

Version: 8.0/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: Hydrated lime, Calcium dihydroxide

Synonyms: Slaked lime, Air slaked lime, Building lime, Fat lime, Chemical lime,

Finishing lime, Mason's lime, Calcium dihydroxide, Calcium hydroxide,

Calcium hydrate, Lime, Lime water.

Chemical name and formula: Calcium dihydroxide - Ca(OH)<sub>2</sub>

Trade name: Hydrated lime 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 Zagorje 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



Version: 8.0/EN

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

### 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 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 person to fresh air and keep 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.



Version: 8.0/EN

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

### 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.

### 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



Version: 8.0/EN

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

### 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<sub>2</sub> 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.

### 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).



Version: 8.0/EN

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

### 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 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.

The storage class is indicated in section 15.1.

### 7.3 Specific end use(s)

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



Version: 8.0/EN

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

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 16.4), COMMISSION DIRECTIVE (EU) 2017/164 of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU and Rules on the protection of workers from the risks related to exposure to chemical substances at work (Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu) - Official Journal of the Republic of Slovenia, No. 100/2001, 39/2005, 53/2007, 102/2010, 38/2015, 78/2018:

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

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

PNEC agua =  $490 \mu g/I$ 

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.

### 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



Version: 8.0/EN

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

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, SIST 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, SIST EN 149, SIST EN140, SIST EN 14683, SIST 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: solid

Colour: White or off white (beige) fine powder

Odour: odourless

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

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 (H<sub>2</sub>O)

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)



Version: 8.0/EN

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

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

Density and/or relative density: 2.24 (study result, EU A.3 method)

Relative vapour density: not applicable Particle characteristics: to 300 µm

### 9.2 Other information

Not available.

### 10 STABILITY AND REACTIVITY

### 10.1 Reactivity

In aqueous media Ca(OH)<sub>2</sub> 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)<sub>2</sub>  $\rightarrow$  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.

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

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



Version: 8.0/EN

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

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

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.



Version: 8.0/EN

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

### 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)<sub>2</sub> 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)<sub>2</sub> 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)<sub>2</sub> 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/m<sup>3</sup> respirable dust (see Section 8.1).

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

### Aspiration hazard

Calcium hydroxide is not known to present an aspiration hazard.

### 11.2 Information on other hazards

Not relevant.



Version: 8.0/EN

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

### 12 ECOLOGICAL INFORMATION

### 12.1 Toxicity

## 12.1.1 Acute/Prolonged toxicity to fish

 $LC_{50}$  (96h) for freshwater fish: 50.6 mg/l  $LC_{50}$  (96h) for marine water fish: 457 mg/l

## 12.1.2 Acute/Prolonged toxicity to aquatic invertebrates

EC<sub>50</sub> (48h) for freshwater invertebrates: 49.1 mg/l  $LC_{50}$  (96h) for marine water invertebrates: 158 mg/l

### 12.1.3 Acute/Prolonged toxicity to aquatic plants

EC<sub>50</sub> (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

 $EC_{10}/LC_{10}$  or NOEC for soil macroorganisms: 2000 mg/kg soil dw  $EC_{10}/LC_{10}$  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

### 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.



Version: 8.0/EN

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

### 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:

15 01 01 paper and cardboard packaging

15 01 02 plastic packaging



Version: 8.0/EN

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

### 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: Rules on Personal Protective Equipment (Pravilnik o osebni varovalni opremi)

- Official Journal of the Republic of Slovenia, No. 29/05, 23/06, 17/11 - ZTZPUS-

1 and 76/11

List of harmonized standards for Personal Protective Equipment (C 412 /

11.12.2015, with all amendments and supplements)

Storage class: 10 - 13



Version: 8.0/EN

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

### 15.2 Chemical safety assessment

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

### 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 person to fresh air and keep comfortable for breathing.

P501: Dispose of contents/container in accordance with local/regional/national/international

regulation

### 16.3 Abbreviations

EC<sub>50</sub>: median effective concentration IMO: International Maritime Organization

LC<sub>50</sub>: median lethal concentration

LD<sub>50</sub>: 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



Version: 8.0/EN

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

### 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]

Anonymous, 2008: Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium dihydroxide (Ca(OH)<sub>2</sub>), 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.

### Disclaimer

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.



Version: 8.0/EN

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

### 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<sup>-</sup> 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<sup>-</sup> 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



Version: 8.0/EN

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

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 (<a href="http://www.ebrc.de/mease.html">http://www.ebrc.de/mease.html</a>) 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.



Version: 8.0/EN

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

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  $\mu$ g/hr or 0.25  $\mu$ 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  $\mu$ 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  $\mu$ g/m³ for small tasks and 120  $\mu$ 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.



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

Version: 8.0/EN

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

			Identified uses		ed	Resultin g life cycle stage				Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Identified		Chemical Product Category (PC)	category	categor y (AC)	release category (ERC)
9.1	Manufacture and industrial uses of aqueous solutions of lime substances	Х	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
9.2	Manufacture and industrial uses of low dusty solids/powders of lime substances	X	Х	X		X	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	5, 6, 7, 8,	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b



prepared in accordance with Annex II of the

**REACH Regulation EC 1907/2006, Regulation (EC)** 

1272/2008 and Regulation (EU) 2020/878

Version: 8.0/EN

			Identified uses		ed	Resultin g life cycle stage		tified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life	(tor articles)	Linked to Ident	Sector of use category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.3	Manufacture and industrial uses of medium dusty solids/powders of lime substances	х	х	×		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
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



prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC)

1272/2008 and Regulation (EU) 2020/878

Version: 8.0/EN

			lde use	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 Iden		Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.5	Manufacture and industrial uses of massive objects containing lime substances	Х	x	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
9.7	Professional uses of low dusty solids/powders of lime substances		x	x		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



prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC)

1272/2008 and Regulation (EU) 2020/878

Version: 8.0/EN

			lde use	ntifie es		Resultin g life cycle stage	ilife S cycle po ctage iji			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.8	Professional uses of medium dusty solids/powders of lime substances		x	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		x	X		X	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
9.10	Professional use of lime substances in soil treatment		х	X			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f



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

Version: 8.0/EN

			lde use		ed	Resultin g life cycle stage	entified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.11	Professional uses of articles/containe rs containing lime substances			X		х	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 <sub>2</sub> absorbent in breathing apparatuses				x		13	21	2			8



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

Version: 8.0/EN

			lde use	ntifie es	ed	cycle stage iji			Process	Article	Environmental	
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden		Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.14	Consumer use of garden lime/fertilizer				Х		14	21	20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				Х		15	21	20, 37			8
9.16	Consumer use of cosmetics containing lime substances				Х		16	21	39			8



Version: 8.0/EN

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

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

1. Title								
Free short title	Manufacture and industrial uses of aque	eous solutions of lime substances						
Systematic title based on use descriptor	\$U14, \$U15, \$U16, \$U17, \$U16, PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC PC34, PC35, PC36, PC37, AC1, AC2, AC3, AC4, AC5, AC6, A	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	Further information is provided in the ECHA						
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Guidance on information requirements and chemical safety assessment, Chapter R.12 Use descriptor system (ECHA-2010-G-05-EN).						
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							
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							



Version: 8.0/EN

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

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
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	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.



Version: 8.0/EN

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

Technical conditions a	Fechnical 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.



Version: 8.0/EN

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

### 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 m<sup>3</sup>/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.



Version: 8.0/EN

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

### 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, de	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.

Environmental emissions	The production of lime substance can potentially result in an aquatic emission and locally increase the lime substance concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from lime substance production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised 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 therefore there is no biological treatment. Therefore, wastewater streams from lime substance production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH 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.



Version: 8.0/EN

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

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 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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.

**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 m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/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 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m³/day



Version: 8.0/EN

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

• The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

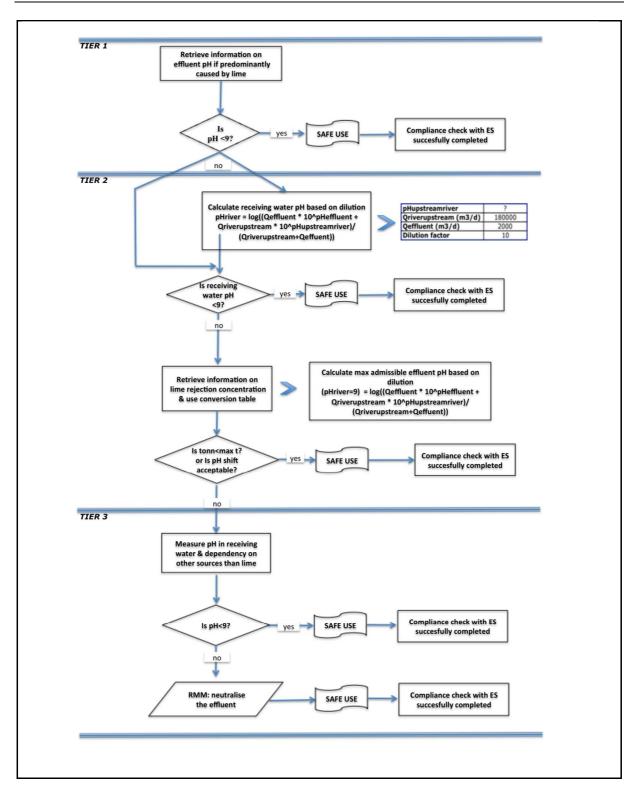
Such equation has to be seen as a worst case scenario, where water conditions are standard and not case specific.

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.



Version: 8.0/EN





Version: 8.0/EN

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

# ES number 9.2: Manufacture and industrial uses of low dusty solids/powders of lime substances

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Manufacture and industrial uses of low dusty solids/powders 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 are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based	d on the exposure estimation tool MEASE.		
2. Operational cond	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 6	Calendering operations	Further information is provided in the ECHA		
PROC 7	Industrial spraying	Guidance on information requirements and		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
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			
PROC 13	Treatment of articles by dipping and pouring			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			



Version: 8.0/EN

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

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 21	Low energy manipulation of substances bound in materials and/or articles		
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting		
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles		
PROC 25	Other hot work operations with metals		
PROC 26	Handling of solid inorganic substances at ambient temperature		
PROC 27a	Production of metal powders (hot processes)		
PROC 27b	Production of metal powders (wet processes)		
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.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
PROC 24	not restricted		solid/powder	high
All other applicable PROCs	not restricted		solid/powder	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.



Version: 8.0/EN

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

Frequency and duration of use/exposure			
PROC	Duration of exposure		
PROC 22	≤ 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 7, 17, 18	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	general ventilation	17 %	-
PROC 19		not applicable	na	-
PROC 22, 23, 24, 25, 26, 27a		local exhaust ventilation	78 %	-
All other applicable PROCs		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.



Version: 8.0/EN

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

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 22, 24, 27a	FFP1 mask	APF=4	Since calcium	Eye protection equipment (e.g. goggles or visors)
All other applicable PROCs	not required	na	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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

### **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 m<sup>3</sup>/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.



Version: 8.0/EN

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

### 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, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 - 0.83)	Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to b 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 emissions**

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium dihydroxide 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 calcium dihydroxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium dihydroxide. 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.

Environmental emissions	The production of calcium dihydroxide can potentially result in an aquatic emission and locally increase the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide 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 calcium dihydroxide: when calcium dihydroxide 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.



Version: 8.0/EN

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

Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide 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 calcium dihydroxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 calcium dihydroxide 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.

**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 m<sup>3</sup>/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.



Version: 8.0/EN

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

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

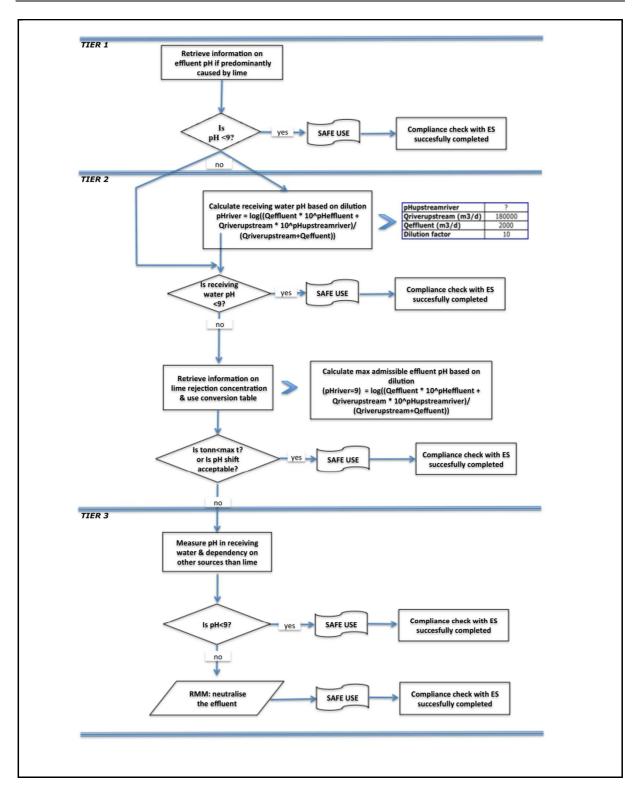
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences 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 calcium dihydroxide.

**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.



Version: 8.0/EN

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





Version: 8.0/EN

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

# ES number 9.3: Manufacture and industrial uses of medium dusty solids/powders of lime substances

<b>Exposure Scenario</b>	Format (1) addressing uses carried out	by workers	
1. Title			
Free short title	Manufacture and industrial uses of medium dusty solids/powders 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 are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based	d 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:	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	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 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		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		



Version: 8.0/EN

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

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 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles
PROC 25	Other hot work operations with metals
PROC 26	Handling of solid inorganic substances at ambient temperature
PROC 27a	Production of metal powders (hot processes)
PROC 27b	Production of metal powders (wet processes)
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.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
PROC 24	not restricted		solid/powder	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 7, 17, 18, 19, 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)



Version: 8.0/EN

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

### 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 1, 2, 15, 27b	Any potentially required	not required	na	-
PROC 3, 13, 14	separation of workers from the emission source is indicated above under "Frequency and	general ventilation	17 %	-
PROC 19	duration of exposure". A reduction of exposure duration	not applicable	na	-
All other applicable PROCs	can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-

## 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.



Version: 8.0/EN

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

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 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4		Eye protection equipment (e.g. goggles or visors)
All other applicable PROCs	not required	na	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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

### **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 m<sup>3</sup>/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.



Version: 8.0/EN

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

### 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, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m³ (0.01 - 0.88)	irritating to skin, derr minimised as far as DNEL for dermal derived. Thus, der	droxide is classified as nal exposure has to be technically feasible. A effects has not been rmal exposure is not exposure scenario.

### **Environmental emissions**

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium dihydroxide 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 calcium dihydroxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium dihydroxide. 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.

Environmental emissions	The production of calcium dihydroxide can potentially result in an aquatic emission and locally increase the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide 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 calcium dihydroxide: when calcium dihydroxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.



Version: 8.0/EN

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

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 calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide 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 calcium dihydroxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: 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 (<a href="https://www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).



Version: 8.0/EN

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

### **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 calcium dihydroxide 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.

**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:

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

$$Ea$$

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 m<sup>3</sup>/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 calcium dihydroxide.

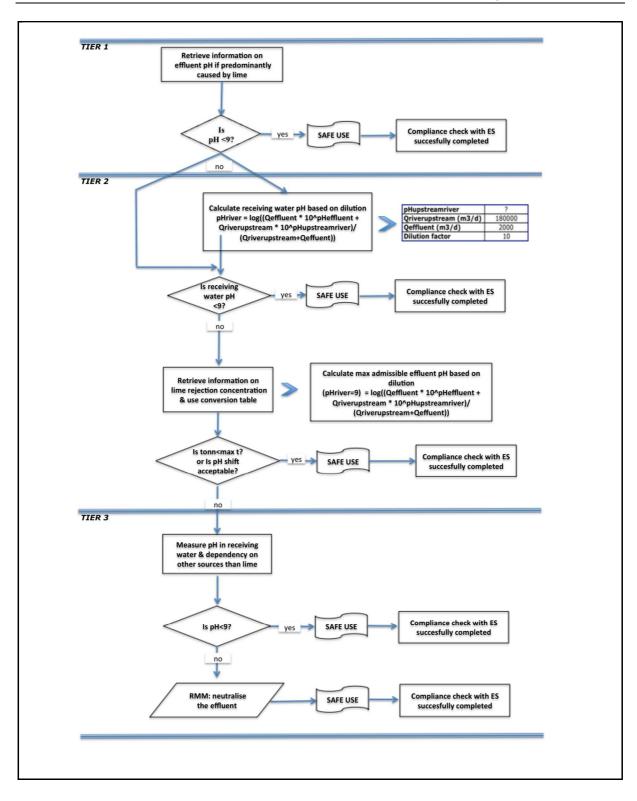


Version: 8.0/ EN	
Revision date: December/ 2021	Printing Date: December / 2021
<b>Tier 3</b> : measure the pH in the receiving water after the discharge point. If pH is b	elow 9. safe use is reasonably demonstrated
and the ES ends here. If pH is found to be above 9, risk management measures	have to be implemented: the effluent has to
undergo neutralisation, thus ensuring safe use of lime during production or use ph	nase.



Version: 8.0/EN

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





Version: 8.0/EN

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

# ES number 9.4: Manufacture and industrial uses of high dusty solids/powders of lime substances

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Manufacture and industrial uses of high dusty solids/powders 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	I 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	Further information is provided in the ECHA		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
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			
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			



Version: 8.0/EN

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

_	
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 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles
PROC 25	Other hot work operations with metals
PROC 26	Handling of solid inorganic substances at ambient temperature
PROC 27a	Production of metal powders (hot processes)
PROC 27b	Production of metal powders (wet processes)
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.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		solid/powder	high

## **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 7, 8a, 17, 18, 19, 22	≤ 240 minutes		
All other applicable PROCs	480 minutes (not restricted)		



Version: 8.0/EN

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

### 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 1	Any potentially required	not required	na	-
PROC 2, 3	separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	general ventilation	17 %	-
PROC 7		integrated local exhaust ventilation	84 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-

# 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.



Version: 8.0/EN

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

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 1, 2, 3, 23, 25, 27b	not required	na	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, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4		
PROC 19	FFP3 mask	APF=20		

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

### **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.



Version: 8.0/EN

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

### 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, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 - 0.96)	irritating to skin, derr minimised as far as DNEL for dermal derived. Thus, der	droxide is classified as mal exposure has to be technically feasible. A effects has not been rmal exposure is not exposure scenario.

### **Environmental emissions**

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium dihydroxide 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 calcium dihydroxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium dihydroxide. 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.

	, , ,
Environmental emissions	The production of calcium dihydroxide can potentially result in an aquatic emission and locally increase the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide 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 calcium dihydroxide: when calcium dihydroxide 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.



Version: 8.0/EN

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

Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide 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 calcium dihydroxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	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<sub>inhalation</sub>: 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 calcium dihydroxide 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.

**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 m<sup>3</sup>/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



Version: 8.0/EN

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

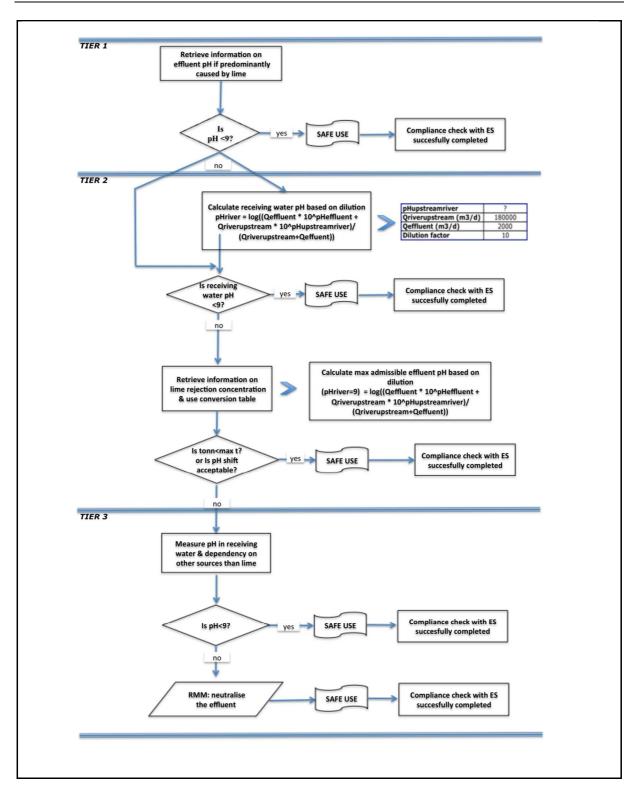
basis. Once the maximum admissible pH value in the effluent is established, it is assumed that the OH- concentrations are all dependent on lime discharge and that there is no buffer capacity conditions to consider (this is a unrealistic worst case scenario, which can be modified where information is 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 calcium dihydroxide.

**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.



Version: 8.0/EN

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





Version: 8.0/EN

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

# ES number 9.5: Manufacture and industrial uses of massive objects containing lime substances

Evnesure Cooperie	Format (1) addressing uses servied out	by werkers			
1. Title	Format (1) addressing uses carried out	by workers			
Free short title	Manufacture and industrial uses of massive	e objects containing 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 are described in Section 2 below.				
Assessment Method	The assessment of inhalation exposure is based	on the exposure estimation tool MEASE.			
2. Operational con	2. Operational conditions and risk management measures				
PROC/ERC	REACH definition	Involved tasks			
PROC 6	Calendering operations				
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation				
PROC 21	Low energy manipulation of substances bound in materials and/or articles				
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	Further information is provided in the ECHA Guidance on information requirements and			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-			
		1 EN).			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	,			
PROC 24		, ,			
	bound in materials and/or articles				



Version: 8.0/EN

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

### 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 22, 23,25	not restricted		massive objects, molten	high
PROC 24	not restricted		massive objects	high
All other applicable PROCs	not restricted		massive objects	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 22	≤ 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.



Version: 8.0/EN

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of workers from the	not required	na	-
PROC 22, 23, 24, 25	emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-

### 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 respiration protective equipment (		RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 22	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.



Version: 8.0/EN

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

### 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 m<sup>3</sup>/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.



Version: 8.0/EN

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

### 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		Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25			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 emissions**

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium dihydroxide 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 calcium dihydroxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium dihydroxide. 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.

Environmental emissions	The production of calcium dihydroxide can potentially result in an aquatic emission and locally increase the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide 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 calcium dihydroxide: when calcium dihydroxide 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.



Version: 8.0/EN

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

Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide 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 calcium dihydroxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 calcium dihydroxide 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.

**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.



Version: 8.0/EN

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

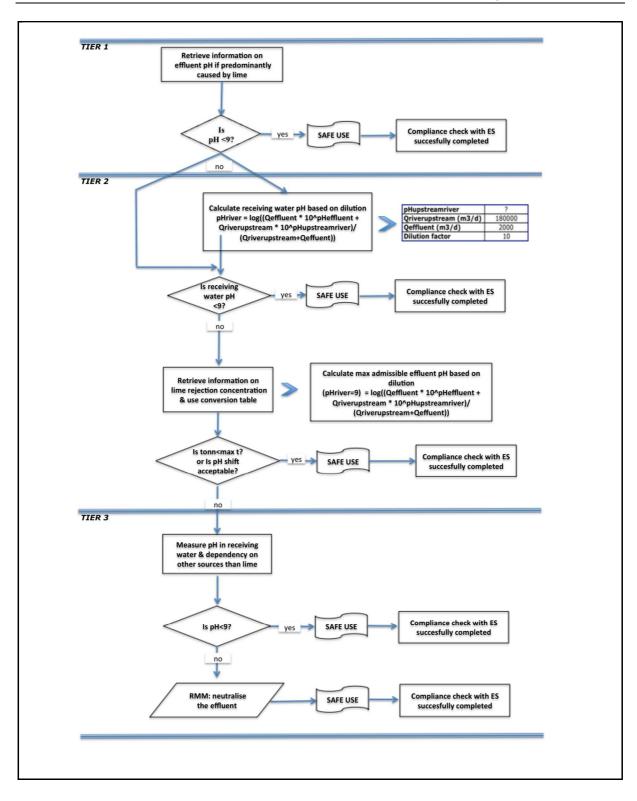
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences 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 calcium dihydroxide.

**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.



Version: 8.0/EN

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





Version: 8.0/EN

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

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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title	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	litions 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 on information requirements and chemical safety		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	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			



Version: 8.0/EN

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

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	ns		
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.



Version: 8.0/EN

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

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.	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.



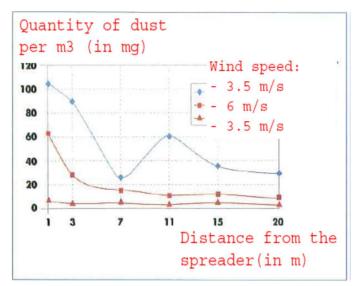
Version: 8.0/EN

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

### 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/m<sup>2</sup>

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.



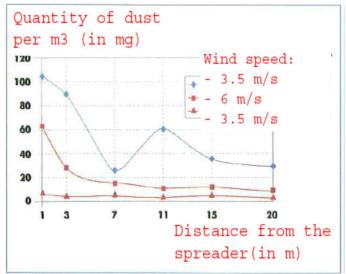
Version: 8.0/EN

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

## 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.



Version: 8.0/EN

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

### 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)	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 concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR		
	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 concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
	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 <sup>-5</sup> Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium dihydroxides 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.					



Version: 8.0/EN

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

### 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 soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
	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 <sup>-5</sup> 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.



Version: 8.0/EN

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

### 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).



Version: 8.0/EN

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

### ES number 9.7: Professional uses of low dusty solids/powders of lime substances

_			
	o Format (1) addressing uses carried ou	t by workers	
1. Title			
Free short title	Professional uses of low dusty solic	ds/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	ed are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based of environmental assessment is be		
2. Operational con	ditions 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	Further information is provided in the ECHA	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Guidance 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)	LIV).	
PROC 10	Roller application or brushing		
PROC 11	Non industrial spraying		
PROC 13	Treatment of articles by dipping and pouring		
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		



Version: 8.0/EN

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

PROC 18	Greasing at high energy conditions
PROC 19	Hand-mixing with intimate contact and only PPE available
PROC 21	Low energy manipulation of substances bound in materials and/or articles
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

### 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	not restricted		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 17 ≤ 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.



Version: 8.0/EN

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

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	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not applicable	na	-
All other applicable PROCs		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 4, 5, 11, 26	FFP1 mask	APF=4		Eye protection
PROC 16, 17, 18, 25	FFP2 mask	APF=10		equipment (e.g.
	not required			goggles or visors) must
		na	Since calcium	be worn, unless
			dihydroxide is	potential contact with
			classified as	the eye can be
			irritating to skin, the	excluded by the nature
All other applicable			use of protective	and type of application
PROCs			gloves is mandatory	(i.e. closed process).
			for all process	Additionally, face
			steps.	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.



Version: 8.0/EN

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

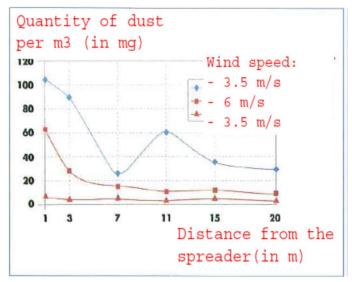
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

### 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/m<sup>2</sup>

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.



Version: 8.0/EN

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

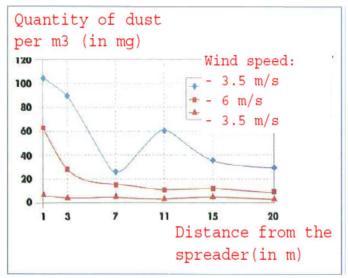
### Organizational measures to prevent/limit release from site

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.

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

Drift should be minimised.



Version: 8.0/EN

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

### 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, 21, 25, 26	MEASE	< 1 mg/m³ (0.01 - 0.75)	Since calcium dihydroxide is classified a irritating to skin, dermal exposure has to minimised as far as technically feasible.  DNEL for dermal effects has not been deri Thus, dermal exposure is not assessed in 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 <sup>-5</sup> 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.			



Version: 8.0/EN

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

### 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.

274 Con 110 model, where parameters oden as diffic our political additional and the control of 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	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 <sup>-5</sup> 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.



Version: 8.0/EN

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

### 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).



Version: 8.0/EN

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

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

<b>Exposure Scenari</b>	o Format (1) addressing uses carried ou	t 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, 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 covere	ed are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based of environmental assessment is be		
2. Operational cor	nditions 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	Further information is provided in the ECHA	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Guidance 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)	LIV).	
PROC 10	Roller application or brushing		
PROC 11	Non industrial spraying		
PROC 13	Treatment of articles by dipping and pouring		
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		



Version: 8.0/EN

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

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	

### 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	not restricted		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.



Version: 8.0/EN

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

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	generic local exhaust ventilation	72 %	-
PROC 17, 18	emission source is indicated above under "Frequency and duration of exposure". A	integrated local exhaust ventilation	87 %	-
PROC 19	reduction of exposure duration can be achieved, for example, by	not applicable	na	-
All other applicable PROCs	the installation of ventilated (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 2, 3, 16, 19	FFP1 mask	APF=4		Eye protection
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be
PROC 11	FFP1 mask	APF=10		
PROC 15	not required	na		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.



Version: 8.0/EN

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

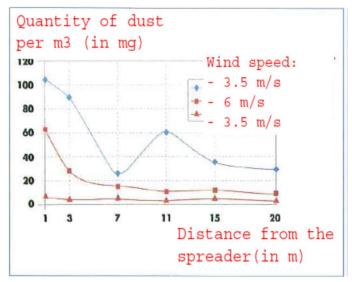
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

### 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/m<sup>2</sup>

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.



Version: 8.0/EN

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

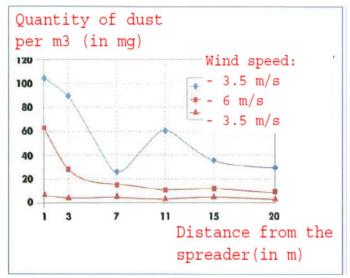
### Organizational measures to prevent/limit release from site

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.

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

Drift should be minimised.



Version: 8.0/EN

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

### 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)	irritating to skin, der minimised as far as DNEL for dermal effe Thus, dermal exposu	droxide is classified as rmal exposure has to be a technically feasible. A cts has not been derived. It is not assessed in this re 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 <sup>-5</sup> 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.			



Version: 8.0/EN

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

### 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.

274 Corr 1.5 model, where parameters oder as drifts our so improved descraing to conceived 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	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 <sup>-5</sup> Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	environment. The uses covered do	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.



Version: 8.0/EN

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

### 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).



Version: 8.0/EN

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

### ES number 9.9: Professional uses of high dusty solids/ powders of lime substances

<b>Exposure Scenari</b>	Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title					
Free short title	Professional uses of high 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.				



Version: 8.0/EN

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

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)	Further information is provided in the ECHA		
PROC 10	Roller application or brushing	Guidance on information requirements and		
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-		
PROC 13	Treatment of articles by dipping and pouring	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			



Version: 8.0/EN

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

### 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
All applicable PROCs	not restricted		solid/powder	high

### **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 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26	≤ 240 minutes			
PROC 11	≤ 60 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.



Version: 8.0/EN

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

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 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)
All other applicable PROCs		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 9, 26	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.
PROC 11, 17, 18, 19	FFP3 mask	APF=20		goggles or visors) must be worn, unless potential contact with the eye can be
PROC 25	FFP2 mask	APF=10		
All other applicable PROCs	FFP2 mask	APF=10		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.



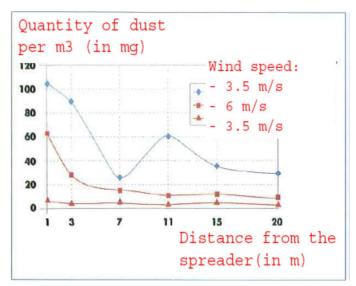
Version: 8.0/EN

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

### - 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.



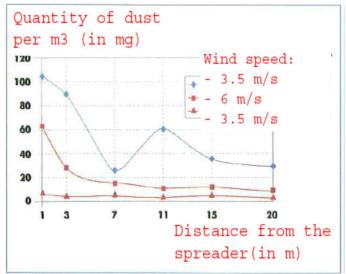
Version: 8.0/EN

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

### 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.



Version: 8.0/EN

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

### 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 (0.5 – 0.825)	irritating to skin, der minimised as far as DNEL for dermal effe Thus, dermal exposu	droxide is classified as mal exposure has to be technically feasible. A cts has not been derived. It is not assessed in this re 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 <sup>-5</sup> Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because of environment. The uses covered do (Ca2+ and OH-) in the environment	not significantly in				



Version: 8.0/EN

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

### 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	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 <sup>-5</sup> Pa.				
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because of environment. The uses covered do (Ca2+ and OH-) in the environmen	not significantly in			

### **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.



Version: 8.0/EN

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

### 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).



Version: 8.0/EN

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

### ES number 9.10: Professional use of lime substances in soil treatment

Exposure Scenario Format (1) addressing uses carried out by workers					
1. Title	1. Title				
Free short title	Professional use of lime substances in soil treatment				
Systematic title based on use descriptor	SU22 (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 measured data and on the exposure estimation tool MEASE.  The environmental assessment is based on FOCUS-Exposit.				



Version: 8.0/EN

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

2. Operational conditions and risk management measures						
Task/ERC	REACH definition	Involved tasks				
Milling	PROC 5					
Loading of spreader	PROC 8b, PROC 26	Preparation and use of calcium dihydroxide for soil				
Application to soil (spreading)	PROC 11	treatment.				
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.

Task	Use in preparation	Content in preparation	Physical form	Emission potential
Milling	not restricted		solid/powder	high
Loading of spreader	not restricted		solid/powder	high
Application to soil (spreading)	not restricted		solid/powder	high

### 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

Task	Duration of exposure		
Milling	240 minutes		
Loading of spreader	240 minutes		
Application to soil (spreading)	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 (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.



Version: 8.0/EN

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

Technical conditions and measures to control dispersion from source towards the worker					
Task	Level of separation	Localised controls (LC)	Efficiency of LC	Further information	
Milling	Separation of workers is generally	not required	na	-	
Loading of spreader	not required in the conducted processes.	not required	na	-	
Application to soil (spreading)	During application the worker is sitting in the cabin of the spreader	Cabin with filtered air supply	99%	-	

### 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

Task	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Milling	FFP3 mask	APF=20	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential
Loading of spreader	FFP3 mask	APF=20	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all	contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective
Application to soil (spreading)	not required	na	process steps.	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.



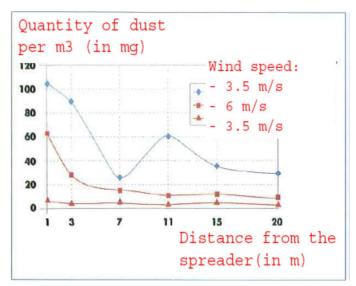
Version: 8.0/EN

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

### 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/m<sup>2</sup>

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.



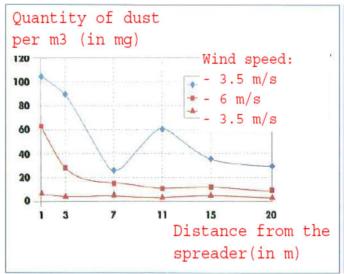
Version: 8.0/EN

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

### 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.



Version: 8.0/EN

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

### 3. Exposure estimation and reference to its source

### **Occupational exposure**

Measured data and modelled exposure estimates (MEASE) were 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).

Task	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m <sup>3</sup> (0.48)	Since calcium dihydroxide is classified as irritating skin, dermal exposure has to be minimised as far technically feasible. A DNEL for dermal effects has been derived. Thus, dermal exposure is not assess in this exposure scenario.	
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m <sup>3</sup> (0.48)		
Application to soil (spreading)	measured data	0.880 mg/m <sup>3</sup> (0.88)		

### 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 <sup>-5</sup> Pa.				
Exposure concentration relevant for the food chain (secondary poisoning)		uses covered do not		omnipresent and essential in distribution of the constituents	



Version: 8.0/EN

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

### 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	Substance	Substance         PEC (mg/L)         PNEC (mg/L)         RCR           Ca(OH)2         701         1080         0.65				
concentrations in soil and groundwater	Ca(OH)2					
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)		uses covered do not		mnipresent 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.



Version: 8.0/EN

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

### 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 (<a href="www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) 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<sub>inhalation</sub>: 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 %).

### PRODUCT SAFETY DATA SHEET for Ca(OH)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/EN

**Revision date: December / 2010** 

**Printing Date: December 10, 2021** 

### ES number 9.11: Professional uses of articles/containers containing lime substances

Exposure Scenario Format (1) addressing uses carried out by workers					
1. Title					
Free short title	Professional uses of articles/containers containing 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  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.				

### PRODUCT SAFETY DATA SHEET for Ca(OH)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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

2. Operational conditions and risk management measures					
PROC/ERC	REACH definition	Involved tasks			
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium dihydroxide/preparations as CO₂ absorbents (e.g. breathing apparatus)			
PROC 21	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting			
PROC 25	Other hot work operations with metals	etals Welding, soldering			
ERC10, ERC11, ERC 12	Wide dispersive indoor and outdoor use of long-life articles and materials with low release	Calcium dihydroxide bound into or onto articles and materials such as: wooden and plastic construction and building materials (e.g. gutters, drains), flooring, furniture, toys, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)			

### 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 0	not restricted		massive objects (pellets), low potential for dust formation due to abrasion during previous filling and handling activities of pellets, not during use of breathing apparatus	low (worst case assumption as no inhalation exposure is assumed during the use of the breathing apparatus due to the very low abrasive potential)
PROC 21	not restricted		massive objects	very low
PROC 24, 25	not restricted		massive objects	high

### **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	of use/exposure

PROC	Duration of exposure
PROC 0	480 minutes (not restricted as far as occupational exposure to calcium dihydroxide is concerned, the actual wearing duration may be restricted due the user instructions of the actual breathing apparatus)
PROC 21	480 minutes (not restricted)
PROC 24, 25	≤ 240 minutes

### 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).



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

#### 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 0, 21, 24, 25	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (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 0, 21	not required	na	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential
PROC 24, 25	FFP1 mask	APF=4	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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.



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/EN

Revision date: December / 2010

Printing Date: December 10, 2021

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

#### **Product characteristics**

Lime is chemically bound into/onto a matrix with very low release potential

#### 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 0	MEASE (PROC 21)	0.5 mg/m <sup>3</sup> (0.5)			
PROC 21	MEASE	0.05 mg/m <sup>3</sup> (0.05)	skin, dermal exposure has to be minimised as far technically feasible. A DNEL for dermal effects has		
PROC 24	MEASE	0.825 mg/m <sup>3</sup> (0.825)			
PROC 25	MEASE	0.6 mg/m <sup>3</sup> (0.6)			

### **Environmental exposure**

Lime is an ingredient and is chemically bound into a matrix: there is no intended release of lime during normal and reasonable foreseeable conditions of use. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water.

### 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<sub>inhalation</sub>: 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 %).



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

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

1. Title Free short title Systematic title based Processes, tasks activ	on use				
Systematic title based	on use				
	on use		Consumer use of building and construction material		
Processes, tasks activ		edescriptor	SU21, PC9a, PC9b, E	RC8c, ERC8d, ERC8e, ER	C8f
	vities c	overed	= : =	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 con	nditio	ns and risk ma	anagement measu	ıres	
RMM		No product integr	ated risk management r	measures are in place.	
PC/ERC		Description of a categories (ERC		cle categories (AC) and er	vironmental release
_			ng of powder containing lime substances. e plaster, putty or slurry to the walls or ceiling. exposure.		
ERC 8c, 8d, 8e, 8f  Wide dispersive control with the dispe			ndoor 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 con	sume	rs exposure			
Product characteristic	:				
Description of the preparation	subst	entration of the tance in the tration	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 %	ó	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	%	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	-	-



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

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 <sup>1</sup> fact sheet)
Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours	2/year (DIY <sup>1</sup> 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 <sup>1</sup> 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 <sup>-1</sup> (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



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Not relevant for exposure assessment

### **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**

#### 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/cm <sup>2</sup> (-) large task: 1 μg/cm <sup>2</sup> (-)	Qualitative assessment  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) Large task: 120 μg/m³ (0.03)	Quantitative assessment  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).



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

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

**Printing Date: December 10, 2021** 

Version: 1.0/EN

Revision date: December / 2010

Route of exposure	Exposure estimate	Method used, comments
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.



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

## ES number 9.13: Consumer use of CO2 absorbent in breathing apparatuses

Exposure Scenario Format (2) addressing uses carried out by consumers						
1. Title						
Free short title			Consumer use of CO <sub>2</sub> absorbent in breathing apparatuses			
Systematic title based	on us	e descriptor	SU21, PC2, ERC8b			
Processes, tasks activ	vities	covered	Filling of the formulation	•		
			Cleaning of equipmen	t		
Assessment Method*			Human health A qualitative assessment has been performed for oral and dermal exposure. The inhalation exposure has been assessed by the Dutch model (van Hemmen, 1992).  Environment A qualitative justification assessment is provided.			
2. Operational cor	nditio	ns and risk ma	anagement measu	ıres		
RMM		18%) is added wh	nich will further reduce t	m. Furthermore, a defined a he dustiness of the absorbe reacting with CO₂ to form th	nt. During the breathing	
PC/ERC		Description of a categories (ERC	ctivity referring to article categories (AC) and environmental release			
CO₂ absorbent. T (catalysed by wat carbonate. The C		cuit breathing apparatus for e.g. recreational diving containing soda lime as the breathed air will flow through the absorbent and $\mathrm{CO}_2$ will quickly react er and sodium hydroxide) with the calcium dihydroxide to form the $\mathrm{O}_2$ -free air can be re-breathed again, after addition of oxygen. Osorbent: The absorbent will be discarded after each use and refilled before				
ERC 8b		Wide dispersive i	ndoor use resulting in ir	nclusion into or onto a matrix	(	
2.1 Control of con	sum	ers exposure				
Product characteristic	:					
Description of the preparation	subs	centration of the stance in the aration	Physical state of the preparation	Dustiness (if relevant)	Packaging design	
CO <sub>2</sub> absorbent	Depending on the application the main component has different additives.  A specific amount of water is always added (14-18%).		Solid, granular	Very low dustiness (reduction by 10 % compared to powder) Dust formation cannot be ruled out during the filling of the scrubber cartridge.	4.5, 18 kg canister	
"Used" CO₂ absorbent ~ 20%		Solid, granular	Very low dustiness (reduction by 10 % compared to powder)	1-3 kg in breathing apparatus		
Amounts used						
CO <sub>2</sub> -Absorbent used in	breath	ing apparatus	1-3 kg depending on t	he kind of breathing appara	tus	



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Frequency and duration of use/exposure					
Description of the task	Duration of exposure per event	frequency of events			
Filling of the formulation into the cartridge	Ca. 1.33 min per filling, in sum < 15 min	Before each dive (up to 4 times)			
Use of closed circuit breathing apparatus	1-2 h	Up to 4 dives a day			
Cleaning and emptying of equipment	< 15 min	After each dive (up to 4 times)			

### Human factors not influenced by risk management

Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Filling of the formulation into the cartridge	adult	1.25 m³/hr (light working activity)	hands	840 (REACH guidance R.15, men)
Use of closed circuit breathing apparatus			-	-
Cleaning and emptying of equipment			hands	840 (REACH guidance R.15, men)

### Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Filling of the formulation into the cartridge	NR	NR	NR
Use of closed circuit breathing apparatus	-	-	-
Cleaning and emptying of equipment	NR	NR	NR

### Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust

Keep container tightly closed as to avoid the soda lime to dry out.

Keep out of reach of children.

Wash thoroughly after handling.

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

Do not mix with acids.

Carefully read the instructions of the breathing apparatus to assure a proper use of the breathing apparatus.

### Conditions and measures related to personal protection and hygiene

Wear suitable gloves, goggles and protective clothes during handling. Use a filtering half mask (mask type FFP2 acc. to EN 149).

### 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

### Environment factors not influenced by risk management



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

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

Due to the very specialised kind of consumers (divers filling their own CO<sub>2</sub> scrubber) it can be assumed that instructions will be taken into account to reduce exposure

#### **Human exposure**

### Filling of the formulation into the cartridge

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	-	Qualitative assessment  If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of granular soda lime or direct contact to the granules 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.
Eye	Dust	Qualitative assessment  If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the granular soda lime is expected to be minimal, therefore eye exposure will be minimal even without protective goggles. Nevertheless, prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 1.2 μg/m³ (3 × 10 <sup>-4</sup> ) Large task: 12 μg/m³ (0.003)	Quantitative assessment  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) and applying a dust reduction factor of 10 for the granular form.
Use of closed circu	uit breathing apparatus	
Route of exposure	Exposure estimate	Method used, comments



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

	1	T				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	-	Qualitative assessment				
		Due to the product characteristics, it can be concluded that dermal exposure to the absorbent in breathing apparatuses is non-existent.				
Eye	-	Qualitative assessment				
		Due to the product characteristics, it can be concluded that eye exposure to the absorbent in breathing apparatuses is non-existent.				
Inhalation	negligible	Qualitative assessment				
		Instructional advice is provided to remove any dust before finishing the assembly of the scrubber. Divers filling their own CO <sub>2</sub> scrubber represent a specific subpopulation within consumers. Proper use of equipment and materials is in their own interest; hence it can be assumed that instructions will be taken into account.				
		Due to the product characteristics and the instructional advices given, it can be concluded that inhalation exposure to the absorbent during the use of the breathing apparatus is negligible.				
Cleaning and emptying of equipment						
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	Dust and splashes	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from emptying granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during cleaning. Furthermore, during the cleaning of the cartridge with water contact to moistened soda lime may occur. This may occasionally result in mild irritation easily avoided by immediate rinsing of with water.				
Eye	Dust and splashes	Qualitative assessment				
•		If risk reduction measures are taken into account no human exposure is expected. However, contact to dust from emptying granular soda limes or during the cleaning of the cartridge with water contact to moisten soda limes may occur in very rare occasions. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.				
Inhalation	Small task: 0.3 μg/m³ (7.5 × 10 <sup>-5</sup> )	Quantitative assessment				
	Large task: $3 \mu g/m^3 (7.5 \times 10^{-4})$	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) and applying a dust reduction factor of 10 for the				
		granular form and a factor of 4 to account for the reduced amount of lime in the "used" absorbent.				

### **Environmental exposure**

The pH impact due to use of lime in breathing apparatuses is expected to be negligible. 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.



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

### ES number 9.14: Consumer use of garden lime/fertilizer

Exposure Scenario Format (2) addressing uses carried out by consumers								
1. Title		(-/			-,			
Free short title				Consumer use of gard	den lime/fe	rtilize	ər	
Systematic title based	on us	se descrip	tor	SU21, PC20, PC12, E				
Processes, tasks acti				Manual application of		e. fe	ertilizer	
,				Post-application expo	-	-,		
Assessment Method*			Human health A qualitative assessment has been performed for oral and dermal exposure as well as for the exposure to the eye. The dust exposure has been assessed by the Dutch model (van Hemmen, 1992).  Environment A qualitative justification assessment is provided.					
2. Operational cor	nditio	ns and	risk m	anagement meas	ures			
RMM		No produ	ct integi	rated risk management	measures	are i	n place.	
PC/ERC		Descript categori		ctivity referring to arti	icle catego	ries	(AC) and er	nvironmental release
			g of the garden lime by exposure to playing chil		nd (v	vorst case) a	nd soil incorporation.	
PC 12			•	ding of the garden lime by shovel/ hand (worst case) and soil incorporation. on exposure to playing children.				
ERC 8e		Wide disp	persive (	e outdoor use of reactive substances in open systems				
2.1 Control of cor	sum	ers expo	sure					
Product characteristic	;							
Description of the preparation	subs	centration stance in t aration		Physical state of the preparation	Dustine	Dustiness (if relevant)		Packaging design
Garden lime	100 9	%		Solid, powder	High dus	High dusty		Bulk in bags or containers of 5, 10 and 25 kg
Fertilizer	Up to	20 %		Solid, granular	Low dus	Low dusty		Bulk in bags or containers of 5, 10 and 25 kg
Amounts used								
Description of the pre	paratio	on		Amount used per ev	ent		Source of	information
Garden lime				100g /m <sup>2</sup> (up to 200g/	m²)		Information	and direction of use
Fertilizer				100g /m² (up to 1kg/m	n² (compost	t))	Information	and direction of use
Frequency and duration	on of u	ıse/exposi	ure					
Description of the task	k		Durati	tion of exposure per event		frequency of events		
Manual application				es-hours nding on the size of the treated		1 tasks per year		
Post-application				oddlers playing on grass (EPA sure factors handbook)		Relevant for up to 7 days after application		



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Human factors not influenced by risk management					
Description of the task  Population exposed Breathing rate Exposed body part Corresponding skin area [cm²]					
Manual application	Adult	1.25 m³/hr	Hands and forearms	1900 (DIY fact sheet)	
Post-application	Child/Toddlers	NR	NR	NR	

### Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Manual application	outdoor	1 m³ (personal space, small area around the user)	NR
Post-application	outdoor	NR	NR

### Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust. Use a filtering half mask (mask type FFP2 acc. to EN 149). Keep container closed and out of reach of children.

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

Wash thoroughly after handling.

Do not mix with acids and always add limes to water and not water to limes.

Incorporation of the garden lime or fertilizer into the soil with subsequent watering will facilitate the effect.

### Conditions and measures related to personal protection and hygiene

Wear suitable gloves, goggles and protection clothes.

### 2.2 Control of environmental exposure

#### **Product characteristics**

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

### **Amounts used**

Amount used	Ca(OH)2	2,244 kg/ha	In professional agricultural soil protection, it is
	CaO	1,700 kg/ha	recommended not to exceed 1700 kg CaO/ha or the corresponding amount of 2244 kg
	CaO.MgO	1,478 kg/ha	Ca(OH) <sub>2</sub> /ha. This rate is three times the amount needed to compensate the annual losses of
	Ca(OH)2.Mg(OH)2	2,030 kg/ha	lime by leaching. For this reason, the value of 1700 kg CaO/ha or the corresponding amount
	CaCO3.MgO	2,149 kg/ha	of 2244 kg Ca(OH) <sub>2</sub> /ha is used in this dossier as
	Ca(OH)2.MgO	1,774 kg/ha	the basis for the risk assessment. The amount used for the other lime variants can be
	Natural hydraulic lime	2,420 kg/ha	calculated based on their composition and the molecular weight.

### 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

Not relevant for exposure assessment

### 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.



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

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

Drift should be minimised.

Conditions and measures related to municipal sewage treatment plant

Not relevant for exposure assessment

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 long-term DNEL for lime substances of 1 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 lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

#### **Human exposure**

### **Manual application**

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product
		use.
Dermal	Dust, powder	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from application of lime substances or by direct contact to the limes cannot be excluded if no protective gloves are worn during application. Due to the relatively long application time, skin irritation would be expected. This can easily be avoided by immediate rinsing with water. It would be assumed that consumers who had experience of skin irritation will protect themselves. Therefore, any occurring skin irritation, which will be reversible, can be assumed to be non-recurring.
Eye	Dust	Qualitative assessment  If risk reduction measures are taken into account no human exposure is expected. Dust from surfacing with lime cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (garden	Small task: 12 μg/m³ (0.0012)	Quantitative assessment
lime)	Large task: 120 μg/m³ (0.012)	No model describing the application of powders by shovel/hand is available, therefore, read-across from the dust formation model while pouring powders has been used as a worst case.
		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).



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Inhalation	Small task: 0.24 μg/m³ (2.4 * 10-4)	Quantitative assessment
(fertilizer)	Large task: 2.4 μg/m³ (0.0024)	No model describing the application of powders by shovel/hand is available, therefore, read across from the dust formation model while pouring powders has been used as a worst case.
		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) and applying a dust reduction factor of 10 for the granular form and a factor of 5 to account for the reduced amount of limes in fertilizer.

#### Post-application

According to the PSD (UK Pesticide Safety Directorate, now called CRD) post-application exposure need to be addressed for products which are applied in parks or amateur products used to treat lawns and plants grown in private gardens. In this case exposure of children, who may have access to these areas soon after treatment, needs to be assessed. The US EPA model predicts the post-application exposure to products used in private gardens (e.g. lawns) by toddlers crawling on the treated area and also via the oral route through hand-to-mouth activities.

Garden lime or fertilizer including lime is used to treat acidic soil. Therefore, after application to the soil and subsequent watering the hazard driving effect of lime (alkalinity) will be quickly neutralized. Exposure to lime substances will be negligible within a short time after application.

### **Environmental exposure**

No quantitative environmental exposure assessment is carried out because the operational conditions and risk management measures for consumer use are less stringent than those outlined for professional agricultural soil protection. Moreover, the neutralisation/pH-effect is the intended and desired effect in the soil compartment. Releases to wastewater are not expected.



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/EN

**Revision date: December / 2010** 

Printing Date: December 10, 2021

## ES number 9.15: Consumer use of lime substances as water treatment chemicals

Exposure Scenario	Forma	at (2) addressin	g uses carried out	by consumers	
1. Title					
Free short title			Consumer use of lime	e substances as water treatn	nent chemicals
Systematic title based	on us	e descriptor	SU21, PC20, PC37, I	ERC8b	
Processes, tasks acti	vities (	covered	of lime milk	illing of solid formulations int	o container/preparation
			Application of lime mi	lk to water	
Assessment Method*			Human health:  A qualitative assessment has been performed for oral and dermal exposure as well as for exposure of the eye. Dust exposure has been assessed by the Dutch model (van Hemmen, 1992).  Environment:  A qualitative justification assessment is provided.		
2. Operational cor	nditio	ns and risk ma	anagement meas	ures	
RMM		No further produc	t integrated risk manag	gement measures are in plac	ee.
PC/ERC		Description of a categories (ERC	ctivity referring to art	icle categories (AC) and er	nvironmental release
Transfer of lime s			ng (transfer of lime substances (solid)) of lime reactor for water treatment. substances (solid) into container for further application. tion of lime milk to water.		
ERC 8b		Wide dispersive i	ndoor use of reactive substances in open systems		
2.1 Control of con	sume	ers exposure			
Product characteristic	;				
Description of the preparation	subs	centration of the tance in the aration	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Water treatment chemical	Up to	100 %	Solid, fine powder	high dustiness (indicative value from DIY fact sheet see section 9.0.3)	Bulk in bags or buckets/containers.
Water treatment chemical Up to 99 %			Solid, granular of different size (D50 value 0.7 D50 value 1.75 D50 value 3.08)	low dustiness (reduction by 10% compared to powder)	Bulk-tank lorry or in "Big Bags" or in sacks
Amounts used					
Description of the pre	paratio	n	Amount used per ev	rent	
Water treatment chemic aquaria	al in lir	ne reactor for	depending on the size	e of the water reactor to be fi	lled (~ 100g /L)
Water treatment chemical in lime reactor for drinking water		depending on the size of the water reactor to be filled (~up to 1.2 kg/L)			
drinking water					



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Frequency and duration of use/exposure						
Description of task	Duration of exposure per event	frequency of events				
Preparation of lime milk (loading, filling and refilling)	1.33 min (DIY-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	1 task/month 1task/week				
Dropwise application of lime milk to water	Several minutes - hours	1 tasks/ month				

### Human factors not influenced by risk management

Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m³/hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)

### Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 m³ (personal space, small area around the user)	0.6 hr <sup>-1</sup> (unspecified room indoor)
Dropwise application of lime milk to water	indoor	NR	NR

### Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust

Keep container closed and out of reach of children.

Use only with adequate ventilation.

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

Wash thoroughly after handling.

Do not mix with acids and always add limes to water and not water to limes.

### Conditions and measures related to personal protection and hygiene

Wear suitable gloves, goggles and protective clothes. Use a filtering half mask (mask type FFP2 acc. to EN 149).

### 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

### Environment factors not influenced by risk management

Default river flow and dilution

### Other given operational conditions affecting environmental exposure

Indoor

### Conditions and measures related to municipal sewage treatment plant

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



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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

### 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 FN 481

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

#### **Human exposure**

### Preparation of lime milk (loading)

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal (powder)	small task: 0.1 μg/cm² (-) large task: 1 μg/cm² (-)	Qualitative assessment  If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes 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 DIY-fact sheet (RIVM report 320104007). For granules the exposure estimate will be even lower.
Eye	Dust	Qualitative assessment  If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the limes cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (powder)	Small task: 12 μg/m³ (0.003) Large task: 120 μg/m³ (0.03)	Quantitative assessment  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).
Inhalation (granules)	Small task: 1.2 μg/m³ (0.0003) Large task: 12 μg/m³ (0.003)	Quantitative assessment  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) and applying a dust reduction factor of 10 for the granular form.
Dropwise application	on of lime milk to water	

Route of exposure	Exposure estimate	Method used, comments	
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product 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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

Dermal	Droplets or 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 application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands in water.
Eye	Droplets or splashes	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application.
		However, it is rare for eye irritation to occur as a result of exposure to a clear solution of calcium hydroxide (lime water) and mild irritation can easily be avoided by immediate rinsing of the eyes with water.
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.

### **Environmental exposure**

The pH impact due to use of lime in cosmetics is expected to be negligible. 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.



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/EN

substances

Revision date: December / 2010

## ES number 9.16: Consumer use of cosmetics containing lime

**Printing Date: December 10, 2021** 

Exposure Scenario Format (2) addressing uses carried out by consumers		
1. Title		
Free short title		Consumer use of cosmetics containing limes
Systematic title based on use descriptor		SU21, PC39 , ERC8a
Processes, tasks activities covered		-
Assessment Method*		Human health: According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.
2. Operational condition	ns and risk ma	anagement measures
ERC 8a	Wide dispersive i	ndoor use of processing aids in open systems
2.1 Control of consume	ers exposure	
Product characteristic		
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Amounts used		
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Frequency and duration of u	se/exposure	
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Human factors not influence	d by risk manage	ment
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Other given operational con-	ditions affecting (	consumers exposure
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Conditions and measures related to information and behavioural advice to consumers		
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
Conditions and measures re	lated to personal	protection and hygiene
Not relevant, as the risk to hun	nan health from this	s use does not need to be considered.
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		
Environment factors not influenced by risk management		
Default river flow and dilution		

# ZAGORIE

### PRODUCT SAFETY DATA SHEET for Ca(OH)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/EN

Revision date: December / 2010 Printing Date: December 10, 2021

#### Other given operational conditions affecting environmental exposure

Indoo

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

#### **Human exposure**

Human exposure to cosmetics will be addressed by other legislation and therefore need not be addressed under regulation (EC) 1907/2006 according to Article 14(5) (b) of this regulation.

#### **Environmental exposure**

The pH impact due to use of lime in cosmetics is expected to be negligible. 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