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| Regulation (EC |) 1272/2008 | and Regulation | (EC |) 453/2010 |
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| Vers | ion:1.0 | | | |
|------|--|---------------------------------|---------------------|---|
| Revi | siondate:December/2010 | | | PrintingDate:June27,2012 |
| | | | | |
| 1 | IDENTIFICATION OF TH | HE SUBSTANCE/n | nixture AND OF TH | IE COMPANY/UNDERTAKING |
| 1.1 | Productidentifier | | | |
| Sub | stance name: | Hydrated lime, Ca | alcium dihydroxide | |
| Synd | onyms: | | - | g lime, Fat lime, Chemical lime, |
| | | Finishing lime, M | ason's lime, Calciu | m dihydroxide, Calcium hydroxide, |
| | | Calcium hydrate, | Lime, Lime water, | Milk of Lime |
| | mical name and formula: le name: | Calcium dihydrox Bennettsbridge | ` , | rated Cubicle Lime |
| CAS | 3: | 1305-62-0 | | |
| EINE | ECS: | 215-137-3 | | |
| Mole | ecular Weight: | 74.09 g/mol | | |
| REA | CH Registration number: | 01-2119475151- | 45-0192 | |
| 1.2 | Relevant identified uses | of the substance o | r mixture and uses | advised against |
| Plea | se check the identified use | es in table 1 of the / | Appendix of this SI | OS. |
| Use | s advised against: | There are no use | s advised against. | |
| 1.3 | Details of the supplier of | the safety data she | eet | |
| Nam | ne: | Benne | etsbridge Limesto | one Ltd |
| Addı | ress: | Kilree | , Sheastown, Co. | Kilkenny, Ireland |
| Pho | ne N°: | 00353 | 56 7727317 | |
| Fax | N°: | 00353 | 56 7727595 | |
| | ail of competent person re SDS in the MS or in the EU | • | ocarroll@bbl.ie | |
| 1.4 | Emergency telephone no | umber | | |
| Euro | ppean Emergency N°: | | 112 | |
| | onal centre for Prevention kications N°: | and Treatment o | | on Information Center spital (00353 18092566) |
| Eme | ergency telephone at the c | ompany | 00353 87 2678 | 3352 |
| Avai | lable outside office hours: | | | □No |

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

2 HAZARDS IDENTIFICATION

- 2.1 Classification of the substance
- 2.1.1 Classification according to Regulation (EC) 1272/2008

STOT Single Exp. 3, Route of exposure: Inhalation

Skin Irritation 2 Eye Damage 1

2.1.2 Classification according to Directive 67/548/EEC

Xi - irritant

- 2.2 Label elements
- 2.2.1 Labelling according to Regulation (EC) 1272/2008

Signalword: Danger

Hazard pictogram:





Hazard statements:

H315: Causes skin irritation

H318: Causes serious eye damage
H335: May cause respiratory irritation

Precautionary statements:

P102: Keep out of reach of children

P280: Wear protective gloves/protective clothing/eye protection/face protection

P305+P351+P310: IF IN EYES: Rinse cautiously with water for several minutes. Immediately call

a POISON CENTRE or doctor/physician

P302+P352: IF ON SKIN: Wash with plenty of water

P261: Avoid breathing dust/spray

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position

comfortable for breathing

P501: Dispose of contents/container to hazardous waste collection point

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

2.2.2 Labelling according to Directive 67/548/EEC

Indication of danger:

Xi irritant



Risk phrases:

R37: Irritating to respiratory system

R38: Irritating to skin

R41: Risk of serious damage to eyes

Safety phrases:

S2: Keep out of the reach of children

S25: Avoid contact with eyes

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S37: Wear suitable glovesS39: Wear eye/face protection

2.3 Other hazards

The substance does not meet the criteria for PBT or vPvB substance.

No other hazards identified.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Main constituent

Name: Calcium dihydroxide

CAS: 1305-62-0 EINECS: 215-137-3

Impurities

No impurities relevant for classification and labelling

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice

No known delayed effects. Consult a physician for all exposures except for minor instances.

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate: December/2010

PrintingDate:June27,2012

Following inhalation

Move source of dust or move person to fresh air. Obtain medical attention immediately.

Following skin contact

Carefully and gently brush the contaminated body surfaces in order to remove all traces of product. Wash affected area immediately with plenty of water. Remove contaminated clothing. If necessary seek medical advice.

Following eye contact

Rinse eyes immediately with plenty of water and seek medical advice.

After ingestion

Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Calcium dihydroxide is not acutely toxic via the oral, dermal, or inhalation route. The substance is classified as irritating to skin and the respiratory tract, and entails a risk of serious damage to the eye. There is no concern for adverse systemic effects because local effects (pH-effect) are the major health hazard.

4.3 Indication of any immediate medical attention and special treatment needed

Follow the advises given in section 4.1

- 5 FIRE FIGHTING MEASURES
- 5.1 Extinguishing media
- 5.1.1 Suitable extinguishing media

Suitable extinguishing media: The product is not combustible. Use a dry powder, foam or CO_2 fire extinguisher to extinguish the surrounding fire.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.1.2 Unsuitable extinguishing media

Do not use water.

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for fire fighters

Avoid generation of dust. Use breathing apparatus. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate: December/2010

PrintingDate:June27,2012

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Ensure adequate ventilation.

Keep dust levels to a minimum.

Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

6.1.2 For emergency responders

Keep dust levels to a minimum.

Ensure adequate ventilation.

Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

6.2 Environmental precautions

Contain the spillage. Keep the material dry if possible. Cover area if possible to avoid unnecessary dust hazard. Avoid uncontrolled spills to watercourses and drains (pH increase). Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body.

6.3 Methods and material for containment and cleaning up

In all cases avoid dust formation.

Keep the material dry if possible.

Pick up the product mechanically in a dry way.

Use vacuum suction unit, or shovel into bags.

6.4 Reference to other sections

For more information on exposure controls/personal protection or disposal considerations, please check section 8 and 13 and the annex of this safety data sheet.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures

Avoid contact with skin and eyes. Wear protective equipment (refer to section 8 of this safety data sheet). Do not wear contact lenses when handling this product. It is also advisable to have individual pocket eyewash. Keep dust levels to a minimum. Minimize dust generation. Enclose dust sources, use

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate: December/2010

PrintingDate:June27,2012

exhaust ventilation (dust collector at handling points). Handling systems should preferably be enclosed. When handling bags usual precautions should be paid to the risks outlined in the Council Directive 90/269/EEC.

7.1.2 Advice on general occupational hygiene

Avoid inhalation or ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking at the workplace. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.

7.2 Conditions for safe storage, including any incompatibilities

The substance should be stored under dry conditions. Any contact with air and moisture should be avoided. Bulk storage should be in purpose – designed silos. Keep away from acids, significant quantities of paper, straw, and nitro compounds. Keep out of reach of children. Do not use aluminium for transport or storage if there is a risk of contact with water.

7.3 Specific end use(s)

Please check the identified uses in table 1 of the Appendix of this SDS.

For more information please see the relevant exposure scenario, available via your supplier/given in the Appendix, and check section 2.1: Control of worker exposure.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

SCOEL recommendation (SCOEL/SUM/137 February 2008; see Section 16.6):

Occupational Exposure Limit (OEL), 8 h TWA: 1 mg/m3 respirable dust of calcium dihydroxide

Short-term exposure limit (STEL), 15 min: 4 mg/m³ respirable dust of calcium dihydroxide

PNEC aqua = $490 \mu g/I$

PNEC soil/groundwater = 1080 mg/l

8.2 Exposure controls

To control potential exposures, generation of dust should be avoided. Further, appropriate protective equipment is recommended. Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.

Please check the relevant exposure scenario, given in the Appendix/available via your supplier.

8.2.1 Appropriate engineering controls

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

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

8.2.2 Individual protection measures, such as personal protective equipment

8.2.2.1 Eye/face protection

Do not wear contact lenses. For powders, tight fitting goggles with side shields, or wide vision full goggles. It is also advisable to have individual pocket eyewash.

8.2.2.2 Skin protection

Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. The use of protective gloves (nitrile), protective standard working clothes fully covering skin, full length trousers, long sleeved overalls, with close fittings at openings and shoes resistant to caustics and avoiding dust penetration are required to be worn.

8.2.2.3 Respiratory protection

Local ventilation to keep levels below established threshold values is recommended. A suitable particle filter mask is recommended, depending on the expected exposure levels - please check the relevant exposure scenario, given in the Appendix/available via your supplier.

8.2.2.4 Thermal hazards

The substance does not represent a thermal hazard, thus special consideration is not required.

8.2.3 Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment.

Contain the spillage. Any large spillage into watercourses must be alerted to the regulatory authority responsible for environmental protection or other regulatory body.

For detailed explanations of the risk management measures that adequately control exposure of the environment to the substance please check the relevant exposure scenario, available via your supplier.

For further detailed information, please check the Appendix of this SDS.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or off white (beige) fine powder

Odour: odourless
Odour threshold: not applicable

pH: 12.4 (saturated solution at 20 °C)

Melting point: > 450 °C (study result, EU A.1 method)

Boiling point: not applicable (solid with a melting point > $450 \,^{\circ}$ C) Flash point: not applicable (solid with a melting point > $450 \,^{\circ}$ C) Evaporation rate: not applicable (solid with a melting point > $450 \,^{\circ}$ C)

Flammability: non flammable (study result, EU A.10 method)

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

Explosive limits: non explosive (void of any chemical structures commonly

associated with explosive properties)

Vapour pressure: not applicable (solid with a melting point > 450 °C)

Vapour density: not applicable

Relative density: 2.24 (study result, EU A.3 method)

Solubility in water: 1844.9 mg/L (study results, EU A.6 method)

Partition coefficient: not applicable (inorganic substance)

Auto ignition temperature: no relative self-ignition temperature below 400 °C (study result, EU

A.16 method)

Decomposition temperature: When heated above 580 °C, calcium dihydroxide decomposes to

produce calcium oxide (CaO) and water (H₂O)

Viscosity: not applicable (solid with a melting point > 450 °C)

Oxidising properties: no oxidising properties (Based on the chemical structure, the

substance does not contain a surplus of oxygen or any structural

groups known to be correlated with a tendency to react

exothermally with combustible material)

9.2 Other information

Not available

10 STABILITY AND REACTIVITY

10.1 Reactivity

In aqueous media Ca(OH)₂ dissociates resulting in the formation of calcium cations and hydroxyl anions (when below the limit of water solubility).

10.2 Chemical stability

Under normal conditions of use and storage, calcium dihydroxide is stable.

10.3 Possibility of hazardous reactions

Calcium dihydroxide reacts exothermically with acids. When heated above 580 °C, calcium dihydroxide decomposes to produce calcium oxide (CaO) and water (H_2O): Ca(OH)₂ • CaO + H_2O . Calcium oxide reacts with water and generates heat. This may cause risk to flammable material.

10.4 Conditions to avoid

Minimise exposure to air and moisture to avoid degradation.

10.5 Incompatible materials

Calcium dihydroxide reacts exothermically with acids to form salts. Calcium dihydroxide reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen.

 $Ca(OH)_2 + 2 AI + 6 H_2O Ca[AI(OH)_4]_2 + 3 H_2$

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010

PrintingDate:June27,2012

10.6 Hazardous decomposition products

None.

Further information: Calcium dihydroxide reacts with carbon dioxide to form calcium carbonate, which is a common material in nature.

- 11 TOXICOLOGICAL INFORMATION
- 11.1 Information on toxicological effects
- a. Acute toxicity

Oral $LD_{50} > 2000 \text{ mg/kg bw (OECD 425, rat)}$

Dermal $LD_{50} > 2500 \text{ mg/kg bw (OECD 402, rabbit)}$

Inhalation no data available

Calcium dihydroxide is not acutely toxic.

Classification for acute toxicity is not warranted.

b. Skin corrosion/irritation

Calcium dihydroxide is irritating to skin (in vivo, rabbit).

Based on experimental results, calcium dihydroxide requires classification as irritating to skin [R38, irritating to skin; Skin Irrit 2 (H315 – Causes skin irritation)].

c. Serious eye damage/irritation

Calcium dihydroxide entails a risk of serious damage to the eye (eye irritation studies (in vivo, rabbit).

Based on experimental results, calcium dihydroxide requires classification as severely irritating to the eye [R41, Risk of serious damage to eye; Eye Damage 1 (H318 - Causes serious eye damage)].

d. Respiratory or skin sensitisation

No data available.

Calcium dihydroxide is considered not to be a skin sensitiser, based on the nature of the effect (pH shift) and the essential requirement of calcium for human nutrition.

Classification for sensitisation is not warranted.

e. Germ cell mutagenicity

Bacterial reverse mutation assay (Ames test, OECD 471): Negative

Mammalian chromosome aberration test: Negative

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010

PrintingDate:June27,2012

In view of the omnipresence and essentiality of Ca and of the physiological non-relevance of any pH shift induced by lime in aqueous media, lime is obviously void of any genotoxic potential, including germ cell mutagenicity.

Classification for genotoxicity is not warranted.

f. Carcinogenicity

Calcium (administered as Ca-lactate) is not carcinogenic (experimental result, rat).

The pH effect of calcium dihydroxide does not give rise to a carcinogenic risk.

Human epidemiological data support lack of any carcinogenic potential of calcium dihydroxide.

Classification for carcinogenicity is not warranted.

g. Reproductive toxicity

Calcium (administered as Ca-carbonate) is not toxic to reproduction (experimental result, mouse).

The pH effect does not give rise to a reproductive risk.

Human epidemiological data support lack of any potential for reproductive toxicity of calcium dihydroxide.

Both in animal studies and human clinical studies on various calcium salts no reproductive or developmental effects were detected. Also see the Scientific Committee on Food (Section 16.6). Thus, calcium dihydroxide is not toxic for reproduction and/or development.

Classification for reproductive toxicity according to regulation (EC) 1272/2008 is not required.

h. STOT-single exposure

From human data it is concluded that Ca(OH)₂ is irritating to the respiratory tract.

As summarised and evaluated in the SCOEL recommendation (Anonymous, 2008), based on human data calcium dihydroxide is classified as irritating to the respiratory system [R37, Irritating to respiratory system; STOT SE 3 (H335 – May cause respiratory irritation)].

i. STOT-repeated exposure

Toxicity of calcium via the oral route is addressed by upper intake levels (UL) for adults determined by the Scientific Committee on Food (SCF), being

UL = 2500 mg/d, corresponding to 36 mg/kg bw/d (70 kg person) for calcium.

Toxicity of Ca(OH)₂ via the dermal route is not considered as relevant in view of the anticipated insignificant absorption through skin and due to local irritation as the primary health effect (pH shift).

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010

PrintingDate:June27,2012

Toxicity of Ca(OH)₂ via inhalation (local effect, irritation of mucous membranes) is addressed by an 8h TWA determined by the Scientific Committee on Occupational Exposure Limits (SCOEL) of 1 mg/m³ respirable dust (see Section 8.1).

Therefore, classification of Ca(OH)₂ for toxicity upon prolonged exposure is not required.

j. Aspiration hazard

Calcium hydroxide is not known to present an aspiration hazard.

12 **ECOLOGICAL INFORMATION**

12.1 Toxicity

12.1.1 Acute/Prolonged toxicity to fish

LC₅₀ (96h) for freshwater fish: 50.6 mg/l

LC₅₀ (96h) for marine water fish: 457 mg/l

12.1.2 Acute/Prolonged toxicity to aquatic invertebrates

EC₅₀ (48h) for freshwater invertebrates: 49.1 mg/l

LC₅₀ (96h) for marine water invertebrates: 158 mg/l

12.1.3 Acute/Prolonged toxicity to aquatic plants

EC₅₀ (72h) for freshwater algae: 184.57 mg/l

NOEC (72h) for freshwater algae: 48 mg/l

12.1.4 Toxicity to micro-organisms e.g. bacteria

At high concentration, through the rise of temperature and pH, calcium dihydroxide is used for disinfection of sewage sludges.

12.1.5 Chronic toxicity to aquatic organisms

NOEC (14d) for marine water invertebrates: 32 mg/l

12.1.6 Toxicity to soil dwelling organisms

EC₁₀/LC₁₀ or NOEC for soil macroorganisms: 2000 mg/kg soil dw

EC₁₀/LC₁₀ or NOEC for soil microorganisms: 12000 mg/kg soil dw

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010

PrintingDate:June27,2012

12.1.7 Toxicity to terrestrial plants

NOEC (21d) for terrestrial plants: 1080 mg/kg

12.1.8 General effect

Acute pH-effect. Although this product is useful to correct water acidity, an excess of more than 1 g/l may be harmful to aquatic life. pH-value of > 12 will rapidly decrease as result of dilution and carbonation.

12.2 Persistence and degradability

Not relevant for inorganic substances

12.3 Bioaccumulative potential

Not relevant for inorganic substances

12.4 Mobility in soil

Calcium dihydroxide, which is sparingly soluble, presents a low mobility in most soils

12.5 Results of PBT and vPvB assessment

Not relevant for inorganic substances

12.6 Other adverse effects

No other adverse effects are identified

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal of calcium dihydroxide should be in accordance with local and national legislation.

Processing, use or contamination of this product may change the waste management options.

Dispose of container and unused contents in accordance with applicable member state and local requirements.

The used packing is only meant for packing this product; it should not be reused for other purposes. After usage, empty the packing completely.

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

14 TRANSPORT INFORMATION

Calcium dihydroxide is not classified as hazardous for transport (ADR (Road), RID (Rail), IMDG / GGVSea (Sea).

14.1 UN-Number

Not regulated

14.2 UN proper shipping name

Not regulated

14.3 Transport hazard class(es)

Not regulated

14.4 Packing group

Not regulated

14.5 Environmental hazards

None

14.6 Special precautions for user

Avoid any release of dust during transportation, by using air-tight tanks

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not regulated

15 REGULATORY INFORMATION

 $15.1 \quad Safety, health and environmental \, regulations/legislation \, specific \, for \, the \, substance$

Authorisations: Not required

Restrictions on use: None

Other EU regulations: Calcium dihydroxide is not a SEVESO substance, not an ozone depleting

substance and not a persistent organic pollutant.

National regulations: Water endangering class 1 (Germany)

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this substance.

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010 PrintingDate:June27,2012

16 OTHERINFORMATION

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.

16.1 Hazard Statements

H315: Causes skin irritation

H318: Causes serious eye damage H335: May cause respiratory irritation

16.2 Precautionary Statements

P102: Keep out of reach of children

P280: Wear protective gloves/protective clothing/eye protection/face protection

P305+P351: IF IN EYES: Rinse cautiously with water for several minutes P310: Immediately call a POISON CENTRE or doctor/physician

P302+P352: IF ON SKIN: Wash with plenty of soap and water P261: Avoid breathing dust/fume/gas/mist/vapours/spray

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable

for breathing

P501: Dispose of contents/container to hazardous waste collection point

16.3 Risk Phrases

R37: Irritating to respiratory system

R38: Irritating to skin

R41: Risk of serious damage to eyes

16.4 Safety Phrases

S2: Keep out of the reach of children

S25: Avoid contact with eyes

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S37: Wear suitable glovesS39: Wear eye/face protection

16.5 Abbreviations

 EC_{50} : median effective concentration LC_{50} : median lethal concentration

LD₅₀: median lethal dose

NOEC: no observable effect concentration

OEL: occupational exposure limit

PBT: persistent, bioaccumulative, toxic chemical

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version:1.0

Revisiondate:December/2010

PrintingDate:June27,2012

PNEC: predicted no-effect concentration

STEL: short-term exposure limit TWA: time weighted average

vPvB: very persistent, very bioaccumulative chemical

16.6 Key literature references

Anonymous, 2006: Tolerable upper intake levels for vitamins and minerals Scientific Committee on Food, European Food Safety Authority, ISBN: 92-9199-014-0 [SCF document]

Anonymous, 2008: Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium dihydroxide (Ca(OH)₂), European Commission, DG Employment, Social Affairs and Equal Opportunities, SCOEL/SUM/137 February 2008

16.7 Revision

Revision 1.0

<u>Disclaimer</u>

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.

ANNEX

See annex provided – also available on www.irishlime.ie

End of the Safety Data Sheet

prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

APPENDIX: EXPOSURE SCENARIOS

The current document includes all relevant occupational and environmental exposure scenarios (ES) for the production and use of calcium dihydroxide as required under the REACH Regulation (Regulation (EC) No 1907/2006). For the development of the ES the Regulation and the relevant REACH Guidance have been considered. For the description of the covered uses and processes, the "R.12 – Use descriptor system" guidance (Version: 2, March 2010, ECHA-2010-G-05-EN), for the description and implementation of risk management measures (RMM) the "R.13 – Risk management measures" guidance (Version: 1.1, May 2008), for the occupational exposure estimation the "R.14 – Occupational exposure estimation" guidance (Version: 2, May 2010, ECHA-2010-G-09-EN) and for the actual environmental exposure assessment the "R.16 – Environmental Exposure Assessment" (Version: 2, May 2010, ECHA-10-G-06-EN) was used.

Methodology used for environmental exposure assessment

The environmental exposure scenarios only address the assessment at the local scale, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, for industrial and professional uses as any effects that might occur is expected to take place on a local scale.

1) Industrial uses (local scale)

The exposure and risk assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions in the industrial stages mainly apply to (waste) water. The aquatic effect and risk assessment only deal with the effect on organisms/ecosystems due to possible pH changes related to OH⁻ discharges. The exposure assessment for the aquatic environment only deals with the possible pH changes in STP effluent and surface water related to the OH⁻ discharges at the local scale and is performed by assessing the resulting pH impact: the surface water pH should not increase above 9 (In general, most aquatic organisms can tolerate pH values in the range of 6-9).

Risk management measures related to the environment aim to avoid discharging calcium dihydroxide solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. Discharges should be carried out such that pH changes in receiving surface waters are minimised. The effluent pH is normally measured and can be neutralised easily, as often required by national laws.

2) Professional uses (local scale)

The exposure and risk assessment is only relevant for the aquatic and terrestrial environment. The aquatic effect and risk assessment is determined by the pH effect. Nevertheless, the classical risk characterisation ratio (RCR), based on PEC (predicted environmental concentration) and PNEC (predicted no effect concentration) is calculated. The professional uses on a local scale refer to applications on agricultural or urban soil. The environmental exposure is assessed based on data and a modelling tool. The modelling FOCUS/ Exposit tool is used to assess terrestrial and aquatic exposure (typically conceived for biocidal applications).

Details and scaling approach indications are reported in the specific scenarios.

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Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

Methodology used for occupational exposure assessment

By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measure (RMMs) the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR). For workers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the scientific committee on occupational exposure limits (SCOEL) being 1 mg/m³ and 4 mg/m³, respectively. In cases where neither measured data nor analogous data are available, human exposure is assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool (http://www.ebrc.de/mease.html) is used to assess inhalation exposure according to the ECHA guidance (R.14).

Since the SCOEL recommendation refers to <u>respirabledust</u> while the exposure estimates in MEASE reflect the <u>inhalable</u> fraction, an additional safety margin is inherently included in the exposure scenarios below when MEASE has been used to derive exposure estimates.

Methodology used for consumer exposure assessment

By definition an ES has to describe under which conditions the substances, preparation or articles can be handled safely. In cases where neither measured data nor analogous data are available, exposure is assessed with the aid of a modelling tool.

For consumers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL), being 1 mg/m³ and 4 mg/m³, respectively.

For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85.), has been used to calculate the inhalation exposure. The inhalation exposure for consumers is estimated at 15 μ g/hr or 0.25 μ g/min. For larger tasks the inhalation exposure is expected to be higher. A factor of 10 is suggested when the product amount exceeds 2.5 kg, resulting in the inhalation exposure of 150 μ g/hr. To convert these values in mg/m³ a default value of 1.25 m³/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 μ g/m³ for small tasks and 120 μ g/m³ for larger tasks.

When the preparation or substance is applied in granular form or as tablets, reduced exposure to dust was assumed. To take this into account if data about particle size distribution and attrition of the granule are lacking, the model for powder formulations is used, assuming a reduction in dust formation by 10 % according to Becks and Falks (Manual for the authorisation of pesticides. Plant protection products. Chapter 4 Human toxicology; risk operator, worker and bystander, version 1.0., 2006).

For dermal exposure and exposure to the eye a qualitative approach has been followed, as no DNEL could be derived for this route due to the irritating properties of calcium oxide. Oral exposure was not assessed as this is not a foreseeable route of exposure regarding the uses addressed. Since the SCOEL recommendation refers to respirable dust while the exposure estimates by the model from van Hemmen reflect the inhalable fraction, an additional safety margin is inherently included in the exposure scenarios below, i.e. the exposure estimates are very conservative.

The exposure assessment of calcium dihydroxide professional and industrial and consumer use is performed and organized based on several scenarios. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.

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Version: 1.0

Table 1: Overview on exposure scenarios and coverage of substance life cycle

| | | | Ide | ntifie es | ed | Resultin g life cycle stage | Identified Use | | | Process | Article | Environmental |
|-----------|---|-------------|-------------|--------------|----------|--------------------------------------|-----------------|---|---|--|--|--|
| ES number | Exposure scenario title | Manufacture | Formulation | End use | Consumer | Service life (for articles) | Linked to Ident | Sector of use category (SU) | Chemical Product Category (PC) | category (PROC) | categor y (AC) | release category (ERC) |
| 9.1 | Manufacture and industrial uses of aqueous solutions of lime substances | х | x | х | | x | 1 | 3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b |
| 9.2 | Manufacture and industrial uses of low dusty solids/powders of lime substances | х | x | x | | х | 2 | 3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b |
| 9.3 | Manufacture and industrial uses of medium dusty solids/powders of lime substances | x | x | x | | Х | 3 | 3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b |

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Version: 1.0

| | | | | Identified uses | | Resultin g life cycle stage | ntified Use | | | Process | Article | Environmental |
|-----------|---|-------------|-------------|--------------------|----------|--------------------------------------|----------------|---|---|---|--|--|
| ES number | Exposure scenario title | Manufacture | Formulation | End use | Consumer | Service life (for articles) | Linked to Iden | Sector of use category (SU) | Chemical Product Category (PC) | category (PROC) | categor y (AC) | release category (ERC) |
| 9.4 | Manufacture and industrial uses of high dusty solids/powders of lime substances | X | х | x | | х | 4 | 3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 11a |
| 9.5 | Manufacture and industrial uses of massive objects containing lime substances | х | х | х | | × | 5 | 3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 6, 14, 21, 22, 23, 24, 25 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b |
| 9.6 | Professional uses of aqueous solutions of lime substances | | х | х | | Х | 6 | 22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 2, 3, 4, 5, 8a, 8b, 9, 10, 12, 13, 15, 16, 17, 18, 19 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 2, 8a, 8b, 8c, 8d, 8e, 8f |

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Version: 1.0

| | | | | Identified uses | | Resultin g life cycle stage | Identified Use | | | Process | Article | Environmental |
|-----------|--|-------------|-------------|--------------------|----------|--------------------------------------|-----------------|---|---|---|--|--------------------------------------|
| ES number | Exposure scenario title | Manufacture | Formulation | End use | Consumer | Service life (for articles) | Linked to Ident | Sector of use category (SU) | Chemical Product Category (PC) | category (PROC) | categor y (AC) | release category (ERC) |
| 9.7 | Professional uses of low dusty solids/powders of lime substances | | х | х | | х | 7 | 22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 21, 25, 26 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 2, 8a, 8b, 8c, 8d, 8e, 8f |
| 9.8 | Professional uses of medium dusty solids/powders of lime substances | | х | x | | х | 8 | 22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 2, 8a, 8b, 8c, 8d, 8e, 8f, 9a, 9b |
| 9.9 | Professional uses of high dusty solids/powders of lime substances | | х | х | | Х | 9 | 22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24 | 1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 | 2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 2, 8a, 8b, 8c, 8d, 8e, 8f |

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Version: 1.0

| | | | Identified | | Resultin g life cycle stage Identified Use | | | | Process | Article | Environmental | |
|-----------|--|-------------|-------------|---------|---|--------------------------------|-----------------|---|---------|---------------------------------|--|------------------------------|
| ES number | Exposure scenario title | Manufacture | Formulation | End use | Consumer | Service life (for articles) | Linked to Ident | ector of use Chemical Product Category (PC) | | category category (PROC) y (AC) | | release category (ERC) |
| 9.10 | Professional use of lime substances in soil treatment | | х | х | | | 10 | 22 | 9b | 5, 8b, 11, 26 | | 2, 8a, 8b, 8c, 8d, 8e, 8f |
| 9.11 | Professional uses of articles/container s containing lime substances | | | х | | x | 11 | 22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24 | | 0, 21, 24, 25 | 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13 | 10a, 11a, 11b, 12a, 12b |
| 9.12 | Consumer use of building and construction material (DIY) | | | | х | | 12 | 21 | 9b, 9a | | | 8 |
| 9.13 | Consumer use of CO ₂ absorbent in breathing apparatuses | | | | x | | 13 | 21 | 2 | | | 8 |

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Version: 1.0

| | | | Identified uses | | | Resultin g life cycle stage | | | | Process | Article | Environmental |
|-----------|---|-------------|--------------------|---------|----------|--------------------------------|-----------------|--------------------------------|--------------------------------|--------------------|-------------------|------------------------------|
| ES number | Exposure scenario title | Manufacture | Formulation | End use | Consumer | Service life (for articles) | Linked to Ideni | Sector of use category (SU) | Chemical Product Category (PC) | category (PROC) | categor y (AC) | release category (ERC) |
| 9.14 | Consumer use of garden lime/fertilizer | | | | x | | 14 | 21 | 20, 12 | | | 8e |
| 9.15 | Consumer use of lime substances as water treatment chemicals in aquaria | | | | x | | 15 | 21 | 20, 37 | | | 8 |
| 9.16 | Consumer use of cosmetics containing lime substances | | | | х | | 16 | 21 | 39 | | | 8 |

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Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

ES number 9.8: Professional uses of medium dusty solids/powders of lime substances

| Exposure Scenario | Exposure Scenario Format (1) addressing uses carried out by workers | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|
| 1. Title | | | | | | | | | | |
| Free short title | Professional uses of medium dusty solids/powders of lime substances | | | | | | | | | |
| Systematic title based on use descriptor | SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below) | | | | | | | | | |
| Processes, tasks and/or activities covered | Processes, tasks and/or activities covered are described in Section 2 below. | | | | | | | | | |
| Assessment Method | The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit. | | | | | | | | | |

2. Operational conditions and risk management measures

| PROC/ERC | REACH definition | Involved tasks |
|---|--|--|
| PROC 2 | Use in closed, continuous process with occasional controlled exposure | |
| PROC 3 | Use in closed batch process (synthesis or formulation) | |
| PROC 4 | Use in batch and other process (synthesis) where opportunity for exposure arises | |
| PROC 5 | Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) | |
| PROC 8a | Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities | |
| PROC 8b | Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities | |
| PROC 9 | Transfer of substance or preparation into small containers (dedicated filling line, including weighing) | |
| PROC 10 | Roller application or brushing | Further information is provided in the ECHA |
| PROC 11 | Non industrial spraying | Guidance on information requirements and chemical safety assessment, Chapter R.12: |
| PROC 13 | Treatment of articles by dipping and pouring | Use descriptor system (ECHA-2010-G-05-EN). |
| PROC 15 | Use as laboratory reagent | |
| PROC 16 | Using material as fuel sources, limited exposure to unburned product to be expected | |
| PROC 17 | Lubrication at high energy conditions and in partly open process | |
| PROC 18 | Greasing at high energy conditions | |
| PROC 19 | Hand-mixing with intimate contact and only PPE available | |
| PROC 25 | Other hot work operations with metals | |
| PROC 26 | Handling of solid inorganic substances at ambient temperature | |
| ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f | Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems | |

prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

| PROC | Use in preparation | Content in preparation | Physical form | Emission potential |
|----------------------------|--------------------|---------------------------|-------------------------|--------------------|
| PROC 25 | not restricted | | solid/powder, molten | high |
| All other applicable PROCs | not restricted | | solid/powder | medium |

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

| PROC | Duration of exposure |
|----------------------------|------------------------------|
| PROC 11, 16, 17, 18, 19 | ≤ 240 minutes |
| All other applicable PROCs | 480 minutes (not restricted) |

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m³/shift (8 hours).

Other given operational conditions affecting workers exposure

Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.

Technical conditions and measures at process level (source) to prevent release

Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.

Technical conditions and measures to control dispersion from source towards the worker

| PROC | Level of separation | Localised controls (LC) | Efficiency of LC (according to MEASE) | Further information |
|----------------------------|--|--|---|---------------------|
| PROC 11, 16 | Any potentially required separation of workers from the emission source is indicated | generic local exhaust ventilation | 72 % | - |
| PROC 17, 18 | above under "Frequency and duration of exposure". A reduction | integrated local exhaust ventilation | 87 % | • |
| PROC 19 | of exposure duration can be achieved, for example, by the installation of ventilated (positive | not applicable | na | - |
| All other applicable PROCs | pressure) control rooms or by removing the worker from workplaces involved with relevant exposure. | not required | na | - |

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

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Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

Conditions and measures related to personal protection, hygiene and health evaluation

| PROC | Specification of respiratory protective equipment (RPE) | RPE efficiency (assigned protection factor, APF) | Specification of gloves | Further personal protective equipment (PPE) |
|--|---|---|---|--|
| PROC 2, 3, 16, 19 | FFP1 mask | APF=4 | Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps. | Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate. |
| PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26 | FFP2 mask | APF=10 | | |
| PROC 11 | FFP1 mask | APF=10 | | |
| PROC 15 | not required | na | | |

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

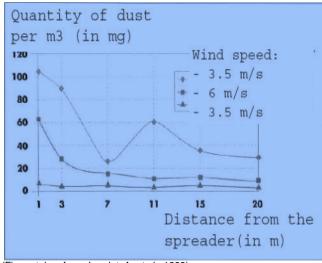
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure – only relevant for agricultural soil protection

Product characteristics

Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)



(Figure taken from: Laudet, A. et al., 1999)

Amounts used

| Ca(OH)2 | 2.244 kg/ha |
|---------|--------------|
| Ca(On)Z | 2,244 KU/IId |

Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2)

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Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

Technical conditions and measures at process level (source) to prevent release

There are no direct releases to adjacent surface waters.

Technical conditions and measures to reduce or limit discharges, air emissions and releases to soil

Drift should be minimised.

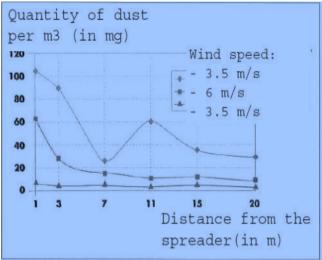
Organizational measures to prevent/limit release from site

In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

2.2 Control of environmental exposure – only relevant for soil treatment in civil engineering

Product characteristics

Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)



(Figure taken from: Laudet, A. et al., 1999)

Amounts used

Ca(OH)2 238,208 kg/ha

Frequency and duration of use

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 238,208 kg/ha is not exceeded (CaOH2)

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

Technical conditions and measures at process level (source) to prevent release

Lime is only applied onto the soil in the technosphere zone before road construction. There are no direct releases to adjacent surface waters.

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Version: 1.0

Revision date: December / 2010 Printing Date: 22/12/2010

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481

| PROC | Method used for inhalation exposure assessment | Inhalation exposure estimate (RCR) | Method used for dermal exposure assessment | Dermal exposure estimate (RCR) |
|--|--|--|---|--------------------------------|
| PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26 | MEASE | < 1 mg/m³ (0.25 - 0.825) | Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario. | |

Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once applied on the soil, calcium dihydroxide can indeed migrate then towards surface waters, via drift.

| Environmental emissions | See amounts used | | | |
|--|---|------------|-------------|-------|
| Exposure concentration in waste water treatment plant (WWTP) | Not relevant for agricultural soil protection | | | |
| Exposure | Substance | PEC (ug/L) | PNEC (ug/L) | RCR |
| concentration in aquatic pelagic compartment | Ca(OH)2 | 7.48 | 490 | 0.015 |
| Exposure concentration in sediments | As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils. | | | |
| Exposure | Substance | PEC (mg/L) | PNEC (mg/L) | RCR |
| concentrations in soil and groundwater | Ca(OH)2 | 660 | 1080 | 0.61 |
| Exposure concentration in atmospheric compartment | This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa. | | | |
| Exposure concentration relevant for the food chain (secondary poisoning) | This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca2+ and OH-) in the environment. | | | |

prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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Environmental exposure for soil treatment in civil engineering

The soil treatment in civil engineering scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

| Environmental emissions | See amounts used | | | |
|--|--|------------|-------------|------|
| Exposure concentration in waste water treatment plant (WWTP) | Not relevant for road border scenario | | | |
| Exposure concentration in aquatic pelagic compartment | Not relevant for road border scenario | | | |
| Exposure concentration in sediments | Not relevant for road border scenario | | | |
| Exposure concentrations in | Substance | PEC (mg/L) | PNEC (mg/L) | RCR |
| soil and groundwater | Ca(OH)2 | 701 | 1080 | 0.65 |
| Exposure concentration in atmospheric compartment | This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa. | | | |
| Exposure concentration relevant for the food chain (secondary poisoning) | This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca2+ and OH-) in the environment. | | | |

Environmental exposure for other uses

For all other uses, no quantitative environmental exposure assessment is carried because

- The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or soil treatment in civil engineering
- Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water
- Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited
- Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.

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4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".

DNEL_{inhalation}: 1 mg/m³ (as respirable dust)

Importantnote: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m³. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).