lime forms slightly more OH^- ions than those liberated from hydrated lime and, by developing heat, causes desiccation of the exposed tissues. In view of this, although the potential systemic effects of burnt lime are expected to be similar to those of hydrated lime and its dissociation products, its potential local effects are likely to be more severe than those of hydrated lime. Hence, as burnt lime represents the worst-case, the risk assessment for local effects of the four 'lime' variants under review has been performed with the burnt lime hazard data.

Hydrated dolomitic lime (tetrahydroxide of calcium and magnesium) is a solid which, when dissolved in water, as occurs on the external surfaces of the body, releases hydrated lime (calcium hydroxide) (67 %) and magnesium hydroxide (33 %). Calcium hydroxide subsequently dissociates into Ca^{2+} and OH^-. Magnesium hydroxide has very low water solubility. This will limit its dissociation to Mg^{2+} and OH^-, its systemic absorption and its potential for local irritative effects; hence, its contribution to the toxicity of hydrated dolomitic lime is likely to be small. Therefore, the toxicological properties of hydrated dolomitic lime are expected to be equivalent to those of hydrated lime and its dissociation products. However, under conditions of exposure to hydrated dolomitic lime (e.g. oral exposure or exposure at irritant concentrations of the component hydrated lime) that will favour the solubilisation and dissociation of magnesium hydroxide to Mg^{2+} and OH^- (i.e. in the acidic environment of the stomach and, possibly, in specific compartments of the body following systemic absorption through damaged surfaces), read-across from data on soluble, readily dissociable magnesium salts is appropriate (for further details, see Document IIA).

Burnt dolomitic lime (oxide of calcium and magnesium) is a solid that, when dissolved in the aqueous environment of the external surfaces of the body, reacts with water through an exothermic reaction to produce calcium hydroxide (hydrated lime) (67 %) and magnesium hydroxide (33 %). Calcium hydroxide subsequently dissociates into Ca^{2+} and OH^-. Magnesium hydroxide has very low water solubility. This will limit its dissociation to Mg^{2+} and OH^-, its systemic absorption and its potential for local irritative effects; hence, its contribution to the toxicity of burnt dolomitic lime is likely to be small. Overall, therefore, the toxicological properties of burnt dolomitic lime are expected to be equivalent to those of burnt lime/hydrated lime and its dissociation products. However, under conditions of exposure to burnt dolomitic lime (e.g. oral exposure or exposure at irritant concentrations of the component burnt lime) that will favour the solubilisation and dissociation of magnesium hydroxide to Mg^{2+} and OH^- (i.e. in the acidic environment of the stomach and, possibly, in specific compartments of the body following systemic absorption through damaged surfaces), read-across from data on soluble, readily dissociable magnesium salts is appropriate (for further details, see Document IIA).

There are no studies which have specifically investigated the toxicokinetics, metabolism and distribution of hydrated lime. Such studies have been waived in view of the fact that existing data on calcium salts and predictions for the hydroxide ion can be used to assess the toxicokinetics of hydrated lime.

Hydrated lime, when dissolved in water on the external surfaces of the body (gastrointestinal tract, skin and respiratory tract), generates the formation of hydroxide ions. These ions produce irritative lesions of these membranes, with loss of surface integrity. Overall, therefore, at irritant concentrations, a worst-case value of 100 % absorption following oral, dermal or inhalation exposure is assumed for use in the risk characterisation for systemic effects. At non-irritant concentrations, the following absorption values have been proposed: an oral absorption value of 40 % (from data on calcium salts); a dermal absorption value of 10 % (TGD default for ions); and an inhalation absorption values of 100 % (prediction). Still, as for the dermal and oral routes the irritation thresholds have not been identified, 100 % absorption will be used for the purpose of the systemic risk assessment, as a worst-case assumption, regardless of the exposure concentration.

Following absorption into the systemic circulation, the calcium ions are widely distributed throughout the body, while the hydroxide ion is neutralised by the tightly controlled pH regulation mechanisms of the body (buffer capacity of extracellular body fluids, respiratory and renal compensation). There is no direct information on whether or not the calcium ions can cross the placenta and reach the foetus. However, because of their wide distribution throughout the body and their well-known role in foetal development, it can be predicted that there is extensive distribution of calcium to the foetal compartment. There is no metabolism of the two dissociation products, Ca^{2+} and OH^- as these are chemically and biologically not further degradable. The absorbed calcium is excreted in urine, faeces and sweat.

Hydrated lime is of low acute systemic toxicity by the oral and dermal routes of exposure. There are no data for the assessment of acute toxicity by the inhalation route; however, it can be predicted that acute systemic toxicity is also low for this route of exposure. The available data do not support classification of hydrated lime for acute toxicity.

The available data indicate that hydrated lime causes significant skin irritation and that classification with Skin Irrit.2 H315 is appropriate. Hydrated lime is also severely irritating to the eye; hence, classification with Eye Dam.1 H318 is appropriate. Two studies in humans involving exposures to hydrated lime and/or burnt lime have shown that hydrated lime causes sensory irritation of the nose, eye and throat. Effects considered adverse have been reported starting from a concentration of 2 mg m^{-3} for 20 min, and a NOAEC of 1 mg m^{-3} for a 20-min exposure has been identified. There is no information on the respiratory effects of hydrated lime at exposure concentrations higher than 5 mg m^{-3}; however, based on its severe skin and eye irritant properties and its strong alkaline properties, it is most likely that overt tissue damage would occur at higher concentrations. These data indicate that classification of hydrated lime with STOT SE 3 H335 is appropriate.

There are no studies, which have investigated the skin sensitisation potential of hydrated lime. The UK CA agrees that the irritant properties of hydrated lime prevent a meaningful assessment of its skin sensitising properties at irritant concentrations; however, there remains an uncertainty as to whether at non-irritant concentrations, hydrated lime, may possess skin sensitisation potential. Still, given the lack of reports of cases of skin sensitisation from workers exposed to hydrated lime, and as the recommended risk mitigation measures resulting from failure to identify a threshold for the irritant properties of the substance will prevent skin exposure, testing for skin sensitisation is deemed unnecessary. In worker health surveys and epidemiological studies of workers exposed to hydrated lime, there has been no mention of effects related to respiratory sensitisation.

There is no standard, good-quality animal study in which the effects of repeated exposure to hydrated lime have been investigated. The limited information available relates to the administration of hydrated lime via the oral route of exposure or to its application on to the buccal mucosa and cheek pouches; there are very little data on dose-response relationships. There is, however, an extensive oral repeated dose database in humans on soluble calcium salts (from SCF, 2003) and two animal chronic studies conducted with calcium lactate and magnesium chloride, which can inform on the potential systemic effects of hydrated lime due to its calcium content. There are also three inhalation studies in humans which have specifically investigated the repeated local effects of hydrated lime and/or burnt lime on the respiratory tract.

Starting with the potential repeated dose systemic effects of hydrated lime (due to its calcium content), the available data show that adverse effects of excess calcium (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) occur only with high intakes of calcium (in excess of 3000 mg supplemental calcium d^{-1}), with no adverse effects occurring up to total daily calcium intakes of 2500 mg (NOAEL) from both the diet and supplements. On this basis, the SCF (2003) proposed an oral total UL for calcium of 2500 mg d^{-1} (equivalent to 42 mg $kg^{-1}d^{-1}$ for a 60 kg individual). Therefore, provided repeated oral, dermal or inhalation exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the oral UL for calcium of 2500 mg d^{-1} (equivalent to 42 mg $kg^{-1}d^{-1}$ for a 60 kg human), adverse systemic effects are unlikely to occur.

With regard to the potential repeated local effects of hydrated lime, the available information shows that chronic direct contact of hydrated lime with the upper parts of the oral tract causes severe local lesions. Serious damage was already seen following chronic (for 16 months) application of 50 mg $kg^{-1}d^{-1}$ hydrated lime into hamster cheek pouches. There is no information on where the NOAEL for these effects would lie.

There are no data on the potential repeated local effects of hydrated lime via the dermal route of exposure. The UK CA considers that the investigation of these effects can be waived provided risk management measures resulting in the prevention of skin exposure are implemented.

Inhalation studies in humans have shown that long-term repeated inhalation exposure to hydrated lime/burnt lime causes respiratory symptoms (cough, phlegm, bronchitis). A long-term NOAEC of 1.2 mg m^{-3} has been identified for these effects from a study in workers exposed to hydrated lime/burnt lime for the duration of their employment. However, it should be noted that due to the small number of subjects investigated, the robustness of this NOAEC is limited.

Although limited, the available data do not support classification of hydrated lime for repeated dose toxicity.

In the available *in vitro* genotoxicity studies hydrated lime and/or its dissociation products have produced either negative results or positive results of no relevance *in vivo* below the threshold for irritation (for further details, see document IIA). There is no *in vivo* mutagenicity study available on hydrated lime and/or its dissociation products. However, based on the *in vitro* data, it can be concluded that hydrated lime has no significant *in vivo* genotoxic activity below the threshold for irritation. Whilst the available data allow the identification of an irritation threshold of around 1 mg m^{-3} for the inhalation route (from a study in human volunteers exposed to burnt lime for 20 min and from a study in workers exposed to hydrated lime/burnt lime for the duration of their employment), there is insufficient evidence for the identification of irritation thresholds for the dermal and oral routes of exposure. For these routes, as local risks cannot be assessed, the implementation of appropriate risk mitigation measures should ensure that exposure is prevented. The available data do not support classification of hydrated lime for mutagenicity.

The data that can inform on the carcinogenicity of hydrated lime are limited to non-standard animal studies investigating the potential local carcinogenicity of hydrated lime and to one chronic study in rats (with calcium lactate) investigating the potential systemic carcinogenicity of hydrated lime due to its calcium content. These data show that hydrated lime is not carcinogenic. However, due to the limitations in the data (inadequate studies for local carcinogenicity and only one species for the systemic carcinogenicity of calcium), this conclusion is applicable only to specific exposure conditions. With regard to systemic carcinogenicity, it is noted that although no study in a second species is available in accordance with the data requirements of the BPD, the conclusion from the mutagenicity section is that calcium has no significant genotoxic potential. Therefore, provided the repeated dose effects of excess calcium in the body are avoided (by ensuring exposures are below the calcium UL value), systemic carcinogenicity of hydrated lime is unlikely to occur. Also, provided exposure to hydrated lime is controlled at levels below the irritation threshold, local carcinogenicity is unlikely to occur. Whilst the available data allow the identification of an irritation threshold of around 1 mg m^{-3} for the inhalation route (from a study in human volunteers exposed to burnt lime for 20 min and from a study in workers exposed to hydrated lime/burnt lime for the duration of their employment), there is insufficient evidence for the identification of irritation thresholds for the dermal and oral routes of exposure. For these routes, as risks of local effects cannot be assessed, the implementation of appropriate risk mitigation measures should ensure that exposure is prevented. The available data do not support classification of hydrated lime for carcinogenicity.

Information on the potential developmental toxicity of hydrated lime derives from two gavage developmental toxicity studies (one in rats and one in mice) conducted with burnt lime and from non-standard animal developmental toxicity studies conducted with calcium salts (in rabbits and rats). In addition, there is an extensive oral database on different soluble calcium salts in pregnant women, young children and adolescents (from SCF, 2003).

The animal and human data are consistent in showing that no pre-natal or post-natal developmental effects of hydrated lime are expected up to a dose producing a calcium level of 600 mg $kg^{-1}d^{-1}$ (NOAEL) in animals and a total calcium level of 42 mg $kg^{-1}d^{-1}$ (UL) in humans. As the human value derives from an extensive database, is consistent with the animal data and is highly relevant, the human UL rather than the animal NOAEL is deemed to be a better starting point for the risk characterisation. Therefore, provided exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the oral UL value of 42 mg $kg^{-1}d^{-1}$, developmental effects are unlikely to occur. The available data do not support classification of hydrated lime for developmental effects.

No multigeneration reproductive toxicity study conducted with hydrated lime is available. Reproductive toxicity data on calcium salts is also limited.

In a very limited 1-generation study conducted in mice with calcium carbonate, no major effects on fertility were observed up to a dose level (1200 mg calcium $kg^{-1}d^{-1}$) causing a slight increase in heart weight in the maternal animals. Normally, this data would not be sufficient for an adequate assessment of the fertility endpoint under the requirements of the BPD. However, it is noted that calcium is an essential element of the human diet and human body, and that there is a long history of safe consumption at levels found in balanced human diet. By considering this, it is reasonable to conclude that, provided exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the oral UL value of 42 mg $kg^{-1}d^{-1}$, fertility effects are unlikely to occur. The available information does not support classification of hydrated lime for fertility effects.

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

With regard to systemic effects, a tolerable Upper oral intake Level (UL) for calcium has been established by the SCF. This is 2500 mg total calcium/person/day (SCF, 2003), corresponding to 42 mg total calcium/kg bw/day for a 60 kg person. Hence, for the purpose of the systemic risk assessment of hydrated lime, the calcium fraction of the exposure estimate will be compared with the calcium UL. If the exposure estimates (whether short-term, medium-term or long-term) give rise to calcium body burdens significantly lower than the UL, then there are no risks of systemic effects from exposure to hydrated lime.

With regard to local irritative effects, no threshold/NOAEC has been identified for the occurrence of such effects on the skin, eyes and gastrointestinal tract. Therefore, for these routes of exposure, as risks cannot be assessed, exposure needs to be prevented by the implementation of risk mitigation measures. For the inhalation route of exposure, a short-term NOAEC of 1 mg m^{-3} burnt lime for a 20-min exposure was identified in a study in human volunteers based on effects of sensory irritation of the nose, eye and throat at 2 and 5 mg m^{-3}. Such effects appear to be concentration-dependent rather than dose (concentration and time) dependent. This is supported by the fact that in another human health survey in which workers had been repeatedly exposed to burnt lime during their employment, no effects were observed up to a mean concentration of 1.2 mg m^{-3}. Therefore, overall, the NOAEC of 1 mg m^{-3} (20-min) is selected for the derivation of the short-term, medium-term and long-term AEC.

Critical endpoints

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

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

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

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

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

Uncertainties

Dermal Absorption Values Used in the Risk Assessment

A dermal absorption value is needed for conducting the systemic risk assessment. There are no data on the dermal absorption of hydrated lime. Therefore, predictions need to be made. Due to its strong alkaline and irritating properties, when dissolved in water or when in contact with sweat on the skin, hydrated lime will result in irritative lesions of the skin, with loss of skin integrity. Therefore, at irritant concentrations of hydrated lime, it can be predicted that 100 % is absorbed. At non-irritant concentrations, the default absorption value of 10 % (TGD, 2003) is proposed due to the ionic nature of its dissociation products and the well-known barrier functions of the skin. However, as the dermal irritation threshold has not been identified, a value of 100 % dermal absorption will be used, as a worst-case assumption, regardless of the exposure concentration. Overall, therefore, there is high uncertainty in the dermal absorption values selected for the systemic risk assessment, and it is most likely that the worst-case defaults chosen represent unrealistic absorption conditions.

Inter- and Intra-Species Variability

Both the reference points for the systemic effects of calcium (calcium UL value) and the NOAEC for the local effects of hydrated lime have been derived/identified from human studies. Therefore, no inter-species extrapolation of these toxicological reference points needs to be performed.

In relation to possible intra-species differences, the reference points for the systemic effects of calcium was identified on the basis of an extensive human database involving exposure of hundreds of individuals, including children, the elderly, subjects with specific medical conditions and pregnant women. On this basis, the SCF did not apply to the selected NOAEL value a factor for interindividual variability in deriving the UL.

With regard to the selected NOAEC for the local effects of hydrated lime on the respiratory tract, this was identified from a study conducted in 10 healthy adult volunteers. There is no information on the potential inter-individual variability of these effects caused by hydrated lime. Therefore, default values for intraspecies extrapolation need to be considered. As the effects concerned are the consequence of direct, pH-driven chemical reactivity of hydrated lime at the portal of entry, and do not involve kinetic processes, it is proposed that only the default value for possible dynamic inter-individual differences of 3.2 is applied (Technical Guidance Document for Risk Characterisation of Local Effects).

Route to Route Extrapolation

Route-to-route extrapolation is not appropriate for the local irritative effects of hydrated lime on the external surfaces of the body and hence, it will not be performed. For these effects, a direct comparison will be made with the external exposure concentrations and the calculated AEC values (inhalation route only).

With regard to the risk assessment of the systemic effects of hydrated lime caused by excess calcium, the oral UL value set by the SCF will be used. Based on the use patterns identified for the proposed biocidal products (Schaefer Precal 50S and Schaefer Precal 50N), dermal and inhalation exposures are anticipated. Therefore, for risk assessment purposes, extrapolation of the oral UL value to the dermal and inhalation routes of exposure is required. The available evidence indicates that the systemic effects of calcium seen after exposure by the oral route will also occur after exposure via the dermal and inhalation routes and that these effects are driven by the internal, systemic dose of calcium. To conduct the risk assessment, the external oral UL value will be converted to an internal systemic value by multiplying it by the oral absorption value selected (100 %) and compared with the calcium internal body burden arising from dermal and inhalation exposures to hydrated lime. The internal body burden of calcium will be calculated by adding together the dose of calcium absorbed by the dermal route and that absorbed by the inhalation route. The dermal dose of calcium will be estimated from the fraction of calcium present in the external dermal exposure estimate that is assumed to be absorbed through the skin (100 %). Similarly, the inhalation dose of calcium will be estimated from the fraction of calcium present in the external inhalation exposure estimate that is assumed to be absorbed through the respiratory tract (100 %).

It should be noted that there is high uncertainty in the absorption values selected for the oral, dermal and inhalation routes of exposure and that, due to the conservative nature of the defaults chosen (100 %), the systemic risk assessment is most likely to overestimate the actual risks.

Dose-Response/Severity of Key Health Effects

In relation to the systemic effects of hydrated lime caused by excess calcium, dose-response relationships have been well characterised and there is a clear and robust NOAEL (identified from an extensive human database) at 2500 mg d^{-1}, with effects starting to occur at around 3000 mg day^{-1}. At this dose level, the effects are still minor in nature (i.e. hypercalcemia of no clinical significance). Overall, therefore, no additional factor for uncertainties in the dose response relationship/severity of the effects at the LOAEL needs to be applied to the systemic reference point. In relation to the local irritative effects of hydrated lime on the respiratory tract, a clear NOAEC of 1 mg m^{-3} (for 20 min) has been identified, with effects starting to occur from a concentration of 2 mg m^{-3} (for 20 min) and above. At this concentration, the effects consist of mild sensory irritative perceptions, not involving overt tissue damage. Overall, therefore, no additional factor for uncertainties in the dose response relationship/severity of the effects of the LOAEC needs to be applied to the reference point for local inhalative effects of hydrated lime.

Duration Extrapolation

The systemic reference point (calcium UL value) represents a safe level of long-term, chronic exposure to calcium. Thus, no additional factor for extrapolation to chronic exposure conditions and derivation of a long-term AEL value needs to be applied to this reference point. There are no specific data on which to base systemic short-term and medium-term AEL values; hence, the long-term AEL (UL) value will be also used for the risk characterisation of short-term and medium-term exposure conditions, as required.

The NOAEC of 1 mg m^{-3} for the local irritative effects of hydrated lime on the respiratory tract was identified following exposure of human volunteers for 20 minutes. However, such effects appear to be concentration-dependent rather than dose (concentration and time)-dependent. Therefore, the same short-, medium- and long-term AEC value will be derived from this NOAEC without the need to apply an additional factor for duration extrapolation.

2.2.1.2. Exposure assessment

Industrial/Professional Users

Manufacture

Manufacture of the active substance, formulation of the products and packaging are not within the scope of BPD (TM V 07, December 2007) and therefore, the manufacture of hydrated lime and the packaging processes have not been addressed within this Dossier. Assessment of exposure begins with the delivery of the product to the immediate end user for PT 2.

Use

A potential for primary exposure to operators occurs as a result of contact with hydrated lime dust resulting from conveying the product from the bags to the process. The potential for exposure resulting from the bulk delivery and conveying of hydrated lime in well-maintained and enclosed processes is considered to be low. The primary concern relates to the manual handling of, and transfer from, sacks and 'big bags' where exposure of the skin and respiratory tract are possible. These processes are common to PT 2.

Table 2.2 Main paths of human exposure to hydrated lime from the use of Schaefer Precal 50S and Schaefer Precal 50N

Exposure path	**Professional use**	**Non-professional**	**General public**[a]	**Via the environment**
Dermal	Yes	Professional use only	n/a	n/a
Oral	Unlikely	Professional use only	n/a	n/a
Inhalation	Yes	Professional use only	n/a	n/a

[a] People other than those handling and applying the product.

Loading operations

There are no indicative exposure values available in the TNsG for the use scenarios described above. The applicant has provided some specific measurements of potential inhalation exposures for loading with small bags, but where the manner of use, i.e. exposure, differs from the conditions under which these were generated, and for dermal exposures, the applicant has relied on established exposure models. There is no single model that accurately predicts both dermal and inhalation exposures from the large scale handling of dusty solids, which is a scenario encountered with the use of lime for the treatment of sewage sludge. There are, however, regulatory models that can be used to predict exposure via one or other route. Therefore, this evaluation is based on modelling dermal exposures with the RISKOFDERM Dermal Exposure Model (as recommended in HEEG Opinion1, MOTA v6) and inhalation exposures with the Advanced Reach Tool (ART, Version 1.5). With these models, particularly the latter, a relatively detailed scenario can be built up to attempt reflect accurately the practical use to be assessed; the assumptions and input parameters can also be recorded for transparency. It is recognised that RISKOFDERM was designed to produce a rough estimate where the user does not have access to information to conduct a detailed assessment and it only includes data for hand exposure during dumping of solids and caution must be taken when considering automated processes as the model was based on manual tasks only for powders. Estimated inhalation and dermal exposures for automated, semi-automated, and manual operations are presented in Tables 2.3 and 2.4.

Table 2.3 Estimated task only (i.e. not full shift) inhalation and dermal exposures for automated, semi-automated, and manual operations

Inhalation exposure – treatment of sewage sludge – automated operations – a typical controlled process		
Tier 1	Maximum concentration [mg m^{-3}] – modelled task duration 120 min	3.9
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.1
Inhalation exposure – treatment of sewage sludge – semi-automated operations		
Tier 1	Maximum concentration [mg m^{-3}] – modelled task duration 120 min	1.1-17
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.03-0.425
Inhalation exposure – treatment of sewage sludge – removal of empty bags		
Tier 1	Maximum concentration [mg m^{-3}] – modelled task duration 10 min	38-57
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.95-1.425
Inhalation exposure – treatment of sewage sludge – manual handling of bags – a worst case		
Tier 1	Maximum concentration [mg m^{-3}] – measured task duration 19-36 min	1.6-23.2
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.04-0.58
Dermal exposure – treatment of sewage sludge – automated operations		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	79.7
Tier 2	PPE, full face RPE [mg]	4.0
Dermal exposure – treatment of sewage sludge – semi-automated operations		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569
Tier 2	PPE, full face RPE [mg]	28.45
Dermal exposure – treatment of sewage sludge – removal of empty bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569
Tier 2	PPE, full face RPE [mg]	28.45
Dermal exposure – treatment of sewage sludge – manual handling of bags		
Tier 1	Dermal exposure [mg] – modelled task duration 10 min	569
Tier 2	PPE, full face RPE [mg]	28.45

*The WPF of 40 is the maximum default value workplace or assigned protection factor recommended for estimating reduction in exposure in ECHA Biocides Human Health Exposure Methodology, October 2015 (see pages 154-5).

Table 2.4 Estimated full shift (8h TWA) inhalation exposures for automated, semi-automated, and manual operations

Inhalation exposure – treatment of sewage sludge – automated operations – a typical controlled process		
Tier 1	Maximum concentration [mg m^{-3}]	0.97
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.02
Inhalation exposure – treatment of sewage sludge – semi-automated operations		
Tier 1	Maximum concentration [mg m^{-3}]	4.2
Tier 2	In-mask concentration estimate [mg m^{-3}] (wpf 40*)	0.105
Inhalation exposure – treatment of sewage sludge – manual handling of bags – a worst case		
Tier 1	Maximum concentration [mg m^{-3}]	2.58
Tier 2	In-mask concentration estimate [mg m^{-3}] RPE during loading only (wpf 40*)	0.07

*The WPF of 40 is the maximum default value workplace or assigned protection factor recommended for estimating reduction in exposure in ECHA Biocides Human Health Exposure Methodology, October 2015 (see pages 154-5).

Application

Hydrated lime 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. It is anticipated there is negligible operator contact with dusty hydrated lime product during this process and in any case, exposures would be well below those predicted for mixing and loading operations involving handling of sacks.

Disposal of treated waste

The UK CA considers that the biocidal products are sufficiently reacted following addition to sewage sludge for them not to be further assessed as hydrated lime. The oxide component would be transformed to hydroxide and a significant degree of further chemical reaction would take place with components of the waste substrate producing a non-dusty product. However, for other reasons related to handling human and animal waste products, the operators would be expected to wear personal protective equipment during the disposal phase and any residual contamination effectively minimised.

2.2.1.3. Risk characterisation

Primary Exposure (Professional Users)

Please see the following risk assessment Tables.

Risk assessment tables

Table 2.5 Hydrated lime – Tier 1, systemic risk assessment for the effects of calcium (UL=42 mg kg $^{-1}$ d^{-1})

Exposure scenario	**Dermal hydrated lime exposure (mg d-1)**	**Dermal Ca exposure (mg d^{-1})***	**Dermal Ca body burden (mg kg bw^{-1} d^{-1})$**	**Inhalation hydrated lime full shift or cleaning task (mg m^{-3})**	**Inhalation Ca exposure (mg m^{-3})***	**Total Ca body burden (mg kg bw^{-1} d^{-1})£**	**Total Ca body burden (%UL)**	**Total body burden << 42 mg kg bw $^{-1}$ d^{-1}**	**Unacceptable risk**
Mixing and loading – automated operations	79.7	42	**0.70**	0.97	0.51	**0.79**	**1.9%**	YES	NO
Mixing and loading – semi automated operations	569	302	**5.03**	4.20	2.2	**5.40**	**12.9%**	YES	NO
Mixing and loading – manual handling of bags	569	302	**5.03**	2.58	1.4	**5.26**	**12.5%**	YES	NO
Cleaning of equipment post application	1641	870	**14.50**	57	30	**14.82**	**35.3%**	NO	YES
Aggregate worst case (semi-automated loading and cleaning combined)	2210	1172	**19.53**	na	na	**20.22**	**48.1%**	NO	YES

*Assumed calcium faction of 53% (assuming hydrated lime 98% Ca(OH)2 and Ca(OH)2 54% Ca and assuming milk of lime is 40% hydrated lime).
$Based on 100 % dermal absorption and bw of 60 kg.
£Based on 100 % inhalation absorption, 1.25 m3/h ventilation rate, 8h shift, 30 min cleaning task, and bw of 60 kg.

Table 2.6 Hydrated lime – Tier 1, systemic risk assessment for the effects of magnesium (UL=4.2 mg kg bw $^{-1}$ d^{-1})

Exposure scenario	**Dermal hydrated lime exposure (mg d^{-1})**	**Dermal Mg exposure (mg d^{-1})***	**Dermal Mg body burden (mg kg bw^{-1} d^{-1})$**	**Inhalation hydrated lime full shift or cleaning task (mg m-3)**	**Inhalation Mg exposure (mg m^{-3})***	**Total Mg body burden (mg kg bw^{-1} d^{-1})£**	**Total Mg body burden (%UL)**	**Total body burden << 4.2 mg kg bw $^{-1}$ d^{-1}**	**Unacceptable risk**
Mixing and loading – automated operations	79.7	2	**0.03**	0.97	0.02	**0.03**	**0.7%**	YES	NO
Mixing and loading – semi automated operations	569	12	**0.20**	4.20	0.09	**0.21**	**5.1%**	YES	NO
Mixing and loading – manual handling of bags	569	12	**0.20**	2.58	0.05	**0.21**	**4.9%**	YES	NO
Cleaning of equipment post application	1641	34	**0.57**	57	1.2	**0.58**	**13.9%**	NO	**YES**
Aggregate worst case (semi-automated loading and cleaning combined)	2210	46	**0.77**	na	na	**0.80**	**19.0%**	NO	**YES**

*Assumed magnesium faction of 2% (assuming hydrated lime 5% $Mg(OH)_2$ and $Mg(OH)_2$ 42% Mg and milk of lime is 40% hydrated lime).
$Based on 100 % dermal absorption and bw of 60 kg.
£Based on 100 % inhalation absorption, 1.25 m^3/h ventilation rate, 8h shift, 30 min cleaning task, and bw of 60 kg.

Table 2.7 Hydrated lime – Tier 1, local risk assessment for the effects on the respiratory tract (AEC=0.3 mg m^{-3})

Exposure scenario	**Inhalation exposure (mg m^{-3})***	**Percentage Exposure/AEC**	**Inhalation exposure < 0.3 mg m^{-3}**	**Unacceptable risk**
Mixing and loading – automated operations	3.9 (modelled 120 min)	1300 %	NO	**YES**
Mixing and loading – semi-automated operations	1.1-17[\$] (modelled 120 min)	366-5700 %[\$]	NO	**YES**
Mixing and loading – manual handling of bags	23.2 (measured 19-36 min)	7730 %	NO	**YES**

***** Although the modelled or actual sample durations exceed 20 minutes these values are considered to be representative of 20 minute samples.

[\$] The range reflects the different combinations of indoor, outdoor, fully cabbed and partially cabbed handling equipment.

Table 2.8 Hydrated lime – Tier 2, systemic risk assessment for the effects of calcium (UL=42 mg kg $^{-1}$ d^{-1})

Exposure scenario	**Dermal hydrated lime exposure (mg d^{-1})**	**Dermal Ca exposure (mg d^{-1})***	**Dermal Ca body burden (mg kg bw^{-1} d^{-1})\$**	**Inhalation hydrated lime full shift or cleaning task (mg m^{-3})**	**Inhalation Ca exposure (mg m^{-3})***	**Total Ca body burden (mg kg bw^{-1} d^{-1})£**	**Total Ca body burden (%UL)**	**Total body burden << 42 mg kg bw $^{-1}$ d^{-1}**	**Unacceptable risk**
Mixing and loading – automated operations	3.99	2.1	**0.04**	0.024	0.013	**0.04**	**0.1%**	YES	NO
Mixing and loading – semi-automated operations	28.5	15	**0.25**	0.105	0.056	**0.26**	**0.6%**	YES	NO
Mixing and loading – manual handling of bags	28.5	15	**0.25**	0.700	0.37	**0.31**	**0.7%**	YES	NO
Cleaning of equipment post application	82.1	44	**0.73**	1.425	0.76	**0.73**	**1.7%**	YES	NO

Aggregate worst case (semi-automated loading and cleaning combined)	110.5	59	**0.98**	na	na	**0.99**	**2.4%**	YES	NO

*Assumed calcium faction of 53% (assuming hydrated lime 98% Ca(OH)2 and Ca(OH)2 54% Ca and assuming milk of lime is 40% hydrated lime).
$Based on 100 % dermal absorption and bw of 60 kg.
£Based on 100 % inhalation absorption, 1.25 m3/h ventilation rate, 8h shift, 30 min cleaning task, and bw of 60 kg.

Table 2.9 Hydrated lime – Tier 2, systemic risk assessment for the effects of magnesium (UL=4.2 mg kg bw $^{-1}$ d^{-1})

Exposure scenario	**Dermal hydrated lime exposure (mg d^{-1})**	**Dermal Mg exposure (mg d^{-1})***	**Dermal Mg body burden (mg kg bw^{-1} d^{-1})$**	**Inhalation hydrated lime full shift or cleaning task (mg m^{-3})**	**Inhalation Mg exposure (mg m^{-3})***	**Total Mg body burden (mg kg bw^{-1} d^{-1})£**	**Total Mg body burden (%UL)**	**Total body burden << 4.2 mg kg bw $^{-1}$ d^{-1}**	**Unacceptable risk**
Mixing and loading – automated operations	3.99	0.08	**0.001**	0.024	0.001	**0.001**	**0.04%**	YES	NO
Mixing and loading – semi-automated operations	28.5	0.60	**0.010**	0.105	0.002	**0.01**	**0.2%**	YES	NO
Mixing and loading – manual handling of bags	28.5	0.60	**0.010**	0.700	0.01	**0.01**	**0.3%**	YES	NO
Cleaning of equipment post application	82.1	1.72	**0.029**	1.425	0.03	**0.03**	**0.7%**	YES	NO
Aggregate worst case (semi-automated loading and cleaning combined)	110.5	2.31	**0.039**	na	na	**0.039**	**0.9%**	YES	NO

*Assumed magnesium faction of 2% (assuming hydrated lime 5% Mg(OH)2 and Mg(OH)2 42% Mg and milk of lime is 40% hydrated lime).
$Based on 100 % dermal absorption and bw of 60 kg.

£Based on 100 % inhalation absorption, 1.25 m3/h ventilation rate, 8h shift, 30 min cleaning task, and bw of 60 kg.

Table 2.10 Hydrated lime – Tier 2, local risk assessment for the effects on the respiratory tract (AEC=0.3 mg m^{-3})

Exposure scenario	**Inhalation exposure (mg m^{-3})***	**Percentage Exposure/AEC**	**Inhalation exposure < 0.3 mg m^{-3}**	**Unacceptable risk**
Mixing and loading – automated operations (modelled 120 min)	0.0975	32.5 %	YES	NO
Mixing and loading – semi-automated operations - outdoors a) Loading closed cab (modelled – 120 min) b) Loading partial cab (modelled 120 min) c) bag removal (modelled -10 min)	a) 0.0275 (closed cab) b) 0.0625 (partial cab) c) 1.425$	a) 9 % b) 21 % c) 475 %	a) YES (closed cab) b) NO (partial cab) c) NO	YES
Mixing and loading – semi-automated operations - indoors a) loading closed cab (modelled 120 min) b) loading partial cab (modelled 120 min) c) bag removal (modelled 10 min)	a) 0.1825 (closed cab) b) 0.425 (partial cab) c) 0.95$	a) 61 % b) 142 % c) 317 %	a) YES (closed cab) b) NO (partial cab) c) NO	YES
Mixing and loading – manual handling of bags (measured 19-36 min)	0.58	193 %	NO	YES

* Although the modelled or actual sample durations exceed 20 minutes these values are considered to be representative of 20 minute samples.

$ The higher estimate for this task outdoors as compared to indoors occurs as it assumed to be close to a building, which is predicted to increase exposure.

Overall conclusion

During use of hydrated lime-based biocidal products for the treatment of sewage sludge (PT 2), primary exposure to operators essentially occurs from conveying the product from the supply bags to the process (mixing and loading scenario). The risk assessment (see Document IIC for more details) has shown that, especially where automated/enclosed processes are not in place, if exposure is minimised by the use of respiratory protection (power-assisted hoods or full-face respiratory protective equipment), protective coveralls, appropriate gloves, then the risks of systemic effects from exposure to hydrated lime are acceptable.

Through the application of personal protective equipment (Tier 2 exposure assessment), dermal and eye exposure is prevented and inhalation exposure during individual tasks is reduced to levels of 0.1, 0.03-0.425, 0.95-1.425, and 0.04-0.58 mg m^{-3} for automated mixing and loading, semi-automated mixing and loading, removing empty bags, and for manual mixing and loading, respectively). The corresponding worst case aggregate calcium (0.99 mg kg $bw^{-1}day^{-1}$) and magnesium body burdens (0.039 mg kg $bw^{-1}day^{-1}$) estimated for the combined activities of semi-automated loading and equipment cleaning are significantly lower than the respective UL values (42 and 4.2 mg kg $bw^{-1}day^{-1}$ for calcium and magnesium respectively). The inhalation concentration level for automated mixing and loading is below the AEC for local effects of 0.3 mg m^{-3}.

Other tasks and further refinements

The predicted concentrations for tasks other than those described above exceed the AEC.

Modelled exposures for semi-automated handling operations, where the operation occurs outdoors and indoor operations where the operator is protected by a closed cab are estimated to be below the AECs. However, where the loading takes place indoors and the operator is not protected by a closed cab the prediction exceeds the AEC. Furthermore, during removal of empty large bags the predicted exposures both outdoors and indoors exceed the AEC indicating an unacceptable risk for this method of handling.

Measured exposures for manual handling of bags demonstrated that exposures may be up to twice the AEC. As these data included some limited instances where the operator collected empty bags this activity has not been considered separately for this scenario. Again this exceedance of the AEC indicates an unacceptable risk for this scenario.

It is also relevant that the above assessments allow for RPE with a workplace protection factor of 40. Published guidance suggests this level of protection can be consistently assured through the use of full-face powered or air fed equipment – realistically the best available options. But RPE performance is most often judged against long term exposures providing assured protection against substances that offer risks of immediate or delayed severe systemic effects. Actual performance may be better, and better performance is achieved when operators are properly trained, when equipment is adequate for the task and it is selected to be the right choice for the operator and job.

It is noted that parts of this assessment are based on the ART model, and that the worst case potential for inhalation exposure has been assumed. This was supported by the applicant, who also stated that actual products were supplied in a range of grade depending on customer requirements. The question of whether a restriction to a coarser grade of products for these scenarios would be a practicable a risk management option was raised with the applicant.

However, according to the applicant, hydrated Lime, in all its variants, is an inherently dusty product. Due to its hygroscopic nature, it is not technically feasible to produce a stable, less dusty material on a commercial scale. In addition, any restriction on the sizing of the product may impact on the overall efficacy of the material in use. Hydrated limes (calcium di-hydroxide or calcium magnesium tetra-hydroxide) are inherently very fine materials. The applicant stated there is no possibility to select coarse materials: for oxides (calcium oxide or calcium magnesium oxide) the possibility to select a product containing fewer fines particles after sieving is possible, but poses this has several problems including the fact that lime is a very crumbly product and new fine particles can be formed during the handling. Furthermore, any benefits will not be demonstrable as the material would remain in the highly dusty class and hence the exposure assessment would not be improved.

To reduce personal exposure with calcium oxide and calcium magnesium oxide, another possible refinement would be to select the coarsest and least dusty material within technical limitations.

The above assessments have also not considered localised controls; again it is not known if controls such as suppression techniques (e.g. wetting empty bags to limit dust generation at the point of release or misting any airborne dust when handling bags) or local ventilation systems would be practicable options. To illustrate potential benefits of such risk management measures the ART model assumes that wetting at the point of release and unspecified exhaust ventilation systems would reduce exposures to 0.1 and 0.5 of the current values.

Another risk refinement option that could be considered is to require the submission of additional exposure monitoring data for the scenarios with higher than acceptable exposures to reduce the level of uncertainty associated with the generic model and so that a decision can be based on realistic data.

Also as discussed above it is possible that the performance of RPE over relatively short work tasks provides a higher level of protection that the agreed workplace protection factor of 40 implies. Given that the effects of failing to achieve an adequate level of protection would be an obvious local effect consideration could be given to requiring the applicants to conduct a systematic health survey to monitoring for such adverse effects among users to support the continued use.

The submitted measurements of exposures during manual loading also indicate that inhalation exposures are about twice the AEC. The applicant indicated in some circumstances local exhaust ventilation is employed. Again, it is not known if the use of LEV would be universally practicable, but the assumption in ART is that unspecified systems could provide a sufficient level of control during manual loading. Options from the other risk management options discussed above could also be applied.

It is concluded that there is a clear need for controls to reduce the risk of exposure. There is a widely accepted general hierarchy of control options to consider based on reliability and likely effectiveness. They include in general order of preference: elimination of the hazardous substance (not relevant in this case); modification of the substance, process and/or workplace; applying controls to the process, such as enclosures and LEV; ways of working that minimise exposure; and equipment or devices worn by exposed individuals. Restricting the grade of product available to reduce the dust emission potential would clearly be high in the order of preference, but the feasibility of such a restriction is subject to technical limitations.

It is also noted that suitable RPE is required to protect against risks from airborne concentrations above the AEC. However, the presented exposure assessments show that in some circumstances the predicted air concentrations are more than 40 times the proposed AEC, and consequently the agreed maximum workplace protection factor indicates that RPE is not estimated to provide adequate protection. It is suggested that a requirement for submission of additional exposure monitoring data for such scenarios could be considered to refine the exposure assessment.

There is also the possibility that that performance of RPE over relatively the short task durations involved might be higher than the standard assumption, and as any failure should produce an obvious local effect consideration could be given to requiring applicants to conduct a systematic health survey among users.

A number of options have been identified to either refine the assessment or manage both the risk of both local dermal and respiratory effects arising from the uses of limes (as discussed above) which include:

1. Consideration of a requirement for submission of additional exposure monitoring data for scenarios where the predicted air concentrations are more than 40 times the AEC (i.e. where RPE is assumed to be insufficient to control exposure) to refine the exposure assessment;
2. Consideration of a requirement for submission of a systematic health survey among users to provide assurance that (despite the usual assumption of a maximum protection factor of 40 for RPE) users do not experience local adverse effects;
3. Limiting the grade of material to the most coarse and least dusty to avoid supplying products with "high dustiness" emission potential for uses without a high degree of technical or engineering control of exposure, i.e. manual, and semi-automated handling;
4. Application of technical/engineering controls when:
    a. handling products (e.g. local exhaust ventilation, LEV) - it is recognised that there might only be limited scope for manual operations;
    b. when handling empty bags (e.g. LEV and dust suppression techniques such as wetting empty bags or misting airborne dust);
    c. during maintenance (e.g. LEV and use of vacuum cleaners during maintenance);
5. Use of PPE including RPE to control personal exposures:
    a. Recommending Type 5 coveralls with hoods (EN ISO 13882-1) when handling products, contaminated sacks, and during other tasks such as cleaning and maintenance;
    b. RPE with a work place protection factor of 10 during automated handling;
    c. RPE with a WPF of 40 during manual and semi-automated handling; and
    d. A need for operators to be properly trained in the use of the required RPE; and
6. Good occupational hygiene practice, i.e. use of pre-work creams and washing off contamination after tasks (pre-work creams do not function as protective gloves but may provide some additional protection so may assist in managing the risk of local effects).

Non-professional Users

Not applicable as exposure, other than to industrial sewage treatment professionals and agricultural workers is not foreseen.

Secondary Exposures

Not applicable as the active substance(s) react significantly during the treatment process and are considered to be no longer the original substrate.

2.2.2. Environmental risk assessment

2.2.2.1. Fate and distribution in the environment

Fate in the Aquatic Compartment

When dissolved in water, hydrated lime dissociates into Ca^{2+} and OH^- ions. The dissociation products Ca^{2+} and OH^- are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. For this reason, the performance of any degradation test with hydrated lime is scientifically unjustified. However, studies that investigated the impact of addition of hydrated lime on the pH of different test media and on the pH of two water-sediment systems were submitted. These studies and their endpoints have been considered relevant because the main toxic effect of hydrated lime is likely to be caused by temporal pH changes in the environment.

The more relevant of the available studies was that of Egeler and Gilberg (2007), in which the pH development of two natural water-sediment systems sampled from Germany was investigated. Hydrated lime was added at concentrations ranging between 14.8 and 100 mg l^{-1} to the water phase and changes in pH were monitored for up to 168 h. Upon addition of hydrated lime to the overlying water, a dose-dependent transient increase in the pH of the water phase was observed. The relative increase in pH following addition of the test substance was noted to be highest in the system with the lowest total hardness (Unterbach Creek system). The water pH was noted to have returned to levels comparable with control systems (pH 7.60 - 7.73) in test concentrations of ≤ 75 mg l^{-1} by the final 7 d sampling point.

Relating concentrations tested in these studies to actual concentrations arising from the biocidal uses of the lime variants, it should be noted that the maximum PECsw value using the Step 2 FOCUSsw tool was only 2.46 mg l^{-1} (as hydrated lime equivalents). Note this PECsw value accounts for buffering/degradation occurring in soil/sludge or manure prior to the runoff or drainflow event transporting the lime material to surface water.

Fate in Air

The Applicant provided a justification that since hydrated lime is expected to have a vapour pressure well below 10^{-5} Pa that exposure via air is not expected. Whilst an estimation using simple calculations could be used to address this data point (e.g. the estimation methods of the Atmospheric Oxidation Program) irrespective of the vapour pressure. For substances such as hydrated lime, such calculations would be largely meaningless as the potential for exposure via air, and subsequent phototransformation in air would be expected to be negligible.

Fate in the Terrestrial Compartment

Standard aerobic degradation studies in soil are not considered necessary for hydrated lime. This is because upon addition to soil, hydrated lime would simply dissociate to its respective ion constituents where they would form part of existing chemical cycles in the natural environment. However, two studies that investigated the impact of addition of hydrated lime on the pH of different soil systems were considered relevant because as in the aquatic compartment, the main toxic effect of hydrated lime is likely to be caused by temporal pH changes in the environment.

In the first study (Schiffner, 2007a) the pH development of a natural and an artificial soil were investigated. Hydrated lime was added at concentrations up to 4.44 g kg^{-1} dry soil and the pH was measured for up to 6 weeks. Upon addition of hydrated lime to the soils, a dose-dependent increase in the pH was observed. The relative increase in pH following addition of the test substance was noted to be marginally higher in the artificial soil system. The soil pH was noted to rise to between 10 and 11 pH units in both soils immediately after addition of the hydrated lime at the highest test concentration (note that initial pH levels in untreated controls were 5.49 for the natural soil and 5.89 for the artificial soil). A decrease in pH of approximately 2 pH units was observed within 72 h following addition. By the end of the 6 week study the pH in the test soils was noted to be elevated above control levels at all concentrations. However, the final pH was within the normal range for typical agricultural soils at all concentrations tested (pH range from 5.88 to 7.95). The estimated DT_{50} and DT_{90} values were determined assuming hockey stick kinetics to reflect the bi-phasic pattern of pH changes observed in the treated soils. Fits were generally good statistically (chi^2 and t-tests) and visually (classical and residual plots). A DT_{50} of **0.742 h** is proposed up to a break point of 6 h, and a DT_{50} of **372 h** is proposed for the time period after the break point. The kinetic modelling endpoints were considered appropriate for direct use in the environmental exposure assessment.

In general, in the soils tested the pH fell back to within normal levels (*ca.* pH 8) within 1 week of application at all concentrations.

In the second study (Schiffner, 2008), the pH development within mixed natural soil after application with hydrated lime treated sewage sludge was investigated. Sewage sludge was treated with four concentrations of hydrated lime ranging from 187.5 to 520 g kg^{-1} wet sludge (dry solids content of sludge was reported to be 25 %). After incubation for 24 h at room temperature, the treated sludge was added to mixed natural soil resulting in nominal hydrated lime concentrations between 1.25and 3.65 g kg^{-1} dry soil. The pH of the amended soil was also measured for up to 24 h.

As with the previous study, upon addition of hydrated lime treated sewage sludge to soil, a dose-dependent increase in pH was observed. The relative impact on pH following addition of hydrated lime direct to soil was noted to be marginally higher than the impact of applying comparable rates of hydrated lime treated sewage to soil. Even though the lowest rate tested was elevated above that which would be proposed for treating sewage sludge, only a relatively minor impact on the final soil pH was noted at this treatment level. This was in contrast with the more pronounced effect on soil pH that was observed either when testing higher sewage sludge application rates or when testing the effect of direct application of hydrated lime to soil.

Both the studies submitted did not provide sufficient information on the soils used to allow any comparison with any areas of the EU. However, the results from this study are likely to at least be indicative of the likely behaviour in terms of temporal pH changes when a soil is either directly treated with hydrated lime or when soil is amended with hydrated lime treated sewage sludge.

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

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

In addition to standard endpoints, further background information was provided on the distribution of hydrated lime in the environment and the use of hydrated lime in agriculture as a measure to counteract soil acidification. With respect to the distribution in the environment, brief summaries of the basic chemical reactions undertaken by the constituents of lime when they are released to the environment were provided. Since these reactions are all well understood processes of the natural calcium cycles they have not been reproduced in detail here. In summary, the level of calcium in soil is governed by the equilibrium between soluble, exchangeable and solid forms. Weathering is enhanced by carbonic acid (CO_2 produced by respiration of organisms dissolved in water). Exchangeable calcium is the dominant ion on soil colloid surfaces and by replacing H^+ ions in exchange sites it largely determines soil pH. In many soils, the steady downward movement of water leaches Ca^{2+} ions over time, H^+ ions take their place on exchange sites and soils become more acidic. Available information suggests that annual losses of lime can be as high as 700 kg ha^{-1} (calculated as CaO). The addition of acidifying nitrogen fertilisers can also enhance the loss of lime along with hydrated lime removal because of crop harvesting.

Extensive information on the lime requirements of typical agricultural soils has been provided. Hydrated lime rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and hydrated lime status of highly deficient soils. Although these figures were derived from a German guidance document, the proposed rates are also consistent with UK guidance issued by the Department of Environment, Food and Rural Affairs. These data suggest that the quantities of hydrated lime used exceed the maximum quantities applied because of sewage sludge using hydrated lime. However, it should be noted that for agricultural liming, in most cases, limestone (calcium carbonate or dolomite) is used instead of hydrated/hydrated dolomitic lime or burnt/burnt dolomitic lime that is used as a biocidal product. However, it would be expected that individual agricultural liming rates would be amended to take into account any additional material added via manure or sewage sludge to ensure that the total neutralising value of the material applied remained within the relevant guidelines.

In addition to the key role that agricultural liming plays in counteracting soil acidification, a number of other benefits are highlighted, such as the importance of divalent cations such as calcium in maintaining good soil physical structure; maintaining optimum nutrient uptake by managing soil pH; adequate soil pH also encourages soil biological activity; calcium and magnesium are also noted to be essential plant nutrients in their own right.

2.2.2.2. Hazard identification and effects assessment

<u>Effects assessment</u>

The assessment factors used to define the PNEC for the various environmental compartments of concern have been taken from the TGD on risk assessment in support of Commission Directive 93/67/EEC (new notified substances) and Directive 98/8/EC (biocidal products) (EC 2003).

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

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

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

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

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

In addition, the biocidal application of lime as either PT2 or PT3 will occur in enclosed settings such that no relevant direct emissions will occur during the application phase that need to be considered as part of the exposure profile. Environmental exposure will potentially occur once the treated manure or sludge is spread on to land and in this situation it is considered to be potentially intermittent. On this basis, no chronic data are considered necessary. For example, lime is mixed in to slurry or manure within the farmyard situation. Therefore, direct exposure of surface water to lime during the application stage is considered unlikely. Exposure will only occur once treated manure/slurry is spread on to fields. Chronic data are not considered necessary due to the fact that spreading of treated manure and slurry will only occur intermittently, and thus exposure via subsequent runoff events will also only occur intermittently.

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

Predicted No Effects Concentration in STP

The PNEC was calculated from the 3 h EC_{50} of against sewage sludge micro-organisms, in accordance with TGD, Table 17:

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

Predicted No Effects Concentration in Surface Waters

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

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

As stated above, the effect of hydrated lime is due to the rapid change in pH, it is considered that the primary effect will be an acute or mortality effect and not to a long-term or reproductive effect. Alternatively, if an aquatic organism survives a change in pH, it is not considered that there will be any chronic or long-term effects. Therefore, the PNECwater is based on acute data only and only addresses the acute effects.

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

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

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

Predicted No Effects Concentration in Sediments

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

Predicted No Effects Concentration in Soil

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

Acute

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

Chronic

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

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

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

Predicted No Effects Concentration in Biota

No studies have been submitted on the potential for hydrated lime to bioaccumulate. It has been agreed that no assessment is required as the dissociation products of hydrated lime

($Ca^{2+,}$ and OH^-) occur naturally in any surface water and in any plant and animal species. Based on the common knowledge of their physiological role, uptake, distribution and excretion in animals and plants, it can be concluded that there is no risk of bioconcentration due to biocidal uses of hydrated lime. Therefore, there is no need to calculate a $PNEC_{oralpredator}$.

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

2.2.2.3. Exposure assessment

The use of hydrated lime in the following product type has been assessed in this section:

- PT 2 (Private area and health area disinfectants), the 'treatment of sewage sludge' (use no. 1) has been identified as the relevant use to be assessed.

For the treatment of sewage sludge (PT 2) a hydrated lime quantity equivalent to 20 – 50 % of the dry solids weight of the sludge should be applied.

The PEC values are derived in terms of hydrated lime equivalents. This is consistent with the ecotoxicological effects section where the PNEC values are also derived in terms of hydrated lime equivalents. This ensures the risk characterisation is performed in a consistent manner.

Note that burnt lime (calcium oxide) forms slightly more hydroxide ions per unit mass than are liberated from hydrated lime (calcium hydroxide). Because all the PNEC values are expressed in terms of hydrated lime, all burnt lime PEC values are converted to hydrated lime equivalents. This ensures all PEC and PNEC values were consistent. This was performed using a simple molecular weight correction procedure. The molecular weight of burnt lime is 56.08, the molecular weight of hydrated lime is 74.09, so to convert the burnt lime PEC to hydrated lime equivalents, multiply by 74.09/56.08, or a factor of 1.321.

With regard to the dolomitic variants, they all contain a proportion of the less reactive, less dissociable magnesium oxide/hydroxide. Therefore per unit mass, the dolomitic forms will generate fewer hydroxide ions compared with the non-dolomitic variants. Across each product type, the application rates of hydrated lime and hydrated dolomitic lime are identical. Similarly the application rates of burnt lime and burnt dolomitic lime are identical. To simplify the CARs, the UK CA produced exposure and risk assessments based on either the hydrated lime or burnt lime application rates only. Since the dolomitic forms produce fewer hydroxide ions per unit mass, the assessments based on hydrated lime or burnt lime effectively cover the risks posed by the dolomitic forms. In addition a simple conversion factor for the dolomitic forms is not possible, since the exact composition in terms of Ca and Mg content differs depending on the location of where the mineral was originally extracted from.

TERRESTRIAL COMPARTMENT

Soil

The main route of environmental exposure that has been assessed is that following direct application of hydrated lime treated sewage sludge to agricultural land. In order to quantify the potential soil loading via this route it is necessary to have information on both the application rate of hydrated lime to sewage sludge as well as information on the typical application rates of the treated sewage sludge to land.

For the application of sewage sludge, a maximum application rate to agricultural land of 5000 kg dry solids ha^{-1} $year^{-1}$ is recommended in the Technical Guidance Document on Risk Assessment (TGD; see Part II, Section 2.3.8.5). Also according to the TGD the depth over which the PEC_{soil} should be calculated for the local assessment in agricultural soil is recommended to be 20 cm (see TGD Part II, Section 2.3.8.5, Table 11). Although for grassland assessments a shallower depth of 10 cm is recommended, which may increase the PEC_{soil} is more than offset by the recommendation that sewage sludge is applied to grassland at the lower rate of only 1000 kg dry solids ha^{-1} $year^{-1}$. Therefore, for the purposes of a simple worst-case exposure assessment the agricultural soil application rate and depth will be used.

The intended use data gives a maximum quantity of hydrated lime equivalent to 50 % of the dry solids weight of the sludge to be added to sewage sludge during treatment. For the maximum application rate of 5000 kg dry solids ha^{-1} $year^{-1}$ the amount of lime added would therefore equate to a maximum of 2500 kg. The total dry weight of treated sludge would therefore equal 7500 kg. Once treated, only 5000 kg of the 7500 kg total could be applied per ha and therefore the mass of lime in the applied amount would equate to 5000/7500 * 2500 = 1667 kg ha^{-1}.

Assuming even incorporation of this applied dose over a 20 cm soil layer, no interception by crop canopy for an application pre-emergence and a dry soil bulk density of 1500 kg m^{-3} the maximum initial PEC_{soil}, local in agricultural soil would be **555.7 mg kg^{-1}**. It should be noted that this PEC assumes that there is no time lapse between treatment and application to agricultural soil, which clearly represents a worst-case assumption.

Based on a revised kinetic assessment, a soil DT50 of **0.742 h** was proposed up to a break point of 6 h, and a DT50 of **372 h** was proposed for the time period after the break point. Using this value the PEC_{soil} declined to **1.98 mg kg^{-1}** within 1 d (derived as hydrated lime equivalents). The use of a 1 d time period in calculating PECsoil is considered acceptable in this specific case, where much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of lime amended material to agricultural land. In this highly specific situation it is therefore acceptable to use a PECsoil taking into account degradation and comparing it against a PNEC based on nominal initial concentrations.

The DT_{50} was subject to a degree of uncertainty since it was only derived from experimental data on a single natural soil only. However, in further consideration of the available data, it was noted that the pH fell back to within normal levels (*ca.* pH 8) within 1 week of application at all concentrations. Also at application levels comparable to the PEC_{soil} above (i.e. 440 to 890 mg $Ca(OH)_2$ kg^{-1}) the soil pH returned to normal levels (*ca.* pH 8) within the 6 h period.

Additional supporting information was available within the study on amended sewage sludge, which was then applied to a natural soil mixture. At the lowest sludge application rate tested (application rate equivalent to 3750 kg ha^{-1} of $Ca(OH)_2$ or an effective PEC_{soil} of 1250 mg kg^{-1} i.e. in excess of the soil loading predicted above) only minimal effects were noted and the pH was never raised above levels typical for normal agricultural soils. Therefore, the relatively high initial PEC_{soil} value listed above is only considered indicative of the likely soil concentration in the period immediately after application and assuming no reactions between the applied lime and soil components have taken place.

The natural reactions of the lime components in treated sewage sludge and subsequently in amended soil would be expected to significantly reduce the exposure levels following treatment and significant pH changes because of this level of lime treatment would not be expected. Therefore, it was concluded that the PEC of 1.98 mg kg^{-1} was considered acceptable for risk assessment purposes.

Groundwater

When dissolved in water, hydrated lime dissociates into Ca^{2+} and OH^- ions. The dissociation products are not further degradable either chemically or biologically because they constitute simple basic structures, which cannot be broken down any further. These ions would be expected to simply form part of existing chemical cycles in the natural environment. In terms of the groundwater compartment, Ca^{2+} ions would be expected to be major constituents in many groundwater zones. They would be expected to be present at concentrations greater than 1 mg l^{-1} 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 would not be expected that these processes would lead to any significant increase in the background groundwater concentrations of these major ions.

On this basis no further detailed assessment of groundwater is considered necessary in this case.

AQUATIC COMPARTMENT

Surface waters

Following application of lime treated sewage sludge to soil the most likely route of entry to adjacent surface water bodies would be expected to be via surface runoff. Surface water exposure via spray drift would not be expected since farmers would not be expected to allow applications of sewage sludge to result in direct contamination of water bodies due to the obvious environmental pollution issues this would cause. For example, in the UK in the Defra Code of Good Agricultural Practice for farmers, growers and land managers (2009) it is stated that manure should not be applied within 10 m of surface waters, including field ditches. It is also stated that application should be via equipment with low spreading trajectory and when applying slurries small droplet formation should be avoided to prevent drift. Note that the reference to UK specific guidance has simply been included as an example of existing national guidance that may be relevant to effectively control emissions from the biocidal uses under consideration here. Other EU legislation, such as the nitrates directive (91/676/EEC) or the sewage sludge directive (86/278/EEC) would provide further means to control how and where manure or sewage sludge is applied to agricultural land in the EU. Both of these directives must be implemented under the Water Framework Directive. Measures to prevent direct exposure of surface water with manure or sewage sludge should be in place across the EU and as a result we do not consider that the risk arising from any misuse of this material (i.e. by not following other widely accepted guidance document) should be included. It should also be noted that the application of lime to sludge or manure has been assumed to be an automated process under controlled conditions. Hence spray drift from this application process will not occur and has not been assessed.

The surface water exposure assessment for application of hydrated lime in sewage sludge has been based on the same assumptions as per the exposure assessment in soil i.e. a maximum application rate of hydrated lime equivalent to 50 % of the dry solids weight of the sludge to be added to sewage sludge during treatment, which equates to a hydrated lime application rate of 1667 kg ha^{-1}.

The EU FOCUS$_{sw}$[2] models would be appropriate to assess the potential environmental exposure resulting from the use of lime. Although the FOCUS$_{sw}$ models were developed specifically to address potential exposure arising from agricultural use of pesticides under EU Directive 91/414, since the use of lime as a biocide potentially results in broad scale applications to agricultural land the basic assumptions underpinning the FOCUS$_{sw}$ models are considered applicable in this case. The FOCUS$_{sw}$ tools represent a tiered exposure assessment scheme from the relatively simple Steps 1 and 2 that use a number of conservative assumptions in a set of basic exposure calculations, up to the more complex Step 3 assessments that combine mechanistic models with defined environmental scenarios to represent vulnerable areas of EU agricultural land. For the purposes of assessing potential exposure resulting from the use of lime only FOCUS$_{sw}$ Step 1 and 2 were deemed necessary by the UK CA, and the main differences between the FOCUS and Exposit model assumptions are listed below:

- At Step 1, FOCUS$_{sw}$ assumes a 10 % loss via runoff/drainage immediately following application.

- At Step 2 reduced loss percentages via runoff/drainage are assumed depending on time of year of application and EU region. For the purposes of the lime assessment, application in Northern Europe in October – February were assumed since these attract the highest Step 2 runoff/drainage entry assumptions of 5 % and may also be

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[2] see http://focus.jrc.ec.europa.eu/sw/index.html accessed on 19/02/2009

consistent with early pre-emergence applications in either autumn or spring.

- At Step 2 the runoff/drainage event is assumed to take place 4 d after application.
- Entry to an adjacent surface water body is assumed. The water body is assumed to be 30 cm deep, and the ratio between the surface area of the field and water body is assumed to be 10:1.
- Upon entering the water body, the substance is assumed to partition between the water and sediment phases according to the Koc value. For the purposes of this assessment the Koc was set to 0 ml g^{-1} as a worst case to maximise the concentrations predicted to occur in the water phase (i.e. partitioning to sediment was effectively disabled).
- The $FOCUS_{sw}$ model assumes that the substance degrades according to simple first order kinetics based on DT_{50} values for soil, water and sediment. In a simple first tier assessment DT_{50} values for all compartments were set to 1000 d as a standard worst case default value. In a refined assessment the soil DT_{50} of **0.742 h** was used up to a break point of 6 h, and a DT50 of **372 h** was used for the time period after the break point.

The $FOCUS_{sw}$ Step 1 and 2 tools were used to simulate an application of hydrated lime in sewage sludge. At the first tier of the assessment, using the default assumptions of the $FOCUS_{sw}$ model, if as an absolute worst case no degradation is assumed to occur between application and the major runoff event (i.e. assuming a soil DT_{50} of 1000 d) then the PEC_{sw} at Step 1 and 2 are predicted to be **556 mg l^{-1}** and **277 mg l^{-1}** respectively.

If a soil DT_{50} of **0.742 h** is assumed up to a break point of 6 h, and a DT50 of **372 h** is assumed for the remaining period as per the soil exposure assessment then the Step 2 PEC_{sw} value reduces to only **0.86 mg l^{-1}** (as hydrated lime equivalents) due to the extensive degradation assumed to take place in soil in the 4 d between application and first major runoff/drainage event. For simplicity only the values derived according to the FOCUSsw models will be taken forward in the risk characterisation section discussed below.

Table 2.11 Summary PECsw values

Tier	**PECsw (mg l^{-1} as hydrated lime equivalents)**
FOCUSsw Step 1	556
FOCUSsw Step 2 (no degradation)	277
FOCUSsw Step 2 (bi-phasic degradation in line with soil assessment)	0.86

Sediment

The risk characterisation reported below indicates that no unacceptable risks are predicted for aquatic organisms based on the existing exposure and effects data. In addition, the review of the fate and behaviour data has indicated that there is unlikely to be any long-term exposure of non-target organisms following the biocidal uses of lime. Upon contact with water, the hydrated forms of lime will react with CO_2 dissolved in water to form poorly soluble $CaCO_3$ that would precipitate under neutral conditions. $CaCO_3$ would be expected to be ubiquitous in the natural aquatic environment and the additional source via the biocidal uses of lime would not be expected to increase levels significantly above existing background levels. On this basis, no requirement for the calculation of a formal $PEC_{sediment}$ was identified.

STP

The main route of environmental exposure resulting from the biocidal use of hydrated lime is expected to arise following the broad scale application of treated sewage sludge to agricultural land. However, there may be theoretically the potential for point source contamination of sewage treatment plants to occur following individual application events. This route of exposure would not be expected to be significant in the opinion of the UK CA. In the event that such point source contamination did occur, it is not expected that the overall PEC would be any higher than already predicted to occur in surface water via runoff following use on agricultural land. Therefore, for the purposes of the risk characterisation exercise for sewage treatment plants it is proposed that the PEC_{sw} values established in for surface waters be used as a surrogate for a specific value for PEC_{STP}.

AIR

For hydrated lime the UK CA considered that exposure via air (and subsequent phototransformation in air) would be negligible based on the structures of the active substances and their expected low vapour pressures. Due to the negligible exposure risk, no formal assessment of PEC_{air} is considered necessary.

BIOTA

The likelihood of hydrated lime being bioaccumulated by aquatic animals has been dismissed. Also, whilst birds or mammals could be exposed to invertebrates present in soil where sewage or manure that has been treated with lime; the exposure will be minimal due to the fate and behaviour profile of lime and the subsequent changes in pH. Hence, it is not considered necessary to determine a PEC_{biota}.

2.2.2.4. Risk characterisation

Introduction

The risk characterisation (PEC:PNEC) values have been expressed for the intended use pattern on sewage sludge (PT 2). The exposure side of the risk characterisation is based on information provided in the TGD with respect to spreading of sewage sludge onto agricultural land.

Risks to the Terrestrial Compartment

Risks to soil

Risk quotients (PEC:PNECs) have been calculated to assess the risk to terrestrial organisms due to the use of hydrated lime on sewage sludge The risks to soil are presented in a tiered way, with the first tier assuming no degradation between application of hydrated lime to sewage sludge and subsequent application to agricultural land as a very simple and conservative worst-case. The second tier assumes degradation (actually buffering in manure of sludge) according to a revised kinetic assessment and a degradation period of 1 d and the appropriateness of the two tiers of the assessment are discussed below Table 2.12.

Table 2.12 PEC:PNEC (soil) values for hydrated lime following application to sewage sludge

Scenario	PEC	PNEC	PEC:PNEC
	mg kg^{-1}		
PT 2: Sewage sludge (assuming an application of 1667 kg ha^{-1} over 20 cm)			
1st tier assuming no degradation between application and soil incorporation	555.7	108	5.1
2nd tier based on a revised kinetic assessment [a]	1.98	108	0.02

[a] revised kinetic assessment assumes a soil DT50 of **0.742 h** up to a break point of 6 h, and a DT50 of **372 h** for the time period after the break point

[b] Tier II PEC soil calculated 1 d after application. The use of a 1 d time period in calculating PECsoil is considered acceptable in this specific case, where much of the degradation (actually buffering in manure or sludge) is likely to have occurred prior to application of lime amended material to agricultural land. In this highly specific situation it is therefore acceptable to use a PECsoil taking into account degradation and comparing it against a PNEC based on nominal initial concentrations.

In general, from the experimental data available for directly treated soils it was noted that the pH fell back to within the range of typical agricultural soils (ca. pH 8) within 1 week of application at all concentrations. However at all concentrations tested, the pH remained above control levels throughout the 6 week study duration.

At application levels comparable to the application level assumed for uses of hydrated lime on sewage sludge the soil pH returned to normal levels (ca. pH 8) within 12 h. Additional information was available where sewage sludge was amended prior to application to a natural soil mixture. At sludge application rates greater than the soil levels estimated above (i.e. 2630 mg $Ca(OH)_2$ kg^{-1} equivalent to an application rate of 1972 kg ha^{-1} over 5 cm) the pH of the final amended soil mixture was only temporarily elevated above pH 8, and fell back to less than pH 8 within 5 h of sludge treatment (Schiffner, 2008).

The natural reactions of the hydrated lime components in sewage sludge and subsequently in amended soil would therefore be expected to significantly reduce the exposure levels following treatment and thus reduce the potential for significant effects in treated fields. Based on the above information, it should be considered that the concentration of 1.98 mg kg^{-1} is appropriate for use in risk characterisation. Significant long-term pH changes because of this level of hydrated lime treatment would therefore not be expected and this is reflected in the low risk quotient of 0.02 when the impact of these natural reactions is accounted for in the risk characterisation.

For the risk assessment of sludge application to soil, the risk should also have been calculated for a period of 10 years. However, during the MS commenting round it was accepted that this was not necessary due to the acute effect arising through the pH shock. However there are studies available showing that the effect on the soil pH is lasting if multiple loads of lime amended sewage sludge is added to the soil (this is after all the intention of the agricultural use of liming materials). Liming is also used to reduce the bioavailability of metals from sludge via pH amendment. However the risk is effectively compensated for as pH is monitored in soils receiving this sludge as part of directive 86/278/EEC. Therefore lasting effects on pH by liming will be detected and only if desired, the lime amended sludge will be applied to that soil. The risk to soil organisms by lime is after all an acute one, and despite an increase in background pH, the effect is in the shock –increase. Therefore the interaction between this risk assessment and the Directive 86/278/EEC should be noted.

Risks to Groundwater

This has been dismissed at the point of exposure.

Risks to the Aquatic Compartment

Surface water

Risk quotients (PEC:PNECs) have been calculated to assess the risk to aquatic organisms due to the use of hydrated lime. Following application of hydrated lime treated sewage sludge to soil the most likely route of entry to adjacent surface water bodies would be expected to be via surface runoff. Surface water exposure via spray drift would not be anticipated since farmers would not be expected to allow applications to result in direct contamination of water bodies with sewage sludge due to the obvious environmental pollution issues this would cause.

EU FOCUS$_{sw}$ models were used to assess the potential for exposure to surface waters.

The surface water exposure assessment for application of hydrated lime in sewage sludge will be based on the same assumptions as per the exposure assessment in soil i.e. a maximum application rate of hydrated lime equivalent to 50 % of the dry solids weight of the sludge to be added to sewage sludge during treatment, which equates to a hydrated lime application rate of 1667 kg ha^{-1}.

The risk of hydrated lime to aquatic organisms has been assessed in a tiered scheme using the FOCUS$_{sw}$ tools and results are presented in Table 2.13 below.

Table 2.13 PEC:PNEC (surface waters) values for hydrated lime resulting from runoff following application to sewage sludge according to the FOCUSsw models

Scenario	**PEC**	**PNEC**	**PEC:PNEC**
	µg l^{-1}		
FOCUS$_{sw}$ Step 1	556000	491	**1132**
FOCUS$_{sw}$ Step 2 (worst case assuming no degradation between application and runoff event)	277000	491	**564**
FOCUSsw Step 2 based on a revised kinetic assessment [a,b]	860	491	**1.8**

[a] revised kinetic assessment assumes a soil DT50 of **0.742 h** up to a break point of 6 h, and a DT50 of **372 h** for the time period after the break point

[b] Step 2 PECsw assuming the runoff/drainage event occurs 4 days after application (FOCUS default assumption).

Based on the information considered during the exposure assessment, the concentration of 860 µg l^{-1} is considered appropriate for use in risk characterisation. Significant long-term pH changes as a result of this level of lime treatment would not be expected, noting that the pH in reconstituted water returned to control levels within 24 h when dosed at concentrations of 14.8 mg l^{-1} hydrated lime. Similarly in two water sediment systems tested the pH returned to within the range of typical natural waters within 24 h when dosed at 14.8 mg l^{-1}. Further supporting information is provided in the form of a qualitative assessment that follows.

Overall, no unacceptable risks to surface water were identified.

Sediment

With respect to assessing risk to sediment dwellers, the risk characterisation reported above indicates that there were no unacceptable risks to aquatic organisms based on the existing exposure and effects data. In addition, the review of the fate and behaviour data has indicated that there is unlikely to be any long-term exposure of non-target organisms following the biocidal uses of hydrated lime. Upon contact with water, hydrated lime will react with CO_2

dissolved in water to form poorly soluble $CaCO_3$ that would precipitate under neutral conditions and may therefore reach sediment. However, $CaCO_3$ would be expected to be ubiquitous in the natural aquatic environment and the additional source via the biocidal uses of hydrated lime would not be expected to increase levels significantly above existing background levels in sediment. On this basis, no requirement for the calculation of a formal $PEC_{sediment}$ was identified and none has been performed.

STP

The main route of environmental exposure resulting from the biocidal use of hydrated lime is expected to arise following the broad scale application of treated sewage sludge to agricultural land. Whilst there is a theoretical potential for point source contamination of sewage treatment plants to occur following individual application events, it is not considered that this will be a significant route of exposure. In the event that such point source contamination did occur, it is not expected that the overall PEC would be any higher than already predicted to occur in surface water via runoff following the broad scale use on agricultural land. Therefore, for the purposes of the risk characterisation exercise for sewage treatment plants it is proposed that the values established for the surface waters be used as a surrogate for a specific value for STPs. The risk characterisation is presented in Table 2.14 below.

Table 2.14 PEC:PNEC (STP) values for hydrated lime resulting from runoff following application to sewage sludge according to the FOCUSsw models

Scenario	**PEC**	**PNEC**	**PEC:PNEC**
	µg l^{-1}		
$FOCUS_{sw}$ Step 1	556000	3004	**185**
$FOCUS_{sw}$ Step 2 (worst case assuming no degradation between application and runoff event)	277000	3004	**92.2**
FOCUSsw Step 2 based on a revised kinetic assessment [a,b]	860	3004	**0.3**

[a] revised kinetic assessment assumes a soil DT50 of **0.742 h** up to a break point of 6 h, and a DT50 of **372 h** for the time period after the break point.

[b] Step 2 PECsw assuming the runoff/drainage event occurs 4 days after application (FOCUS default assumption).

Overall significant long-term pH changes as a result of this level of hydrated lime treatment would not be expected and this is reflected in the low risk quotient of 0.3 when the impact of these natural reactions is accounted for in the risk characterisation.

Qualitative environmental exposure assessment

During the discussion of this substance at the WGV2015 meeting it was agreed that in addition to the standard tiered quantitative exposure assessment an additional qualitative assessment would be added. This was agreed by MS experts to be appropriate and useful to build a weight of evidence to support the consideration of active substance approval.

At WGV2015 MS experts cited the following substances as examples where qualitative approaches had been used successfully in the past; *Bacillus amyloliquefaciens*, hydrochloric acid and silicon dioxide. The UK CA has reviewed these previous assessments and considered that the substance with the most similarity to lime variants is hydrochloric acid, due to the main effects being on environmental pH in both cases. The basis of the qualitative assessment for hydrochloric acid was that predictions indicated *'negligible perturbations of environmental pH levels'*. Hence there was no need to perform a standard quantitative approach utilising PEC and PNEC values in that case. A similar approach is discussed below based on the information available for the lime variants.

Based on the quantitative assessment in soil above the maximum tier 1 PECsoil value was 1200 mg kg^{-1} (as hydrated lime equivalents). Note this PECsoil value assumes no time lapse between the application of lime and spreading of treated material onto agricultural soil. In a refined tier 2 assessment, conservatively assuming a 1 d time period between lime application and subsequent application to land, the PECsoil reduced to 4.27 mg kg^{-1}. An indication of the possible impact on environmental pH can be estimated based on the laboratory studies provided. In those studies, an application of 1330 mg kg^{-1} (i.e. in excess of the simple tier 1 PECsoil value) direct to soil did not result in an increase in the pH of natural soil outside of the typical environmental range (pH increased from control levels of 5.49 to 8.34 at time 0 and declined to 7.31 within 24 h). At the lowest dose tested (444 mg kg^{-1}) the maximum initial pH was 7.52, declining to 6.41 within 24 h. Although these perturbations cannot be described as *negligible* (as was the case for hydrochloric acid) it can at least be stated that these changes would be within the typical range of agricultural soils encountered across the EU and no significant effect on non-target organisms would be expected as a result of pH changes in this range. Agricultural soils may be routinely lime treated to amend the pH within these ranges as part of good agricultural practice. In addition, it should be noted that the quantitative assessment has been based on a PNEC soil value of 108 mg kg^{-1}. Again based on the data provided for effects of lime on soil, no significant adverse effect on soil pH would be expected at a concentration level of 108 mg kg^{-1}. This further highlights the likely conservativism of the standard quantitative risk assessment presented.

Further supporting information from tests performed where lime treated sewage sludge was applied to soil has been provided. At the lowest concentration tested (1.25 g kg^{-1} sludge), which was in excess of the proposed target application rate, negligible changes in the pH of the treated soil were observed. This suggests that the qualitative approach taken for the hydrochloric acid assessment based on negligible perturbations of environmental pH levels may also be applied in the case of the lime variants.

Based on the quantitative assessment in surface water in Section 3.3.3.2.1 above the tier II FOCUS$_{sw}$ Step 2 PEC$_{sw}$ value was 2.46 mg l^{-1} (as hydrated lime equivalents). Significant long-term pH changes in natural waters because of this level of lime treatment would not be expected, noting that the pH in reconstituted water returned to control levels within 24 h when dosed at concentrations of 14.8 mg l^{-1} hydrated lime, the lowest concentration tested during laboratory tests. Similarly in two water sediment systems tested the pH returned to within the range of typical natural waters within 24 h when dosed at 14.8 mg l^{-1}. Therefore the biocidal uses of lime are not expected to have an adverse effect on the environmental pH of natural surface water bodies.

Further supporting information on the agricultural use of lime is provided in the Appendix to Doc IIA. Lime rates as high as 16 tons ha^{-1} (expressed as CaO) can be required to adjust the pH and lime status of highly deficient soils. In comparison, the application of burnt or burnt dolomitic lime would equate to only around 3 tons ha^{-1} (as hydrated lime). The contribution via agricultural liming, outside of the scope of the BPR, is therefore likely to be far in excess of the lime added to soil via the biocidal uses in many soils.

Finally additional information has been included considering the likely natural background levels of the key constituents of the lime variants in soil, surface water and ground water. Information on background concentrations in soil and surface waters in the EU are available in the Statistical Data of Analytical Results Annexed to the Geochemical Atlas of Europe (part 1) as downloaded from http://weppi.gtk.fi/publ/foregsatlas/index.php. The mean topsoil calcium concentration (measured as CaO) in this survey is reported to be 3.54%, equivalent to 35.5g/kg (minimum and maximum values ranged from 0.026 to 470.7%). For surface water the mean calcium concentration was reported to be 55.2mg/l (minimum and maximum values ranged from 0.226 to 592mg/l). For magnesium (measured as MgO), the mean topsoil concentration was 1.18%, equivalent to 11.8 g/kg (minimum and maximum values ranged from <0.01 to 24.6%). For surface water the mean magnesium concentration was reported to be 11.5mg/l (minimum and maximum values ranged from 0.048 to 230mg/l). Calcium and magnesium are the major ion constituents of groundwater along with Na+, Cl-, HCO3- and

SO42-. These major constituents are typically found at levels in excess of 5mg/l. Actual levels are largely dependent on the surrounding rock formations from which Ca2+ and Mg2+ may dissolve but vary from low mg/l levels up to hundreds of mg/l in areas where the surrounding rock formations contain high levels of calcium or magnesium (e.g. chalk, limestone, dolomite etc.). Water hardness is often expressed in units of equivalent mg/l of CaCO3 (Ca2+ and Mg2+ are the two most prevalent divalent cations responsible for hardness). Various scales exist, but water is often described as hard above around 200 mg/l (equivalent to around 80 mg/l calcium). In contrast soft water generally contains the equivalent of less than 30mg/l calcium. Based on widespread evidence over the ubiquitous nature of calcium and magnesium in the environment at levels in excess of those arising from the biocidal use, no further detailed specific references have been included here.

Overall, based on the qualitative arguments above, the biocidal uses of lime are not expected to have an adverse effect on environmental pH and no unacceptable impacts on non-target organisms is predicted.

2.2.2.5. PBT and POP assessment

PBT assessment

Introduction

According to the TGD, 'The Persistent, Bioaccumulative and Toxic (PBT) assessment is considered to be different from the local and regional assessments approaches, as it seeks to protect ecosystems where risks are more difficult to estimate'. Under the Biocidal Products Directive (BPD), a PBT assessment is needed to demonstrate that a substance does not fulfil selection under the United Nations Environment Programme – Persistent Organic Pollutants convention (UNEP-POPs) to limit emissions to the environment of those chemicals with high potential for persistence, bioaccumulation, long-range transport and adverse effects on human health and the environment. Any substance, which is found to be either a PBT or very Persistent very Bioaccumulative (vPvB) substance shall not be Approved unless releases to the environment can be effectively prevented.

Persistence

Standard aerobic aquatic degradation studies are not considered necessary hydrated lime. This is because upon addition to water, hydrated lime simply dissociates to its respective ion constituents where they would form part of existing chemical cycles in the natural environment. The main impact on the aquatic environment from the addition of lime is short-term elevations in pH. Data have been presented, which shows that the impact on pH because of hydrated lime application in both soil and aquatic compartments declines within days.

The measure of persistence in the environment has been borne out of the need to quantify the potential for long-term environmental risks from xenobiotics introduced to the environment because of biocidal use. However, in the case of hydrated lime, it would be more appropriate to look at the persistence of the effect since identifying the origin of the dissociated ion constituents in the soil or aquatic environment would not be possible. Therefore, as the water pH was noted to have returned to levels comparable with control systems in test concentrations of ≤ 75 mg l^{-1} by the final 7 d sampling point, the impact of additional hydrated lime to the aquatic environment has not been shown to be persistent. It is on this criterion that hydrated lime is not considered persistent in the environment.

Bioaccumulation

No studies have been submitted on the potential for hydrated lime to bioaccumulate. It has been agreed that no assessment is required as the dissociation products of hydrated lime ($Ca^{2+,}$ and OH^{-}) occur naturally in any surface water and in any plant and animal species. Based on the common knowledge of their physiological role, uptake, distribution and excretion in animals and plants, it can be concluded that there is no risk of bioconcentration due to biocidal uses of hydrated lime. Therefore, it is assumed that hydrated lime does not fulfil the

'B' criterion.

Toxic

According to the most sensitive endpoint available for hydrated lime (a 48 h EC_{50} for *Daphnia magna* = 49.1 mg l^{-1} based on hydrated lime data) the acute endpoint is above the trigger of < 0.01 mg l^{-1}. Therefore, the toxic criterion is not fulfilled according to the TGD.

Conclusion: As hydrated lime fulfilled none of the three criteria, it can be accepted that it is not a PBT substance. In addition, according to ECHA Chapter R.11 guidance (November, 2014) the PBT criteria are generally applicable to any substance containing an organic moiety. Based on the common definition of an organic substance in chemistry, PBT and vPvB criteria are not applicable to inorganic substances. Therefore no further information is required to assess the lime variants against the PBT/vPvB criteria.

POP assessment

Not applicable as hydrated lime is an inorganic compound.

2.2.3. Assessment of endocrine disruptor properties

The endocrine disrupting effects cannot be determined at present as the criteria are not yet agreed. However, in the absence of significant effects on endocrine organs and/or reproduction in standard mammalian toxicity studies it has been concluded that hydrated lime does not have endocrine-disrupting properties in mammals.

2.3. Overall conclusions

The outcome of the assessment for hydrated lime in Product Type 2 is specified in the BPC opinion following discussions at the fifteenth meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

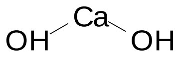
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Hydrated lime
Product Type	PT 2, PT 3

Identity

Chemical name (IUPAC)	Calcium dihydroxide
Chemical name (CA)	Calcium hydroxide
CAS No	1305-62-0
EC No	215-137-3
Other substance No.	No other numbers available
Minimum purity of the active substance as manufactured (g/kg or g/l)	800 g/kg The value provides the content of Ca expressed as $Ca(OH)_2$.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No substances of concern have been identified in the typical products whose analyses are included in this dossier. Detailed analysis, including screening for any heavy metal content should be provided at product authorisation.
Molecular formula	$Ca(OH)_2$
Molecular mass	74.09 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	Not applicable (decomposition >360°C)
Boiling point (state purity)	Not applicable (decomposition >360°C)
Temperature of decomposition	Decomposition 450 - 580 °C
Appearance (state purity)	Solid, (colour depends on impurities) Odourless, bitter taste
Relative density (state purity)	2,080 – 2,300 kg/m^3 (literature)

	Precal 50S (98.2 %)	Precal 50N (97.0 %)
Pour density:	0.45 g/mL	0.39 g/mL
Tap density:	0.57 g/mL;	0.51 g/mL
Relative density (D_4^{20}):	2.22	2.26

Surface tension	72.5 mN/m, determined for a 90 % saturated solution of $Ca(OH)_2$
Vapour pressure (in Pa, state temperature)	Below 10^{-5} Pa (estimated)
Henry's law constant (Pa m^3 mol $^{-1}$)	Not relevant (see vapour pressure)
	1.26 g/L at 20°C (literature)

Solubility in water (g/l or mg/l, state temperature)	1.85 g/L cold water ca 0°C (literature) 0.77 g/L hot water ca 100°C (literature) Effect of pH not determined
Solubility in organic solvents (in g/l or mg/l, state temperature)	Not known to be soluble in organic solvents (except glycerine).
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant
Partition coefficient (log P_{OW}) (state temperature)	The $Ca(OH)_2$ content in the test solutions was all found in the aqueous phase. $Ca(OH)_2$ does not dissolve in n-octanol and a partition coefficient could therefore not be calculated. It is expected that the logPow is << 3
Hydrolytic stability (DT_{50}) (state pH and temperature)	When dissolved in water, Hydrated lime dissociates into Ca^{2+} and OH^-, which are chemically and biologically not further degradable.
Dissociation constant	pH of a saturated $Ca(OH)_2$ solution is 12.4. This value is consistent with the solubility and the fact that $Ca(OH)_2$ is a strong base. pKb = 2.37
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Not measured
Photostability (DT_{50}) (aqueous, sunlight, state pH)	When dissolved in water, Hydrated lime dissociates into Ca^{2+} and OH^-, which are chemically and biologically not further degradable.
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable
Flammability	Hydrated lime is not flammable.
Explosive properties	Hydrated lime is not explosive.

Classification and proposed labelling

with regard to physical/chemical data	Not Classified
with regard to toxicological data	Skin Irrit. 2 Eye Dam. 1 STOT SE 3 H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation
with regard to fate and behaviour data	Not Classified
with regard to ecotoxicological data	Not Classified

Chapter 2: Methods of Analysis

Analytical methods for the active substance – See note below

Technical active substance (principle of method)	Common analytical techniques are based on wet chemical separation procedures, combined e.g. with gravimetric, volumetric (complexometric-, redox-; acid-base-titration) and photometric methods. X-ray Spectrometric Analysis, Coupled Plasma-Atomic Spectroscopy (ICP) and Atomic Absorption (AA) are also suitable methods for the determination of the main and trace elements in the different Lime variants.
Impurities in technical active substance (principle of method)	X-ray Spectrometric Analysis, Coupled Plasma-Atomic Spectroscopy (ICP) and Atomic Absorption (AA) are also suitable methods for the determination of the main and trace elements in the different Lime variants

Analytical methods for residues

Soil (principle of method and LOQ)	In soil science, the determination of pH-values of soil and the determination of calcium and magnesium is well established. Basically the methods to determine calcium and magnesium are based on the same principles as described in Section 4.1 for the determination of Calcium and Magnesium in Lime variants. Given the nature of the active and its uses any more detailed analysis is unnecessary.
Air (principle of method and LOQ)	Whether or not measurement of the active/residues in air is required will depend on a combination of factors such as particle size, method of application and degree of enclosure. This should be determined at product authorisation. The applicant has provided a published paper that gives brief information on dust collection and analysis; An air stream is conveyed over a filter. The retained dust is weighed and its basicity is determined by means of a calibrated pH-metric method. If the method is required additional information should be provided at product authorisation.
Water (principle of method and LOQ)	Analytical methods for the determination of the concentration of any of the Lime variants in water are based on the determination of Ca^{2+} and Mg^{2+} as well as on the determination of the pH-values. The methods to determine pH-values, calcium and magnesium in water are described in Document IIIA Section 4.1.
Body fluids and tissues (principle of method and LOQ)	Not relevant.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	For the determination of Calcium and Magnesium in foodstuffs and animal feeding stuffs two standard methods have been included in Document IIIA Section 4.3. 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.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	See above

NOTE:

Whilst the nature of the impurities in the active are likely to be consistent, the actual amounts of each will vary depending on the source of the limestone. Due to the nature of the active it is considered inappropriate to require standard batch analysis to support a tight specification that will then be used as a reference source. Therefore a very lenient specification has been provided by the applicant based on their knowledge. Normally the specification is indicative of the substance that was tested and in order to refer to the risk assessment produced an active from another source would have to be deemed technically equivalent. However, given that much of the data provided to support Approval relates to sources of unknown purity, it seems inappropriate to set a specification limit for its use. It is our opinion the risk assessment is valid for an active of the minimum purity as stated in the LOEP.

The Lime variants, including hydrated lime, are derived from naturally occurring limestone and as such the main constituents are calcium, magnesium and their oxides and hydroxides. Impurities are inorganic salts and minerals of a great variety. The impurities mainly contain minerals of silicon (silicates), aluminium, iron (pyrite), manganese, carbon (carbonates, traces of organic carbon), sulphur (sulphates, pyrite) and water.

The analytical methods used for the determination of the composition of lime do not allow for the determination of the specific forms in which their constituents actually occur. By consent within the lime industry, the composition of lime is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides. The content of Ca is expressed as $Ca(OH)_2$, which is the form actually present in Hydrated lime, and additionally as CaO. The content of Mg is only expressed as MgO though the form in which it is present in Hydrated lime is $Mg(OH)_2$.

The contents of the other constituents are calculated and expressed as oxides:

- The content of Silicon (Si) is expressed as SiO_2,
- The content of Aluminium (Al) as Al_2O_3,
- The content of Iron (Fe) as F_2O_3,
- The content of Manganese (Mn) as Mn_3O_4, and
- The Sulphur (S) content as SO_3.

However, these indicated oxides are not identical with the actual forms in which these elements are present in Hydrated lime.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	A worst-case value of 100 % absorption following oral exposure to hydrated lime has been assumed for use in the risk characterisation for systemic effects.
Rate and extent of dermal absorption:	A worst-case value of 100 % absorption following dermal exposure to hydrated lime has been assumed for use in the risk characterisation for systemic effects.
Rate and extent of inhalational absorption	A worst-case value of 100 % absorption following inhalation exposure to hydrated lime has been assumed for use in the risk characterisation for systemic effects.
Distribution:	Following absorption of hydrated lime into the systemic circulation, the calcium ions are widely distributed throughout the body, while the hydroxide ion is neutralised by the tightly controlled pH regulation mechanisms of the body (buffer capacity of extracellular body fluids, respiratory and renal compensation).
Potential for accumulation:	Bioaccumulation of calcium in bones and teeth is a normal physiological process.
Rate and extent of excretion:	The absorbed calcium is excreted in urine, faeces and sweat.
Toxicologically significant metabolite	There is no metabolism of the dissociation products, Ca^{2+} and OH^- as these are chemically and biologically not further degradable.

Acute toxicity

Rat LD_{50} oral	$LD_{50} > 2000$ mg kg^{-1}
LD_{50} dermal	No suitable study available.
Rat LC_{50} inhalation Mouse LC_{50} inhalation	No suitable study available.
Skin irritation	Classified with R38
Eye irritation	Classified with R41
Respiratory tract irritation	Classified with R37. Two studies in humans involving exposures to hydrated lime and/or burnt lime have shown that hydrated lime causes sensory irritation of the nose, eye and throat. There is no information on the respiratory effects of hydrated lime at exposure concentrations higher than 5 mg m^{-3}; however, on the basis of its severe skin and eye irritant properties and its strong alkaline properties, it is most likely that overt tissue damage would occur at higher concentrations.
Skin sensitization	There are no studies which have investigated the skin sensitisation potential of hydrated lime. However, as the recommended risk mitigation measures resulting from failure to identify a threshold for the irritant properties of the substance will prevent skin exposure, testing for skin sensitisation is deemed unnecessary. In addition, as both the Ca and OH ions are abundant natural components of the body,

	skin sensitisation is not expected.

Repeated dose toxicity

Species/ target/critical effect	The repeated dose systemic effects of hydrated lime (due to its calcium content), are those of excess calcium (hypercalciuria, kidney stones, hypercalcemia, renal insufficiency, lethargy, coma and death) in the body. Hydrated lime also causes local irritative effects on the external surfaces of the body (skin, eye, respiratory tract and gastrointestinal tract). These are caused by the hydroxide ion.
Lowest relevant oral NOAEL/LOAEL	Calcium $NOAEL_{long\text{-}term}$: 42 mg/kg/d, extensive oral repeated dose studies in humans; No NOAEL is available for the local effects of hydrated lime via the oral route.
Lowest relevant dermal NOAEL/LOAEL	No data are available for the dermal route. The UK CA considers that the investigation of these effects can be waived provided risk management measures resulting in the prevention of skin exposure are implemented.
Lowest relevant inhalation NOAEL/LOAEL	Local NOAEC: 1 mg/m^3 (20-min), human studies.

Genotoxicity	Hydrated lime has no significant *in vivo* genotoxic activity below the threshold for irritation.

Carcinogenicity

Species/type of tumour	Hydrated lime is not carcinogenic provided the repeated dose effects of excess calcium and the local irritative effects of the hydroxide ion are avoided.
Lowest dose with tumours	Not applicable.

Reproductive toxicity

Species/reproduction target/critical effect	Limited information is available. However, provided exposures to hydrated lime contribute to an overall calcium body burden that does not exceed the oral UL value of 42 mg kg^{-1}d^{-1}, fertility effects are unlikely to occur.
Lowest relevant NOAEL	Not applicable.
Species/developmental target / critical effect	Hydrated lime is not a developmental toxicant.
Lowest relevant NOAEL	Not applicable.

Neurotoxicity / Delayed neurotoxicity

2-day acute neurotoxicity study in rats	Hydrated lime is not neurotoxic. Not applicable.
13-weeks neurotoxicity study in rats	Not applicable.
12-month chronic neurotoxicity study in	Not applicable,

rats

Medical data

None submitted.

Summary	**Value**	**Study**	**Safety factor**
ADI (if residues in food or feed)	Not required.		
AEL (short, medium, long-term)	Calcium tolerable Upper Level (UL) = 42 mg $kg^{-1}d^{-1}$, but it needs to account for other sources of exposure to Ca especially through the diet.	Extensive oral database in humans on calcium salts;	None applied
$AEC_{inhalation}$ (short, medium, long-term)	0.3 mg m^{-3}	Human volunteers, 20 min exposure to burnt lime	3.2
Drinking water limit	Not required.		
ARfD (acute reference dose)	Not required		

Acceptable exposure scenarios (including method of calculation)

Professional users

During use of hydrated lime -based biocidal products for the treatment of sewage sludge (PT 2), primary exposure to operators essentially occurs from conveying the product from the supply bags to the process (manual, semi-automated, and automated mixing/loading scenario). Estimates of inhalation exposures during manual mixing and loading are based on a specific study where such exposure was measured. Other exposure calculations are based on the ART model for inhalation estimates and RISKOFDERM for dermal aspects.

The risk assessment has shown that through the application of personal protective equipment (Tier 2 exposure assessment), dermal and eye exposure is prevented and inhalation exposure during individual tasks is reduced to levels of 0.1, 0.03-0.425, 0.95-1.425, and 0.04-0.58 mg m^{-3} for automated mixing and loading, semi-automated mixing and loading, removing empty bags, and for manual mixing and loading, respectively). The corresponding worst case aggregate calcium (0.99 mg kg $bw^{-1}day^{-1}$) and magnesium body burdens (0.039 mg kg $bw^{-1}day^{-1}$) estimated for the combined activities of semi-automated loading and equipment cleaning are significantly lower than the respective UL values (42 and 4.2 mg kg $bw^{-1}day^{-1}$ for calcium and magnesium respectively).

The inhalation concentration levels for automated mixing and loading is below the AEC for local effects of 0.3 mg m^{-3}. However, the predicted concentrations for the other tasks exceed the AEC.

A number of options have been identified to either refine the assessment or manage both the risk of both local dermal and respiratory effects arising from the uses of limes which include:

1. Consideration of a requirement for submission of additional exposure monitoring data for scenarios where the predicted air concentrations are

	more than 40 times the AEC (i.e. where RPE is assumed to be insufficient to control exposure) to refine the exposure assessment; 2. Consideration of a requirement for submission of a systematic health survey among users to provide assurance that (despite the usual assumption of a maximum protection factor of 40 for RPE) users do not experience local adverse effects; 3. Limiting the grade of material to the most coarse and least dusty to avoid supplying products with "high dustiness" emission potential for uses without a high degree of technical or engineering control of exposure, i.e. manual, and semi-automated handling; 4. Application of technical/engineering controls when: a. handling products (e.g. local exhaust ventilation, LEV) - it is recognised that there might only be limited scope for manual operations; b. when handling empty bags (e.g. LEV and dust suppression techniques such as wetting empty bags or misting airborne dust); c. during maintenance (e.g. LEV and use of vacuum cleaners during maintenance); 5. Use of PPE including RPE to control personal exposures: a. Recommending Type 5 coveralls with hoods (EN ISO 13882-1) when handling products, contaminated sacks, and during other tasks such as cleaning and maintenance; b. RPE with a work place protection factor of 10 during automated handling; c. RPE with a WPF of 40 during manual and semi-automated handling; and d. A need for operators to be properly trained in the use of the required RPE; and 6. Good occupational hygiene practice, i.e. use of pre-work creams and washing off contamination after tasks.
Workers (re-entry)	Not applicable
Non-professional users	Not applicable
Indirect exposure as a result of use	Not applicable

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Hydrated lime dissociates in Ca^{2+} and OH^- when in contact with water.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not applicable: see hydrolysis
Readily biodegradable (yes/no)	Not applicable: see hydrolysis
Inherent biodegradability	Not applicable: see hydrolysis
Biodegradation in seawater	Not applicable: see hydrolysis
Non-extractable residues	Not relevant. The dissociation products Ca^{2+} and OH^- are natural constituents of any environmental compartment.
Distribution in water / sediment systems (active substance)	Not relevant. The dissociation products Ca^{2+} and OH^- are natural constituents of any environmental compartment.
Distribution in water / sediment systems (metabolites)	Not applicable: no metabolites

Route and rate of degradation in soil

Mineralization (aerobic)	Hydrated lime dissociates into Ca^{2+} and OH^- when in contact with water. No further degradation is possible. Hydrated lime forms Calcium carbonate in soil due to incorporation of CO_2. DT_{50} values for carbonisation ranging between 1.36 and 2.34 hours have been estimated based on pH measurements in soil over time.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not applicable: see "mineralisation"
Non-extractable residues	Not applicable: see "mineralisation"
Field studies (state location, range or median with number of measurements)	Not applicable: see "mineralisation"
Anaerobic degradation	Not applicable: see "mineralisation"
Soil photolysis	Not applicable: see "mineralisation"
Relevant metabolites - name and/or code, % of applied a.s. (range and maximum)	Not applicable: see "mineralisation"
Soil accumulation and plateau concentration	Not applicable: see "mineralisation". Hydrated lime can form calcium carbonate in soil due to incorporation of CO_2.

Adsorption/desorption

No study available: When applied to soil, Burnt (dolomitic) lime is transformed to Hydrated (dolomitic) lime upon contact with water. Hydrated (dolomitic) lime dissociates into Ca^{2+}, (Mg^{2+}), and OH^-. These compounds are omnipresent, they occur naturally in high rates in soils, groundwater and surface waters.

The fate of Lime and its constituents in soils is the object of research of the soil sciences and is well understood. It is known that under the climatic conditions of Western-Europe, high losses of Lime take place due to leaching of Ca^{2+}, Mg^{2+} and OH^- from soil. Consequently, natural waters (groundwater and surface water) always contain Ca^{2+} and Mg^{2+} in considerable quantities.

To compensate agricultural soils for Lime losses and to maintain the soil pH at favourable levels (target pH depends on soil texture), Lime must be regularly applied to agricultural soils. Heavy soils (when used as arable land) need to receive 500 kg Lime (calculated as CaO) per ha and year under low-rainfall conditions (<600 mm/year) and 700 kg Lime per ha and year under high-rainfall conditions (>750 mm/year), while sandy soils need to receive lower amounts in the range of 300 to 500 Lime per ha and year, depending on rainfall. It is recommended that every 3 to 4 years the Lime demand should be determined by soil analysis. Depending on the results of this analysis, up to 9 tons of Lime (calculated as CaO) can be applied by one application to heavy soils while the maximum quantity for sandy soils is 3 tons (calculated as CaO).

A study has been performed in which Hydrated lime was mixed with dry soil after which water was added to the mixture. Analysis of water percolating through the soil/Lime mixture has shown that only immediately after addition of Hydrated lime to soil a significant increase in pH of the percolate was detected, corresponding to the analysed calcium hydroxide concentration in the percolate. This result shows that calcium hydroxide itself is not prone to leaching when present in moist soil.

Fate and behaviour in air

Hydrated lime is not volatile: estimated vapour pressure < 10^{-5} Pa.

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Note all endpoints are based on nominal concentrations (as hydrated lime equivalents) and are from static studies.

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	LC_{50}	50.3 mg l^{-1}
Invertebrates			
Daphnia magna	48 h	EC_{50}	49.1 mg l^{-1}
Algae			
Pseudokirchneriella subcapitata	72 h	EyC_{50}	99.87 mg l^{-1}
	72 h	ErC_{50}	184.57 mg l^{-1}
Microorganisms			
Activated sludge	3 hours	EC_{50} Respiration inhibition	300.4 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms (Annex IIIA, point XIII.3.2)	LC_{50} (14 d) = > 5000 mg a.s. kg^{-1} dw
Reproductive toxicity to earthworms (Annex IIIA, point XIII.3.2)	NOEC (56 d) = 2000 mg a.s. kg^{-1} dw

Effects on soil micro-organisms

Nitrogen mineralization	NOEC: 8, 10 and 12 g/kg soil dry weight after 28, 48 and 96 days of exposure, respectively. EC_{50}: 9.7 g/kg, > 10 g/kg and > 12 g/kg soil dry weight on days 28, 48 and 96 days after application, respectively.
Carbon mineralization	The dehydrogenase activity was determined after 28, 48 and 96 days of exposure. NOEC: 4 g/kg soil dry weight after 28, 48 and 96 days of exposure. EC_{50}: > 12.0 g/kg, 8.1 g/kg and 8.7 g/kg soil dry weight on days 28, 48 and 96 days after application, respectively.

Effects on plants (Annex IIIA, XIII.3.4)

Toxicity to plants	*Spinacia oleracea* was the most sensitive species based on shoot fresh weight: EC_{50} = 2670 mg/kg soil dry weight *Spinacia oleracea*, *Brassica napus* and *Beta vulgaris*: NOEL = 1080 mg/kg soil dry weight

Effects on terrestrial vertebrates

Acute toxicity to mammals	No study available, waiver provided.
Acute toxicity to birds	No study available, waiver provided.
Dietary toxicity to birds	No study available, waiver provided.
Reproductive toxicity to birds	No study available, waiver provided.

Effects on honeybees

Acute oral toxicity	No study available, waiver provided.
Acute contact toxicity	No study available, waiver provided.

Effects on other beneficial arthropods

Acute oral toxicity	No study available, waiver provided.
Acute contact toxicity	No study available, waiver provided.

Bioconcentration

Bioconcentration factor (BCF)	No study available, waiver provided.
Depuration time (DT_{50}) (DT_{90})	N/A
Level of metabolites (%) in organisms accounting for > 10 % of residues	N/A

Chapter 6: Other End Points

No other endpoints are considered relevant.

Appendix II: List of Intended Uses

Hydrated lime has been evaluated for its intended use as disinfectants and algaecides not intended for direct application to humans or animals (PT 2).

The products are for use by industrial and professional users. Hydrated lime is mixed into sewage sludge and in large scale operations, this application is largely automated. In small scale operations, hydrated lime can also be manually loaded into the dosing equipment of the mixer. The method of application for the two main uses of hydrated lime is automated dosing of dry powder or by automated dosing of milk of lime (a saturated calcium hydroxide solution prepared by re-suspending hydrated lime in water). Treatment is performed only once for each batch of sewage sludge. The frequency of treatments depends on the size of the sewage treatment plant or farm. Depending on the pathogen that needs to be controlled, the storage time of the lime-treated material can be prolonged (up to 3 months).

Product Type	Disinfectants and algaecides not intended for direct application to humans or animals (PT 2)
Object and/or situation	Disinfectant for the treatment of sewage sludge
Formulation	Powder Aqueous solution
Product name	Schaefer Precal 50S
	Schaefer Precal 50N
Concentration Used	Lime quantity equivalent to 20 – 50 % of the dry solids weight of the sludge
Application	Single application using automated dosing
Applied amount per treatment	The application rate used is the amount required to achieve a pH of > 12 for a minimum of 3 hours and therefore the rate will vary between applications
Organisms controlled	Bacteria, viruses and parasites present in sewage sludge
Categories of User	Industrial and professional users
Packaging	Bags; paper or plastic lined paper; 20-50 kg
	Big bags; polypropylene plastic plait; 500-1000 kg
	IBC; polyethylene; 500-1000 L
Type of Application	Automated dosing of dry powder into substrate Automated dosing of milk of lime into substrate
Storage	Bagged material should be stored under dry conditions Bulk material is stored (silos) in closed systems
Remarks	Schaefer Precal 50S and Schaefer Precal 50N can also be delivered as bulk, commonly by 25 tons batches. The internal surface of the silo is plastic coated aluminium for transportation of powder and stainless steel for transportation of aqueous suspensions

Data supporting hydrated lime for its use against the intended target organisms have demonstrated sufficient efficacy for Approval to be recommended.

To date, there are no known resistance issues when using hydrated lime against the target organisms.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3	Anoous	2003	OPINION OF THE SCIENTIFIC COMMITTEE ON FOOD ON THE TOLERABLE UPPER INTAKE LEVEL OF CALCIUM Source: European Commission, Health & Consumer Protection Directorate-General Report No.: SCF/CS/NUT/UPPLEV/64 Final Not GLP; (published) Doc. No.: 592-093	No	N.R.
A3	Anonymous	2001	OPINION OF THE SCIENTIFIC COMMITTEE ON FOOD ON THE TOLERABLE UPPER INTAKE LEVEL OF MAGNESIUM Source: European Commission, Health & Consumer Protection Directorate-General Report No.: SCF/CS/NUT/UPPLEV/54 Final Not GLP; (published) Doc. No.: 592-094	No	N.R.
A3.1.1/01	Weast, R.C.	1990	HANDBOOK OF CHEMISTRY AND PHYSICS - A READY-REFERENCE BOOK OF CHEMICAL AND PHYSICAL DATA Source: Handbook of Chemistry and Physics, 1989-1990, 70th Edition, CRC Press Inc., pp. B-80, B-81, B-104 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-002	No	N.R.
A3.1.1/02	Wiberg, N.	1985	LEHRBUCH DER ANORGANISCHEN CHEMIE - INCLUDING ENGLISH TRANSLATION Source: 91.-100. verbesserte und stark erweiterte Auflage, von Nils Wiberg, 2. Magnesium, pp. 907-908, ISBN: 3-11-007511-3, 3. Das Calcium, pp. 913-914 Report No.: Not applicable Not GLP; (published)	No	N.R.

Section No / Reference No	**Author(s)**	**Year**	**Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			Doc. No.: 192-001		
A3.1.3/01	Anonymous	1995	CD RÖMPP CHEMIE LEXIKON - MAGNESIUMHYDROXID, MAGNESIUMOXID, DOLOMIT, CALCIUMHYDROXID, CALCIUMOXID - INCLUDING ENGLISH TRANSLATION Source: CD Römpp Chemie Lexikon - Version 1.0, Stuttgart/New York, Georg Thieme Verlag 1995 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-003	No	N.R.
A3.1.3/02	Remnant, V.	2007	PRECAL 50S - PHYSICO-CHEMICAL PROPERTIES: RELATIVE DENSITY SURFACE TENSION OF AN AQUEOUS SOLUTION BULK DENSITY Source: Huntingdon Life Science Report No.: LIM/0004/073143 GLP; (unpublished) Doc. No.: 113-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A3.1.3/03	Remnant, V.	2007	PRECAL 50N - PHYSICO-CHEMICAL PROPERTIES: RELATIVE DENSITY BULK DENSITY Source: Huntingdon Life Science Report No.: LIM/0003/073142 GLP; (unpublished) Doc. No.: 113-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A3.4.2/01	Lohmann, D.	N.I.	UNTERSUCHUNGEN ZUR VERMEIDUNG ZU HOHER PH-WERTE IN WEICHEN TRINKWÄSSERN BEI DER INBETRIEBNAHME VON ROHRLEITUNGEN MIT EINER ZEMENTMÖRTELAUSKLEIDUNG - INCLUDING ENGLISH TRANSLATION Source: IWW,Rheinisch-Westfälisches Institut für Wasserforschung Gemeinnützige GmbH, 27 Seiten. Report No.: Not applicable Not GLP; (published) Doc. No.: 192-005	No	N.R.
A3.4.2/02	Kaufman, J.W. Hauge, R.H. Margrave, J.L.	1984	INFRARED MATRIX ISOLATION STUDIES OF THE INTERACTIONS OF MG, CA, SR, AND BA ATOMS AND SMALL CLUSTERS WITH	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			WATER Source: High Temperature Science, Vol. 18, 1994, pp. 97-118 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-004		
A3.9/01	Schiffner, H.M.	2007	TEST OF PHYSICO-CHEMICAL PROPERTIES OF: PRECAL 30S, PRECAL 50S, PRECAL 30N, PRECAL 50N, NEUTRALAC QM, NEUTRALAC HM Source: Institut für Kalk- und Mörtelforschung e. V. Report No.: WA 064/07 Not GLP; (unpublished) Doc. No.: 154-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
Doc II A4 Appendix I	Molitor, H. et al.	2007	DLG-MERKBLATT - HINWEISE ZUR KALKDÜNGUNG Source: DLG-Merkblatt, 2007, 2. Auflage, 1- 52 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-005	No	N.R.
A4.1/01	Anonymous	1999	STANDARD TEST METHODS FOR CHEMICAL ANALYSIS OF LIMESTONE, QUICKLIME, AND HYDRATED LIME Source: Designation: C 25 - 99 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-007	No	N.R.
A4.1/02	Anonymous	1999	STANDARD TEST METHOD FOR X-RAY SPECTROMETRIC ANALYSIS OF LIME AND LIMESTONE Source: Not applicable Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 492-003	No	N.R.
A4.1/03	Anonymous	2001	STANDARD TEST METHOD FOR MAJOR AND TRACE ELEMENTS IN LIMESTONE AND LIME BY INDUCTIVELY COUPLED PLASMA-ATOMIC EMISSION SPECTROSCOPY (ICP) AND ATOMIC ABSORPTION (AA) Source: Designation: C 1301 - 95 (Reapproved 2001), pp. 1-4 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-010	No	N.R.

Section No / Reference No	**Author(s)**	**Year**	**Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
A4.1/04	Anonymous	2001	EUROPEAN STANDARD - LIMING MATERIALS - DETERMINATION OF NEUTRALIZING VALUE - TITRIMETRIC METHODS Source: CEN, 2001, 01/124294 Report No.: 01/124294 Not GLP; (published) Doc. No.: 492-015	No	N.R.
A4.1/05	Anonymous	2000	DEUTSCHE NORM - BESTIMMUNG DES CALCIUM- UND MAGNESIUMGEHALTES - KOMPLEXOMETRISCHES VERFAHREN - DIN EN 12946 (INCLUDING ENGLISH TRANSLATION) Source: Deutsche Norm, DIN Deutsches Institut für Normung e.V., März 2000 Report No.: DIN EN 12946: 2000-03 Not GLP; (published) Doc. No.: 492-008	No	N.R.
A4.1/06	Anonymous	2000	DEUTSCHE NORM - CALCIUM-/MAGNESIUM-BODENVERBESSERUNGSMITTEL - BESTIMMUNG DES MAGNESIUMGEHALTES - ATOMABSORPTIONSSPEKTROMETRISCHES VERFAHREN (INCLUDING ENGLISH TRANSLATION) Source: © DIN Deutsches Institut für Normung e.V., Ref.-Nr. DIN EN 12947:2000-09, Preisgr. 07, Vertr.-Nr. 2307 Report No.: EN 12947 Not GLP; (published) Doc. No.: 492-009	No	N.R.
A4.1/07	Anonymous	1996	DEUTSCHE NORM - FESTE DÜNGEMITTEL UND CALCIUM-/MAGNESIUM-BODENVERBESSERUNGSMITTEL - BESTIMMUNG DES FEUCHTEGEHALTES - GRAVIMETRISCHES VERFAHREN DURCH TROCKNUNG BEI (105+-2)°C (INCLUDING ENGLISH TRANSLATION) Source: © DIN Deutsches Institut für Normung e.V. - Ref. Nr. DIN EN 12048:1996-11, Preisgr. 07, Vertr.-Nr.	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			2307 Report No.: EN 12048 Not GLP; (published) Doc. No.: 492-006		
A4.1/08	Anonymous	2004	DEUTSCHE NORM - DÜNGEMITTEL UND CALCIUM-/MAGNESIUM-BODENVERBESSERUNGSMITTEL-BESTIMMUNG VON KOHLENSTOFFDIOXID-TEIL 2: VERFAHREN FÜR CALCIUM-/MAGNESIUM-BODENVERBESSERUNGSMITTEL; DEUTSCHE FASSUNG EN 14397-2:2004 (INCLUDING ENGLISH TRANSLATION) Source: © DIN Deutsches Institut für Normung e.V., Preisgruppe 9 Report No.: DIN EN 14397-2 Not GLP; (published) Doc. No.: 492-012	No	N.R.
A4.1/09	Anonymous	2001	BUILDING LIME - PART 2 - TEST METHODS Source: European Committee for Standardization, Brussels Report No.: CEN/TC 51/WG 11 N 0369 EN 459-2 Not GLP; (unpublished) Doc. No.: 272-008	No	N.R.
A4.2a/01	Anonymous	2005	DÉTERMINATION DU PH Source: Association Francaise de Normalisation, Mai 2005 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-020	No	N.R.
A4.2a/02	Anonymous	2006	DÉTERMINATION DES CATIONS CA++, MG++, K+, NA+ EXTRACTIBLES PAR L´ACÉTATE D´AMMONIUM Source: Association Francaise de Normalisation, Septembre 2002 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-019	No	N.R.
A4.2b/01	Cain, W.S. et al.	2004	SENSORY AND ASSOCIATED REACTIONS TO MINERAL DUSTS: SODIUM BORATE, CALCIUM OXIDE, AND CALCIUM SULFATE Source: Journal of Occupational and Environmental Hygiene, Vol. 1,	No	N.R.

Section No / Reference No	**Author(s)**	**Year**	**Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			pp. 222-236, ISSN: 1545-9624 print / 1545-9632 online Report No.: Not applicable Not GLP; (published) Doc. No.: 592-020		
A4.3/01	Anonymous	2006	LEBENSMITTEL - BESTIMMUNG VON ELEMENTSPUREN - BESTIMMUNG VON NATRIUM, MAGNESIUM UND CALCIUM MIT FLAMMEN-ATOMABSORPTIONSSPEKTROMETRIE (AAS) NACH MIKROWELLENAUFSCHLUSS Source: Deutsche Norm, DIN EN 15505, Mai 2006 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-022	No	N.R.
A4.3/02	Anonymous	2006	FUTTERMITTEL - BESTIMMUNG VON CALCIUM, NATRIUM, PHOSPOHR, MAGNESIUM KALIUM, EISEN, ZINK, KUPFER, MANGAN, COBALT, MOLYBDÄN, ARSEN, BLEI UND CADMIUM MITTELS ICP-AES Source: Deutsche Norm, DIN EN 15510, Juni 2006 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-021	No	N.R.
A5 Attachment 1	Anonymous	2006	EULA LIME TREATMENT FOR MANURE AND DIGESTIVE TRACT CONTENT BY TF BIOCIDE & TF ANIMAL PRODUCT OF EULA Source: EULA - European Lime Association - Europäischer Kalkverband Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 032-003	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A5 Attachment 2	Anonymous	2006	LITERATURE SEARCH - LIME RESISTANCE Source: Not applicable Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 391-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A5.3.1/01	O´Mahony, M. Whyte, P. Fanning, S.	2004	LIME TREATMENT - INACTIVATION OF MICROBIOLOGICAL HAZARDS IN ANIMAL BY-PRODUCTS Source: Not applicable Report No.: Not applicable Not GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Doc. No.: 381-004		
A5.3.1/02	Pfuderer, G.	1985	INFLUENCE OF LIME TREATMENT OF RAW SLUDGE ON THE SURVIVAL OF PATHOGENS, ON THE DIGESTABILITY OF THE SLUDGE AND ON THE PRODUCTION OF METHANE - HYGIENIC INVESTIGATIONS Source: Proceedings of a seminar held in Hohenheim 8-10 October 1984 "Hygenic aspects related to treadment and use of sewage sludge. Ed P. L`Hermite.Elsvier Applied Science Publishers, Brussels., 1985, Pp. 85-97 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-035	No	N.R.
A5.3.1/03	Marcinkowski, T.	1985	DECONTAMINATION OF SEWAGE SLUDGES WITH QUICKLIME Source: Waste Management & Research (1985), Vol. 3, pp. 55-64 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.
A5.3.1/04	Jepsen, S.-E. Krause, M. Grüttner, H.	1997	REDUCTION OF FECAL STREPTOCOCCUS AND SALMONELLA BY SELECTED TREATMENT METHODS FOR SLUDGE AND ORGANIC WASTE Source: Wat. Sci. Tech. Vol. 36, No. 11, pp. 203-210, 1997 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-016	No	N.R.
A5.3.1/05	Bosch, A. Lucena, F. Jofre, J.	1986	FATE OF HUMAN ENTERIC VIRUSES (ROTA VIRUSES AND ENTEROVIRUSES) IN SEWAGE AFTER PRIMARY SEDIMENTATION Source: Wat. Sci. Tech. Vol. 18, No. 10, pp. 47-52, 1986 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-012	No	N.R.
A5.3.1/06	Schirm, V. et al.	2003	ENTWICKLUNG EINER SICHEREN METHODE ZUR BIOABFALLHYGIENISIERUNG MIT KALK - INCLUDING ENGLISH TRANSLATION	Yes (Data on existing a.s. submitted for the first time	Forschungsgemeinschaft Kalk und Mörtel

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Source: Forschungsgemeinschaft Kalk und Mörtel Report No.: Forschungsbericht Nr. 1/03 / C 023 i/e Not GLP; (unpublished) Doc. No.: 336-0201	for Approval.)	
A5.3.1/07	Zacherl-König, J. Helm, M. Gronauer, A.	1994	AUSWIRKUNGEN UNTERSCHIEDLICHER ZUSCHLAGSTOFFE AUF DIE GERUCHSENTSTEHUNG, DIE KEIMFLORA UND DIE MADENENTWICKLUNG IN DER BIOTONNE - INCLUDING ENGLISH TRANSLATION Source: Bayerische Landesanstalt für Landtechnik, Weihenstephan Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 392-015	No	N.R.
A5.3.1/08	Koch, K. Strauch, D.	1981	INAKTIVIERUNG VON POLIO- UND PAROVIRUS IM KLÄRSCHLAMM DURCH KALKBEHANDLUNG - INCLUDING ENGLISH TRANSLATION Source: Zbl. Bakt. Hyg., I. Abt. Orig. B 174, pp. 335-347, (1981) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-007	No	N.R.
A5.3.1/09	Capizzi-Banas, S. et al.	2004	LIMING AS AN ADVANCED TREATMENT FOR SLUDGE SANITISATION: HELMINTH EGGS ELIMINATION - ASCARIS EGGS AS MODEL Source: Water Research 38 (2004), pp. 3251-3258 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-024	No	N.R.
A5.3.1/10	Carrington, E.G.	2001	EVALUATION OF SLUDGE TREATMENTS FOR PATHOGEN REDUCTION Source: European Commission, 2001, ISBN 92-894-1734-X Report No.: CO 5026/1 Not GLP; (published) Doc. No.: 381-011	No	N.R.
A5.3.1/11	Christy, R.W.	1990	PROCESS EQUIPMENT CONSIDERATIONS FOR LIME STABILIZATION SYSTEMS	No	N.R.

Section No / Reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			PRODUCING PSRP AND PFRP QUALITY SLUDGE Source: Presentation during a NLA seminar 1990 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-036		
A5.3.1/12	Anonymous	1967	LIMES AND LIMESTONES Source: Encyclopedia of Chemical Technology, Vol. 12, pp. 423-430, 1967 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-008	No	N.R.
A5.3.1/13	Anonymous	2007	INACTIVATING EFFECT OF LIME ON INFECTIVITY OF AVIAN INFLUENZA A VIRUS SUBTYPE H5N1 Source: Unité de Sécurité Microbiologique, Institut Pasteur de Lille, France Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0303	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.1/01	[redacted]	2007	NEUTRALAC QM3 - NEUTRALAC HM - PRECAL 30S AND PRECAL 50S - ACUTE ORAL TOXICITY STUDY IN THE RAT [redacted] GLP; (unpublished) Doc. No.: 521-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.2/01	[redacted]	1994	AKUTE DERMALE TOXIZITÄT VON WEISSKALKTEIG - BERICHT ÜBER EINE UNTERSUCHUNG AN KANINCHEN GEMÄSS RICHTLINIE 92/69/EWG - INCLUDING ENGLISH TRANSLATION [redacted] Not GLP; (unpublished) Doc. No.: 522-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/01	[redacted]	1995	IRRITATION OCULAIRE AIGUE CHEZ LE LAPIN - HYDROXYDE DE CALCIUM - INCLUDING ENGLISH TRANSLATION [redacted]	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

Section No / Reference No	**Author(s)**	**Year**	**Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			[redacted] GLP; (unpublished) Doc. No.: 566-002		
A6.1.4/02	[redacted]	1995	IRRITATION OCULAIRE AIGUE CHEZ LE LAPIN - OXYDE DE CALCIUM - INCLUDING ENGLISH TRANSLATION [redacted] GLP; (unpublished) Doc. No.: 566-003	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/03	[redacted]	1995	IRRITATION OCULAIRE AIGUE CHEZ LE LAPIN - HYDROXYDE DE CALCIUM A LA CONCENTRATION DE 150 G/L - INCLUDING ENGLISH TRANSLATION [redacted] GLP; (unpublished) Doc. No.: 566-004	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/04	[redacted]	2000	SCHLEIMHAUTIRRITIERENDE WIRKUNG VON KALK UND WEISSKALKTEIG - BERICHT ÜBER EINE UNTERSUCHUNG AM EMBRYONIERTEN HÜHNEREI - INCLUDING ENGLISH TRANSLATION [redacted] Not GLP; (unpublished) Doc. No.: 566-006	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/05	[redacted]	1995	IRRITATION CUTANEE AIGUE CHEZ LE LAPIN - OXYDE DE CALCIUM - INCLUDING ENGLISH TRANSLATION [redacted] GLP; (unpublished) Doc. No.: 565-004	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/06	[redacted]	1994	HAUTIRRITIERENDE WIRKUNG (AKTUE TOXIZITÄT, HAUTIRRITATION) VON WEISSKALKTEIG - INCLUDING ENGLISH TRANSLATION	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

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			[redacted] Not GLP; (unpublished) Doc. No.: 565-003		
A6.1.4/07	[redacted]	1994	ACUTE DERMAL IRRITATION / CORROSION TEST OF "WEISSKALKHYDRAT" IN RABBITS [redacted] GLP; (unpublished) Doc. No.: 565-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.1.4/08	[redacted]	1994	ACUTE DERMAL IRRITATION / CORROSION TEST OF "WEISSFEINKALK" IN RABBITS [redacted] GLP; (unpublished) Doc. No.: 565-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.3.2 Attachment	Anonymous	2006	APPLICANT´S RESPONSE TO COMMENTS MADE BY HSE (EMAIL TO EULA DATED 19 DECEMBER 2005) ON WAIVING OF THE REPEATED DERMAL TOXICITY STUDY ON LIME [redacted] Not GLP; (unpublished) Doc. No.: 975-1101	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.5/01	Merne, M. Syrjänen, K.J. Syrjänen, S.M.	2001	SYSTEMIC AND LOCAL EFFECTS OF LONG-TERM EXPOSURE TO ALKALINE DRINKING WATER IN RATS Source: Int. J. Exp. Path., 2001, Vol. 82, pp. 213-219 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-027	No	N.R.
A6.6.1/01	[redacted]	1975	MUTAGENIC EVALUATION OF COMPOUND FDA 73-41, CALCIUM OXIDE [redacted] Not GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Doc. No.: 557-001		
A6.6.1/02	Oguma, Y. et al.	1998	MUTAGENICITY STUDIES OF MAGNESIUM SULFATE - REVERSE MUTATION TEST WITH BACTERIA AND CHROMOSOMAL ABERRATION TEST WITH MAMMALIAN CELLS IN CULTURE Source: The Journal of Toxicological Sciences, Vol. 23, Supplement I, pp. 81-90, 1998 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-041	No	N.R.
A6.6.1/03	Fujita, H. Nakano, M. Sasaki, M.	1988	MUTAGENICITY TEST OF FOOD ADDITIVES WITH SALMONELLA TYPHIMURIUM TA97 AND TA102 Source: Ann. Rep. Tokyo Metr. Res. Lab. P.H., Vol. 39, pp. 343-350, 1988 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-106	No	N.R.
A6.6.1/04	Ishidate Jr., M. et al.	1984	PRIMARY MUTAGENICITY SCREENING OF FOOD ADDITIVES CURRENTLY USED IN JAPAN Source: Fd. Chem. Toxic. Vol. 22, No. 8, pp. 623-636, 1984 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-108	No	N.R.
A6.6.1/05	[redacted]	2007	SALMONELLA THYPHIMURIUM AND ESCHERICHIA COLI REVERSE MUTATION ASSAY WITH PRECAL 50S [redacted] GLP; (unpublished) Doc. No.: 557-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.6.1/06	[redacted]	2007	SALMONELLA TYPHIMURIUM AND ESCHERICHIA COLI REVERSE MUTATION ASSAY WITH PRECAL 30S [redacted] GLP; (unpublished) Doc. No.: 557-003	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.6.1/07	[redacted]	2007	SALMONELLA TYPHIMURIUM AND ESCHERICHIA COLI REVERSE MUTATION ASSAY WITH NEUTRALAC HM [redacted]	Yes (Data on existing a.s. submitted for the first time	EULA

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted] GLP; (unpublished) Doc. No.: 557-004	for Approval.)	
A6.6.1/08	[redacted]	2007	SALMONELLA TYPHIMURIUM AND ESCHERICHIA COLI REVERSE MUTATION ASSAY WITH NEUTRALAC QM [redacted] GLP; (unpublished) Doc. No.: 557-005	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.6.3/01	Ribeiro, D.A. et al.	2005	GENOTOXICITY OF ANTIMICROBIAL ENDODONTIC COMPOUNDS BY SINGLE CELL GEL (COMET) ASSAY IN CHINESE HAMSTER OVARY (CHO) CELLS Source: 2005 Elservier Inc. Report No.: Not applicable Not GLP; (published) Doc. No.: 592-043	No	N.R.
A6.6.3/02	Ribeiro, D.A. Marques, M.E.A. Salvadori, D.M.F.	2004	LACK OF GENOTOXICITY OF FORMOCRESOL PARAMONOCHLORPHENOL, AND CALCIUM HYDROXIDE ON MAMMALIAN CELLS BY COMET ASSAY Source: Journal of Endontics, Vol. 30, No. 8, August 2004, pp. 593-596 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-042	No	N.R.
A6.6.3/03	Oberly, T.J. Piper, C.E. McDonald, D.S.	1982	MUTAGENICITY OF METAL SALTS IN THE L5178Y MOUSE LYMPHOMA ASSAY Source: Journal of Toxicology and Environmental Health, Vol. 9, pp. 367-376, 1982 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-113	No	N.R.
A6.7/01	Agrawal, R.C. Sarode, A.V. Bhide, S.V.	1986	HISTOPATHOLOGY OF HAMSTER CHEEK & LIVER FOLLOWING TOPICAL APPLICATION OF LIME Source: Indian J Med Res 84, November 1986, pp. 542-547 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-014	No	N.R.
A6.7/02	Sirsat, S.M. Kandarkar, S.V.	1967	HISTOLOGICAL CHANGES IN THE ORAL MUCOSA OF THE WISTAR RAT TREATED WITH COMMERCIAL LIME (CALCIUM	No	N.R.

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			HYDROXIDE) - AN OPTICAL AND SUBMICROSCOPIC STUDY Source: From the Cancer Research Institute, Parel, Bombay-12, India Report No.: Not applicable Not GLP; (published) Doc. No.: 592-008		
A6.7/03	Kurata, Y. et al.	1989	LACK OF CARCINOGENICITY OF MAGNESIUM CHLORIDE IN A LONG-TERM FEEDING STUDY IN B6C3F MICE Source: Fd. Chem. Toxic. Vol. 27, No. 9, pp. 559-563, 1989 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-036	No	N.R.
A6.7/04	Maekawa, A. et al.	1991	LONG-TERM TOXICITY / CARCINOGENICITY STUDY OF CALCIUM LACTATE IN F344 RATS Source: Fd. Chem. Toxic. Vol. 29, No. 9, pp. 589-594, 1991 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-037	No	N.R.
A6.8.1/01	[redacted]	1974	TERATOLOGIC EVALUATION OF FDA 73-41, CALCIUM OXIDE IN MICE AND RATS [redacted] Not GLP; (unpublished) Doc. No.: 551-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A6.8.1/02	Shackelford, M.E. et al.	1993	FOETAL DEVELOPMENT IN RATS FED AIN-76A DIETS SUPPLEMENTED WITH EXCESS CALCIUM Source: Fd Chem. Toxic., Vol. 31, No. 12, pp. 953-961, 1993 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-048	No	N.R.
A6.8.1/03	Katsumata, Y. Inoue, K. Shimamura, K.	1998	A STUDY FOR EFFECTS ON PRE- AND POSTNATAL DEVELOPMENT, INCLUDING MATERNAL FUNCTION IN RATS TREATED SUBCUTANEOUSLY WITH MAGNESIUM SULFATE Source: The Journal of Toxicological Sciences, Vol. 23, Supplement I, pp. 67-79, 1998	No	N.R.

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			Report No.: Not applicable Not GLP; (published) Doc. No.: 592-046		
A6.8.1/04	Usami, M. et al.	1996	TERATOGENICITY STUDY OF MAGNESIUM CHLORIDE HEXAYDRATE IN RATS Source: Bull. Natl. Inst. Health Sci., Vol. 114, pp. 16-20, 1996 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-049	No	N.R.
A6.8.1/05	Elmore, A.R.	2003	FINAL REPORT ON THE SAFETY ASSESSMENT OF ALUMINUM SILICATE,CALCIUM SILICATE,MAGNESIUM ALUMINUM SILICATE,MAGNESIUM SILICATE,ZIRCONIUM SILICATE,ATTAPULGITE,BENTONITE,FULLER´S EARTH,HECTORITE,KAOLIN,LITHIUM MAGNESIUM SILICATE,LITHIUM MAGNESIUM SODIUM Source: International Journal of Toxicology, Vol. 22 (Suppl. 1), pp. 37-102, 2003, ISSN: 1091-5818 print / 1092-874X online Report No.: Not applicable Not GLP; (published) Doc. No.: 592-028	No	N.R.
A6.8.2/01	Richards, M.B. Greig, W.A.	1952	THE EFFECTS OF ADDITIONS OF CALCIUM CARBOMATE TO THE DIET OF BREEDING MICE Source: British Journal of Nutrition, Vol. 6, No. 3, pp. 265-280 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-123	No	N.R.
A6.8.2/02	Andrieux-Domont, C. van Hung, L.	1973	EFFECTS OF MAGNESIUM DEFICIENCY ON REPRODUCTION IN THE WHITE RAT Source: Br. J. Nutr. 29, (1973), pp. 203-210 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-131	No	N.R.
A6.12.2/01	Cain, W.S. et al.	2004	SENSORY AND ASSOCIATED REACTIONS TO MINERAL DUSTS: SODIUM BORATE, CALCIUM OXIDE, AND CALCIUM SULFATE	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Source: Journal of Occupational and Environmental Hygiene, Vol. 1, pp. 222-236, ISSN: 1545-9624 print / 1545-9632 online Report No.: Not applicable Not GLP; (published) Doc. No.: 592-020		
A6.12.2/02	Kuschner, W.G. et al.	1997	HUMAN PULMONARY RESPONSES TO EXPERIMENTAL INHALATION OF HIGH CONCENTRATION FINE AND ULTRAFINE MAGNESIUM OXIDE PARTICLES Source: Environmental Health Perspectives, Vol. 105, No. 11, November 1997 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-111	No	N.R.
A6.12.2/03	Kilic, S. et al.	1996	EFFECT OF TOTAL AND IONIZED CALCIUM LEVELS OF SEMINAL FLUID ON SPERM MOTILITY Source: Urol Int. 56, (1996), pp. 215-218 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-125	No	N.R.
A6.12.2/04	Meseguer, M. et al.	2004	RELATIONSHIP BETWEEN STANDARD SEMEN PARAMETERS, CALCIUM, CHOLESTEROL CONTENTS, AND MITOCHONDRIAL ACTIVITY IN EJACULATED SPERMATOZOA FROM FERTILE AND INFERTILE MALES Source: Journal of Assisted Reproduction and Genetics, Vol. 21, No. 12, December 2004, pp. 445-451 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-127	No	N.R.
A6.12.2/05	Pandy, V.K. Parmeshwaran, M. Soman, S.D.	1983	CONCENTRATIONS OF MORPHOLOGICALLY NORMAL, MOTILE SPERMATOZOA: MG, CA AND ZN IN THE SEMEN OF INFERTILE MEN Source: The Science of the Total Environment. 27, (1983), pp. 49-52 Report No.: Not applicable	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Not GLP; (published) Doc. No.: 592-129		
A6.12.3/01	Hahn, A. et al	2002	ÄRZTLICHE MITTEILUNGEN BEI VERGIFTUNGEN NACH §16E CHEMIKALIENGESETZ 2002 - INCLUDING ENGLISH TRANSLATION Source: Ärztliche Mitteilungen bei Vergiftungen 2002, ISBN 3-931675-83-1 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-023	No	N.R.
A6.12.4/01	Toren, K. et al.	1996	IMPROVED NASAL CLEARANCE AMONG PULP-MILL WORKERS AFTER THE REDUCTION OF LIME DUST Source: Scand J Work Environ Health 1996, Vol. 22, pp. 102-107 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-017	No	N.R.
A6.12.4/02	Lahaye, D.	1987	ETUDE DE LA FONCTION PULOMONAIRE DE TRAVAILLEURS EXPOSÉS AUX POUSSIÈRES DE CHAUX VIVE - INCLUDING ENGLISH TRANSLATION Source: Arch B Med Soc Hyg Med Tr & Med leg 45 : 144-153 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-001	No	N.R.
A6.12.4/03	Villar, J. Repke, J.T.	1990	CALCIUM SUPPLEMENTATION DURING PREGNANCY MAY REDUCE PRETERM DELIVERY IN HIGH-RUSK POPULATIONS Source: Am. J. Obstet Gynecol, October 1990, Vol. 163, No. 4, Part 1 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-091	No	N.R.
A6.12.4/04	Belizán, J.M.	1991	CALCIUM SUPPLEMENTATION TO PREVENT HYPERTENSIVE DISORDERS OF PREGNANCY Source: The New England Journal of Medicine, Vol. 325, No. 20, pp. 1399-1405 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-073	No	N.R.
A6.12.4/05	Levine, R.J.	1997	TRIAL OF CALCIUM TO	No	N.R.

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	et al.		PREVENT PREECLAMPSIA Source: The New England Journal of Medicine, Vol. 337, No. 2, pp. 69-76, 1997 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-084		
A6.12.4/06	Bucher, H.C. et al.	1996	EFFECT OF CALCIUM SUPPLEMENTATION ON PREGNANCY-INDUCED HYPERTENSION AND PREECLAMPSIA Source: JAMA, Vol. 275, No. 14, pp. 1113-1117 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-076	No	N.R.
A6.12.4/07	Koo, W.W.K. et al.	1999	MATERNAL CALCIUM SUPPLEMENTATION AND FETAL BONE MINERALIZATION Source: Obstetrics & Gynecology, Vol. 94, No. 4, October 1999 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-083	No	N.R.
A6.12.4/08	Johnston, C.C. et al.	1992	CALCIUM SUPPLEMENTATION AND INCREASES IN BONE MINERAL DENSITY IN CHILDREN Source: The New England Journal of Medicine, Vol. 327, No. 2, pp. 82-87 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-081	No	N.R.
A6.12.4/09	Lloyd, T. et al.	1993	CALCIUM SUPPLEMENTATION AND BONE MINERAL DENSITY IN ADOLESCENT GIRLS Source: JAMA, 18 August 1993, Vol. 270, No. 7, pp. 841-844 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-085	No	N.R.
A6.12.4/10	Elders, P.J.M. et al.	1994	LONG-TERM EFFECT OF CALCIUM SUPPLEMENTATION ON BONE LOSS IN PERIMENOPAUSAL WOMEN Source: Journal of Bone and Mineral Research, Vol. 9, Number 7, 1997, pp. 963-970 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-079	No	N.R.

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A6.12.4/11	Reid, I.R. et al.	1993	EFFECT OF CALCIUM SUPPLEMENTATION ON BONE LOSS IN POSTMENOPAUSAL WOMEN Source: The New England Journal of Medicine, Vol. 328, No. 7, pp. 460-464, 1993 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-087	No	N.R.
A6.12.4/12	Baron, J.A. et al.	1999	CALCIUM SUPPLEMENTS FOR THE PREVENTION OF COLORECTAL ADENOMAS Source: The New England Journal of Medicine, Volume 340, Number 2, pp. 101-107 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-072	No	N.R.
A6.12.4/13	Mimouni, F. Tsang, R.C.	1991	PERINATAL MAGNESIUM METABOLISM - PERSONAL DATA AND CHALLENGES FOR THE 1990S Source: Magnesium Research, 1991, Vol. 4, 2, pp. 109-117 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-047	No	N.R.
A6.13/01	[redacted]	2002	THE USE OF HYDRATED LIME TO CONTROL LAMENESS IN HOUSED EWES [redacted] Not GLP; (unpublished) Doc. No.: 336-0302	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.1.2.2.1/01	Egeler, P. et al.	2007	PRECAL 50S: RESULTS OF THE PRE-TESTING PROGRAMME Source: ECT Oekotoxikologie GmbH, Flörsheim Report No.: P7003 Not GLP; (unpublished) Doc. No.: 714-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.1.2.2.2/01	Egeler, P. Gilberg, D.	2007	PRECAL 50S - A SHORT-TERM STUDY ON THE EFFECTS ON THE PH IN A SEDIMENT-WATER SYSTEM Source: ECT Oekotoxikologie GmbH, Flörsheim Report No.: AW1/SW Not GLP; (unpublished) Doc. No.: 714-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.2.2.4/01	Schiffner, H.M.	2007	PRE TEST ON THE DEVELOPMENT OF THE PH-	Yes (Data on	EULA

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			VALUE IN SOIL AND IN ARTIFICIAL SOIL Source: Institut für Kalk- und Mörtelforschung e. V. Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 721-001	existing a.s. submitted for the first time for Approval.)	
A7.2.2.4/02	Schiffner, H.M.	2007	PRE-TEST FREE LIME IN SOIL Source: Institut für Kalk- und Mörtelforschung e. V. Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 721-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.4.1.1./01	Ufodike, E.B.C. Onusiriuka, B.C.	1990	ACUTE TOXICITY OF INORGANIC FERTILITERS TO AFRICAN CATFISH, CLARIAS GARIEPINUS (TEUGALS) Source: Aquaculture and Fisheries Management 1990, Vol. 21, pp. 181-185 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-004	No	N.R.
A7.4.1.1./02	Konar, S.K. Sarkar, S.K.	1983	ACUTE TOXICITY OF AGRICULTURAL FERTILIZERS TO FISHES Source: Geobios 10, pp. 6-9, 1983 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-005	No	N.R.
A7.4.1.1/03	[redacted]	2007	PRECAL 50S: A STUDY ON THE ACUTE TOXICITY TO FRESHWATER FISH (RAINBOW TROUT) [redacted] GLP; (unpublished) Doc. No.: 821-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.4.1.2/01	Mehta, S. Gupta, A.N. Srivastava, R.C.	1982	COMPARATIVE TOXICITY OF CERTAIN NON-INSECTICIDAL CHEMICALS TO MENOCYCLOPS LEUCKARTI, THE CARRIER HOST OF DRACUNCULOSIS Source: Acta hydrochim. Hydrobiol., Vol. 10, 1982, pp. 361-365 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-006	No	N.R.
A7.4.1.2/02	Egeler, P. Goth, M.	2007	A STUDY ON THE ACUTE TOXICITY TO DAPHNIA	Yes (Data on	EULA

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	Knoch, E.		MAGNA Source: ECT Oekotoxikologie GmbH, Flörsheim Report No.: AW1DA IF-07/00927737 GLP; (unpublished) Doc. No.: 822-001	existing a.s. submitted for the first time for Approval.)	
A7.4.1.3/01	DePinto, J.V. Edzwald, J.K.	1982	AN EVALUATION OF THE RECOVERY OF ADIRONDACK ACID LAKEN BY CHEMICAL MANIPULATION Source: US Department of Commerce, National Technical Information Service, PB83-108498 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-007	No	N.R.
A7.4.1.3/02	Murphy, T.P. Prepas, E.E.	1990	LIME TREATMENT OF HARDWATER LAKES TO REDUCE EUTROPHICATION Source: Verh. Internat. Verein. Limnol., Vol. 24, pp. 327-334, September 1990 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-018	No	N.R.
A7.4.1.3/03	Romeyer, P.	1973	MÉTHODE CHIMIQUE DE DESTRUCTION DES ALGUES SUR LES PLANS D´EAU Source: 98 Congrés national des societes savandes, Saint-Etienne, 1973, Vol. 1, pp. 141-143 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-017	No	N.R.
A7.4.1.3/04	Egeler, P. Junker, T. Knoch, E.	2007	A STUDY ON THE TOXICITY TO ALGAE (PSEUDOKIRCHNERIELLA SUBCAPITATA) OVER 72 H Source: ECT Oekotoxikologie GmbH, Flörsheim Report No.: AW1AO IF-07/00927739 GLP; (unpublished) Doc. No.: 823-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.4.1.4/01	Egeler, P. Goth, M.	2007	PRECAL 50S - A STUDY ON THE RESPIRATION INHIBITION OF ACTIVATED SLUDGE Source: ECT Oekotoxikologie GmbH, Flörsheim Report No.: AW1XA GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

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			Doc. No.: 842-001		
A7.4.1/01	Weatherley, N.S.	1988	LIMING TO MITIGATE ACIDIFICATION IN FRESHWATER ECOSYSTEMS - A REVIEW OF THE BIOLOGICAL CONSEQUENCES Source: Water, Air and Soil Pollution 39: 421-437 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-028	No	N.R.
A7.4.3.2/01	Norrgren, L. et al.	1993	LIMING OF A SWEDISH RIVER - EFFECTS ON ATLANTIC SALMON (SALMO SALAR) Source: Nordic J. Freshw. Res., 1993, Vol. 68, pp. 42-54 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-016	No	N.R.
A7.4.3.2/02	Appelberg, M. Degerman, E. Norrgren, L.	1992	EFFECTS OF ACIDIFICATION AND LIMING ON FISH IN SWEDEN - A REVIEW Source: Finnish Fisheries Research 13, pp. 77-91, 1992 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-022	No	N.R.
A7.4.3.2/03	Traaen, T.S. et al.	1997	WHOLE-CATCHMENT LIMING AT TJONNSTROND, NORWAY: AN 11-YEAR RECORD Source: Water, Air and Soil Pollution 94: 163-180 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-004	No	N.R.
A7.4.3.4/01	Miskimmin, B.M. Donahue, W.F. Watson, D.	1995	INVERTEBRATE COMMUNITY RESPONSE TO EXPERIMENTAL LIME (CA(OH)2) TREATMENT OF AN EUTROPHIC POND Source: Aquatic Sciences 57/1, 1995 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-019	No	N.R.
A7.5.1.1/01	Nodar, R. Acea, M.J. Carballas, T.	1992	MICROBIOLOGICAL RESPONSE TO CA(OH)2 TREATMENTS IN A FOREST SOIL Source: FEMS Microbiology Ecology 86, 1992, pp. 213-219 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-024	No	N.R.
A7.5.1.1/02	Schulz, L.	2007	EFFECTS OF CALCIUM DIHYDROXIDE (HYDRATED LIME) ON THE ACTIVITY OF	Yes (Data on existing a.s.	EULA

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			SOIL MICROFLORA (DEHYDROGENASE ACTIVITY) Source: BioChem agrar GmbH, Gerichshain Report No.: 07 10 48 030 C GLP; (unpublished) Doc. No.: 841-002	submitted for the first time for Approval.)	
A7.5.1.1/03	Schulz, L.	2007	EFFECTS OF CALCIUM DIHYDROXIDE (HYDRATED LIME) ON THE ACTIVITY OF SOIL MICROFLORA (NITROGEN TRANSFORMATION TEST) Source: BioChem agrar GmbH, Gerichshain Report No.: 07 10 48 016 N GLP; (unpublished) Doc. No.: 841-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.5.1.2/01	Friedrich, S.	2007	ACUTE TOXICITY (14 DAYS) OF CALCIUM DIHYDROXIDE (HYDRATED LIME) TO THE EARTHWORM EISENIA FETIA IN ARTIFICIAL SOIL Source: BioChem agrar GmbH, Gerichshain Report No.: 07 10 48 006 S GLP; (unpublished) Doc. No.: 833-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.5.1.3./01	Martinez, J.F. Robertson, W.K. Martin, F.G.	1977	SOIL AND SEED TREATMENTS WITH LIME, MOLYBDENUM AND BORON FOR SOYBEAN (GLYCINE MAX (L.) MERR.) PRODUCTION ON A FLORIDA SPODOSOL Source: Proceedings, Volume 36, pp. 58 60, 1977 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-011	No	N.R.
A7.5.1.3./02	Waliyar, F. et al.	1992	EFFECT OF LIMING AND CARBOFURAN ON GROUNDNUT YIELD IN SANDY SOILS IN NIGER Source: Fertilizer Research 33, pp. 203-208, 1992 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-021	No	N.R.
A7.5.1.3/03	Friedrich, S.	2007	EFFECTS OF CALCIUM DIHYDROXIDE (HYDRATED LIME) ON SEEDLING EMERGENCE AND SEEDLING GROWTH TEST OF NON-TARGET TERRESTRIAL PLANTS Source: BioChem agrar GmbH,	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA

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			Gerichshain Report No.: 07 10 48 007 S GLP; (unpublished) Doc. No.: 851-001		
A7.5.2.1/01	Burton, C.H. Turner, C.	2003	MANURE MANAGEMENT - TREATMENT STRATEGIES FOR SUSTAINABLE AGRICULTURE Source: Manure Management, Silsoe Research Institute 2003, pp. 190-191;194-205 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-031	No	N.R.
A7.5.2.1/02	Rundgren, S.	1994	EARTHWORMS AND SOIL REMDIATION - LIMING OF ACIDIC CONFEROUS FOREST SOILS IN SOUTHERN SWEDEN Source: Pedobiologia 38, pp. 519-529, 1994 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-020	No	N.R.
A7.5.2.1/03	Friedrich, S.	2007	SUBLETHAL TOXICITY OF CALCIUM DIHYDROXIDE (HYDRATED LIME) TO THE EARTHWORM EISENIA FETIDA IN ARTIFICIAL SOIL Source: BioChem agrar GmbH, Gerichshain Report No.: 07 10 48 038 S GLP; (unpublished) Doc. No.: 833-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
A7.5.3.1/01	Schafer Jr., E.W. Bowles Jr., W.A. Hurlbut, J.	1983	THE ACUTE ORAL TOXICTY, REPELLENCY, AND HAZARD POTENTIAL OF 998 CHEMCIALS TO ONE OR MORE SPECIES OF WILD AND DOMESTIC BIRDS Source: Arch. Envrionm. Contam. Toxicol. 12, pp. 355-382, 1983 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-013	No	N.R.
A7.5.4.1/01	Barata, J.M.S. et al.	N1992	EVALUATION OF TRIATOMINE BEHAVIOR UNDER THE EFFECT OF CONTACT WITH CALCIUM HYDROXIDE [Ca(OH)2] - MORTALITY RATES OF TRIATOMA INFESTANS AND RHODINUS NEGLECTUS (HEMIPTERA, REDUVIIDAE) Source: An. Soc. Ent. Brasil: 169-177	No	N.R.

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			Report No.: Not applicable Not GLP; (published) Doc. No.: 892-012		
A7.5.6/01	Mueller, B.R. Roth, M. Rittner, P.	1993	INFLUENCE OF COMPOST AND LIME ON POPULATION STRUCTURE AND ELEMENT CONCENTRATIONS OF FOREST SOIL INVERTEBRATES Source: Biol. Fertil Soils, 1993, Vol. 15, pp. 165-173 Report No.: Not applicable Not GLP; (published) Doc. No.: 892-023	No	N.R.
Doc II B8 Attachment 1	Anonymous	2005	LIME TREATMENT OF MANURE & DIGESTIVE TRACT CONTENT - 6 KEY COMPONENTS DOCUMENT Source: Not applicable Report No.: 1774/2002 Not GLP; (unpublished) Doc. No.: 381-005	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
Doc II B8 Attachment 2	de Lespinay, Y.	2006	EULA LETTER TO EFSA - EFSA EVALUATION OF EULA LIME TREATMENT PROCESS FOR MANURE AND DIGESTIVE TRACT CONTENT SOME ADDITIONAL QUESTIONS Source: EULA - European Lime Association - Europäischer Kalkverband Report No.: EFSA (2006) FB/ak Not GLP; (unpublished) Doc. No.: 989-001	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA
Doc II B8 Attachment 3	de Lespinay, Y.	2006	EULA LETTER TO EFSA - EFSA EVALUATION OF EULA LIME TREATMENT PROCESS FOR MANURE AND DIGESTIVE TRACT CONTENT FURTHER QUESTIONS Source: EULA - European Lime Association - Europäischer Kalkverband Report No.: EFSA (2006) FB/ak Not GLP; (unpublished) Doc. No.: 989-002	Yes (Data on existing a.s. submitted for the first time for Approval.)	EULA