

PUTTY prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) 2020/878

Version: 5.0/EN

Revision date: December / 2021 Printing Date: December / 2021

1 IDENTIFICATION OF THE SUBSTANCE/mixture AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Substance name: Lime putty, Calcium dihydroxide

Synonyms: Lime putty, Slaked lime, Building lime, Fat lime, Chemical lime,

Finishing lime, Calcium dihydroxide, Calcium hydroxide, Calcium

hydrate, Lime, Lime water.

Chemical name and formula: Calcium dihydroxide - Ca(OH)₂

Trade name: Lime putty
CAS: 1305-62-0
EINECS: 215-137-3
Molecular Weight: 74.09 g/mol

REACH Registration number: 01-2119475151-45-0126

1.2 Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against:

There are no uses advised against.

1.3 Details of the supplier of the safety data sheet

Name: InterCal Slovenija, proizvodnja apna in apnenca d.o.o.

Address: Savska cesta 1, 1410 Zagorie ob Savi, Slovenia

Phone N°: +386 (0)3 56 55 560

Sales department: +386 (0)3 56 55 583

Fax N°: +386 (0)3 56 55 596

E-mail of competent person responsible info.reach@intercal.si

for SDS in the MS or in the EU:

1.4 Emergency telephone number

European Emergency N°: 112

Emergency telephone at the company +386 (0)3 56 55 583

Available outside office hours: NO

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance

Classification according to Regulation (EC) 1272/2008

STOT Single Exp. 3, Route of exposure: Inhalation - H335

Skin Irritation 2 - H315



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Eye Damage 1 - H318

2.2 Label elements

2.2.1 Labelling according to Regulation (EC) 1272/2008

Signal word: 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+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing. 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 in accordance with

local/regional/national/international regulation.

2.3 Other hazards

The substance does not meet the criteria for PBT or vPvB substance and does not have endocrine disrupting properties.

No other hazards identified.

COMPOSITION/INFORMATION ON INGREDIENTS 3

3.1 Substances

Main constituent

Name: Calcium dihydroxide (35-40% of dry matter)

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



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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.

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 CO₂ 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.



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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.

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/mist 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/mist – 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/mist 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/mist – 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 pasty 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 or formation of mist.

Keep the material pasty 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.



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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/mist levels to a minimum. Minimize dust generation or formation of mist. Enclose dust sources, use exhaust ventilation (dust collector at handling points). Handling systems should preferably be enclosed.

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 in original sealed packaging. Any contact with air and moisture should be avoided. Keep away from acids. Keep out of reach of children. Do not use aluminium for transport or storage.

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 or mist 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.



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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/mist levels below recommended exposure limits.

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 – EN 166. 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 – EN 20345.

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 (EN 149, EN140, EN 14683, EN 14387).

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

Physical state: paste

Color: White or off white (beige)

Odour: odourless

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



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Boiling point: not applicable (solid with a melting point > 450 °C) Flammability: non flammable (study result, EU A.10 method)

Lower and upper explosion limit: non explosive (void of any chemical structures commonly

associated with explosive properties)

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

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)

pH: 12.4 (saturated solution at 20 °C)

Kinematic viscosity: not applicable (solid with a melting point > 450 °C) Solubility in water: 1844.9 mg/L (study results, EU A.6 method)

Partition coefficient n-octanol/water: not applicable (inorganic substance)

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

Density and/or relative density: not applicable
Relative vapour density: not applicable
Particle characteristics: not applicable

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 \rightarrow 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.

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



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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 hazard classes as defined in Regulation (EC) No 1272/2008

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)].

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

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.



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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).

Toxicity of Ca(OH)₂ via inhalation (local effect, irritation of mucous membranes) is addressed by an 8-h 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.



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j. Aspiration hazard

Calcium hydroxide is not known to present an aspiration hazard.

11.2 Information on other hazards

Not relevant.

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

12.1.7 Toxicity to terrestrial plants

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



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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 Endocrine disrupting properties

Not relevant.

12.7 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.

EWC codes for waste:

10 13 04 wastes from calcination and hydration of lime

10 13 06 particulates and dust (except 10 13 12 and 10 13 13)

The used packing is only meant for packing this product; it should not be reused for other purposes.

After usage, empty the packing completely.

EWC codes for waste packaging:



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15 01 01 paper and cardboard packaging 15 01 02 plastic packaging

14 TRANSPORT INFORMATION

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

14.1 UN-Number or ID 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 Maritime transport in bulk according to IMO instruments

Not regulated

15 REGULATORY INFORMATION

15.1 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.



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16 OTHER INFORMATION

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 in accordance with local/regional/national/international

regulation

16.3 Abbreviations

EC₅₀: median effective concentration IMO: International Maritime Organization

LC₅₀: median lethal concentration

LD₅₀: median lethal dose

NOEC: no observable effect concentration

OEL: occupational exposure limit

PBT: persistent, bioaccumulative, toxic chemical

PNEC: predicted no-effect concentration

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

vPvB: very persistent, very bioaccumulative chemical

16.4 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]



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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

16.5 Revision

This Safety Data Sheet is in accordance with Regulation (EU) 2020/878 and is changed in points 2.3, 9.1, 11.1, 11.2, 12.6, 12.7, 13.1, 14.1, 14.7 and 16.3.

<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

Includes exposure scenarios for identified uses.



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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



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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.

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>respirable dust</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.



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

		Identified g life uses cycle stage	g life cycle stage			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)
9.1	Manufacture and industrial uses of aqueous solutions of lime substances	X	x	x		Х	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
9.6	Professional uses of aqueous solutions of lime substances		Х	Х		X	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
9.12	Consumer use of building and construction material (DIY)				Х		12	21	9b, 9a			8



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ES number 9.1: Manufacture and industrial uses of aqueous solutions of lime substances

Exposure Scenario	Format (1) addressing uses carried out	by workers				
1. Title						
Free short title	Manufacture and industrial uses of aque	eous solutions of lime substances				
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, 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, PC38, 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	d are described in Section 2 below.				
Assessment Method	The assessment of inhalation exposure is based	on the exposure estimation tool MEASE.				
2. Operational con	ditions and risk management measures					
PROC/ERC	REACH definition	Involved tasks				
PROC 1	Use in closed process, no likelihood of exposure					
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 7	Industrial spraying					
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12 Use descriptor system (ECHA-2010-G-05-				
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	EN).				
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	1				
PROC 10	Roller application or brushing					
PROC 12	Use of blowing agents in manufacture of foam					
PROC 13	Treatment of articles by dipping and pouring					
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation					
PROC 15	Use as laboratory reagent					



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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				
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses				
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials				

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. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 7	not restricted		aqueous solution	medium
All other applicable PROCs	not restricted		aqueous solution	very low

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	OC Duration of exposure				
PROC 7	≤ 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

Since aqueous solutions are not used in hot-metallurgical processes, operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes.

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.



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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 7	Any potentially required separation of workers from the emission source is indicated above under "Frequency and	local exhaust ventilation	78 %	-		
PROC 19	duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated	not applicable	na	-		
All other applicable PROCs	(positive 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.

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 7	FFP1 mask	APF=4	Since calcium dihydroxide is	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be
All other applicable PROCs	not required	na	classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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.



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2.2 Control of environmental exposure

Amounts used

The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.

Frequency and duration of use

Intermittent (< 12 time per year) or continuous use/release

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime 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. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.

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 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (0.001 – 0.66)	irritating to skin, derr minimised as far as DNEL for dermal derived. Thus, der	roxide are classified as mal exposure has to be technically feasible. A effects has not been rmal exposure is not exposure scenario.

Environmental exposure

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of lime substance in the different life-cycle stages (production and use) 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, being the toxicity of Ca2+ is expected to be negligible compared to the (potential) pH effect. Only the local scale is being addressed, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, both for production and industrial use as any effects that might occur would be expected to take place on a local scale. The high water solubility and very low vapour pressure indicate that lime substance will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of lime substance. Significant emissions or exposure to the terrestrial environment are not expected either for this exposure scenario. The exposure assessment for the aquatic environment will therefore only deal with the possible pH changes in STP effluent and surface water related to the OH- discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.



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Environmental emissions The production of lime substance can potentially result in an aquatic emission and locate the lime substance concentration and affect the pH in the aquatic environment. When neutralised, the discharge of effluent from lime substance production sites may impact receiving water. The pH of effluents is normally measured very frequently and can be easily as often required by national laws.		
Exposure concentration in waste water treatment plant (WWTP) Waste water from lime substance production is an inorganic wastewater stream and is no biological treatment. Therefore, wastewater streams from lime substance production is an inorganic wastewater stream and is no biological treatment. Therefore, wastewater streams from lime substance production is an inorganic wastewater stream and is no biological treatment plants (WWTPs), but can control of acid wastewater streams that are treated in biological WWTPs.		
Exposure concentration in aquatic pelagic compartment	When lime substance is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).	
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when lime substance is emitted to the aquatic compartment, sorption of to sediment particles is negligible.	
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.	
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for lime substance: when emitted to air as an aerosol in water, lime substance is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised lime substance largely end up in soil and water.	
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.	

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

Occupational exposure

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)

Important note: 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 %).

Environmental exposure

If a site does not comply with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to perform a more site-specific assessment. For that assessment, the following stepwise approach is recommended.

Tier 1: retrieve information on effluent pH and the contribution of the lime substance on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.



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Tier 2a: retrieve information on receiving water pH after the discharge point. The pH of the receiving water shall not exceed the value of 9. If the measures are not available, the pH in the river can be calculated as follows:

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$
(Eq. 1)

Where:

Q effluent refers to the effluent flow (in m³/day)

Q river upstream refers to the upstream river flow (in m³/day)

pH effluent refers to the pH of the effluent

pH upstream river refers to the pH of the river upstream of the discharge point

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

Such equation has to be seen as a worst case scenario, where water conditions are standard and not case specific.

Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences lime solubility, pH effluent might require to be adjusted on a case-by-case basis. Once the maximum admissible pH value in the effluent is established, it is assumed that the OH- concentrations are all dependent on lime discharge and that there is no buffer capacity conditions to consider (this is a unrealistic worst case scenario, which can be modified where information is available). Maximum load of lime that can be annually rejected without negatively affecting the pH of the receiving water is calculated assuming chemical equilibrium. OH- expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the lime substance.

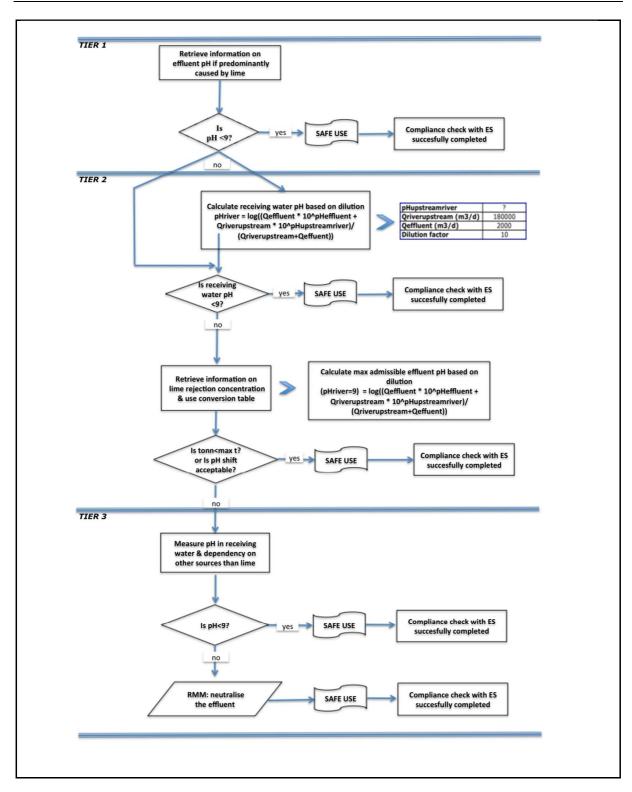
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime during production or use phase.



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ES number 9.6: Professional uses of aqueous solutions of lime substances

Exposure Scenario	Format (1) addressing uses carri	ed out by workers			
1. Title					
Free short title	Professional uses of aq	ueous solutions 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 activitie	s covered are described in Section 2 below.			
Assessment Method		based on the exposure estimation tool MEASE. The ment is based on FOCUS-Exposit.			
2. Operational cond	ditions and risk management mea	sures			
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	Further information is provided in the ECHA Guidance			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)				
PROC 10	Roller application or brushing				
PROC 11	Non industrial spraying				
PROC 12	Use of blowing agents in manufacture of foam				
PROC 13	Treatment of articles by dipping and pouring				
PROC 15	Use as laboratory reagent				



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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	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Calcium dihydroxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.

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. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restricted		aqueous solution	very low

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	≤ 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

Since aqueous solutions are not used in hot-metallurgical processes, operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes.

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.



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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 19	Separation of workers from the emission	not applicable	na	-	
All other applicable PROCs	source is generally not required in the conducted processes.	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.

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 11	FFP3 mask	APF=20	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential	
PROC 17	FFP1 mask	APF=4	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	classified as irritating excluded by to skin, the use of type of app	contact with the eye can be excluded by the nature and type of application (i.e. closed process).
All other applicable PROCs	not required	na		Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.	

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.



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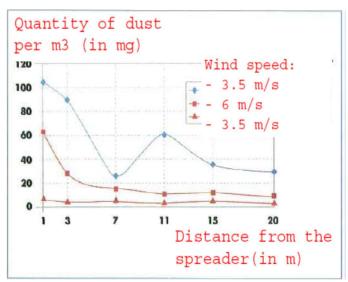
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2.2 Control of environmental exposure - only relevant for agricultural soil protection

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

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)

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.



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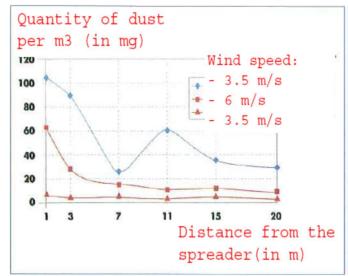
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2.2 Control of environmental exposure - only relevant for soil treatment in civil engineering

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.

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

Drift should be minimised.



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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, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (<0.001 – 0.6)	skin, dermal exposure technically feasible. A not been derived. Th	ide is classified as irritating to has to be minimised as far as DNEL for dermal effects has us, dermal exposure is not is 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	natural waters the hydro CaCO3 by reacting with	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)		nent. The uses cove	red do not significantly inf	dered to be omnipresent and fluence the distribution of the	



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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	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 bor	Not relevant for road border scenario			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
concentrations in 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)		ses covered do not si		nnipresent and essential in distribution of the constituents	

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)

Important note: 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 %).



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ES number 9.12: Consumer use of building and construction material (DIY – do it yourself)

Exposure Scenario	Form	at (2) addressin	g uses carried out b	y consumers	
1. Title					
Free short title			Consumer use of building and construction material		
Systematic title based	on us	e descriptor	SU21, PC9a, PC9b, E	RC8c, ERC8d, ERC8e, ER	C8f
Processes, tasks act	ivities	covered	= : =	filling) of powder formulation asty lime preparations.	ns
Assessment Method*		Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.			
2. Operational co	nditio	ns and risk ma	anagement measu	ires	
RMM		No product integr	ated risk management r	neasures are in place.	
PC/ERC		Description of accategories (ERC		cle categories (AC) and er	vironmental release
PC 9a, 9b	=		ng of powder containing lime substances. e plaster, putty or slurry to the walls or ceiling. exposure.		
ERC 8c, 8d, 8e, 8f	C 8c, 8d, 8e, 8f Wide dispersive of Wide dispersiv		indoor use resulting in inclusion into or onto a matrix outdoor use of processing aids in open systems outdoor use of reactive substances in open systems outdoor use resulting in inclusion into or onto a matrix		
2.1 Control of cor	sume	ers exposure			
Product characteristic	0				
Description of the preparation	subs	centration of the stance in the aration	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 9	%	Solid, powder	High, medium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%		Solid, powder	depending on the kind of lime substance (indicative value from DIY¹ fact sheet see section 9.0.3)	35 kg.
Plaster, Mortar	20-40	0%	Pasty	-	-
Putty, filler	30-55%		Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint	~30%		Solid, powder	High - low (indicative value from DIY¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~ 30	%	Milk of lime preparation	-	-
Amounts used					



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Description of the preparation	Amount used per event
Filler, putty	250 g – 1 kg powder (2:1 powder water) Difficult to determine, because the amount is heavily dependent on the depth and size of the holes to be filled.
Plaster/lime wash paint	~ 25 kg depending on the size of the room, wall to be treated.
Floor/wall equalizer	~ 25 kg depending on the size of the room, wall to be equalized.

Frequency and duration of use/exposure

Description of task	Duration of exposure per event	frequency of events	
Mixing and loading of lime containing powder.	1.33 min (DIY¹-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY ¹ fact sheet)	
Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours	2/year (DIY ¹ fact sheet)	

Human factors not influenced by risk management

Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Handling of powder	Adult	1.25 m³/hr	Half of both hands	430 (DIY1 fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY ¹ fact sheet)

Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Handling of powder	indoor	1 m³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room)
Application of liquid, pasty lime preparations.	indoor	NR	NR

Conditions and measures related to information and behavioural advice to consumers

In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:

- Change wet clothing, shoes and gloves immediately.
- Protect uncovered areas of skin (arms, legs, face): there are various effective skin protection products which should be used in accordance with a skin protection plan (skin protection, cleansing and care). Cleanse the skin thoroughly after the work and apply a care product.

Conditions and measures related to personal protection and hygiene

In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:

- When preparing or mixing building materials, during demolition or caulking and, above all, during overhead work, wear protective goggles as well as face masks during dusty work.
- Choose work gloves carefully. Leather gloves become wet and can facilitate burns. When working in a wet
 environment, cotton gloves with plastic covering (nitrile) are better. Wear gauntlet gloves during overhead work
 because they can considerably reduce the amount of humidity which permeates the working clothes.

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment



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Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Direct discharge to the wastewater is avoided.

Conditions and measures related to municipal sewage treatment plant

Default size of municipal sewage system/treatment plant and sludge treatment technique

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.

Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

exposure

Handling of powder

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment
		Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 μg/cm² (-)	Qualitative assessment
	large task: 1 μg/cm² (-)	If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.
		Quantitative assessment
		The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY¹-fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 μg/m³ (0.003)	Quantitative assessment
	Large task: 120 μg/m³ (0.03)	Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Application of	liquid, pasty lime preparations.	
Route of	Exposure estimate	Method used, comments



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Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.
Eye	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.

Post-application exposure

No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.

Environmental exposure

Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.

End of the safety data sheet