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

1.1 Product Identifier

Substance name:	Dolime; Calcium Magnesium Oxide
Synonyms:	Dolomitic Lime, Dolomitic quicklime, Calcined dolomite, Burnt dolomite, Dolomite dead burned refractory, Calcium magnesium oxide.
Chemical name and formula:	Calcium Magnesium Oxide – CaMgO2
Trade name:	Dolomitic Lime
CAS:	37247-91-9
EINECS:	253-425-0
Molecular Weight:	96.39 g/mol
REACH Registration number:	01-2119474202-47-0024

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°:	n.c.: +386 (0)3 56 55 560
	+386 (0)3 56 55 583
Fax N°:	+386 (0)3 56 55 596
E-mail of competent person responsible for SDS in the MS or in the EU:	info.reach@intercal.si

1.4 Emergency telephone number

European Emergency N°:	112
Emergency telephone at the company	+386 (0)3 56 55 583
Available outside office hours:	No

2 HAZARDS IDENTIFICATION

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

STOT Single Exp. 3, Route of exposure: Inhalation Skin Irritation 2 Eye Damage 1



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2.2 Label elements

Labelling according to Regulation (EC) 1272/2008

Signal word: Danger

Hazard pictogram:



Hazard statements:

H315:	Causes skin irritation
H318:	Causes serious eye damage
H335:	May cause respiratory irritation

Precautionary statements:

P102:	Keep out of reach of children.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338+P310:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact
	lenses, if present and easy to do. Continue rinsing. Immediately call a
	POISON CENTRE or doctor/physician.
P302+P352:	IF ON SKIN: Wash with plenty of water.
P261:	Avoid breathing dust/spray.
P304+P340:	IF INHALED: Remove victim to fresh air and keep at rest in a position
	comfortable for breathing.
P501:	Dispose of contents/container in accordance with
	local/regional/national/international regulation.

2.3 Other hazards

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

No other hazards identified.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Main constituent	
Name:	Calcium magnesium oxide
CAS:	37247-91-9
EINECS:	253-425-0



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Impurities

No impurities relevant for classification and labelling.

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice

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

Following inhalation

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

Following skin contact

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

Following eye contact

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

After ingestion

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

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Follow the advises given in section 4.1

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

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

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

5.1.2 Unsuitable extinguishing media

Do not use water. Avoid humidification.



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5.2 Special hazards arising from the substance or mixture

Calcium magnesium oxide reacts with water and generates heat. This may cause risk to flammable material.

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). Avoid humidification.

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).

Avoid humidification.

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.



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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.

7.3 Specific end use(s)

Please check the identified uses in section 1.2 of this safety data sheet. For more information please see the relevant exposure scenario, available via your supplier/given in the Appendix, and check section 2.1: Control of worker exposure.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

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

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

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

These values are read-across to calcium magnesium oxide. Magnesium is – like calcium – an essential mineral nutrient which will in itself not exert any local effects in contact with mucous membranes of the respiratory system. Human data support the finding that effects of calcium



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magnesium oxide are limited to the external surfaces of the body (local irritation, pH-effect) and no systemic effects are anticipated.

PNEC aqua = 320 µg/l

PNEC soil/groundwater = 712 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. It is also advisable to have individual pocket eyewash.

8.2.2.2 Skin protection

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

8.2.2.3 Respiratory protection

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

8.2.2.4 Thermal hazards

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

8.2.3 Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment.

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



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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
Color:	White or off white (beige) to grey for refractory solid material of varying sizes: Lump, granular or 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:	not applicable
pH:	12.4 (saturated solution at 20 °C)
Kinematic viscosity:	not applicable (solid with a melting point > 450 $^{\circ}$ C)
Solubility in water:	1385.2 mg/L (study results, EU A.6 method)
Partition coefficient n-octanol/wate	er: not applicable (inorganic substance)
Vapour pressure:	not applicable (solid with a melting point > 450 °C)
Density and/or relative density:	3.41 (study result, EU A.3 method)
Relative vapour density:	not applicable
Particle characteristics:	fine powder - to 200 μm
	lump: 0 – 100 mm

9.2 Other information

Not available

10 STABILITY AND REACTIVITY

10.1 Reactivity

Calcium magnesium oxide reacts exothermically with water to form Calcium dihydroxide.

10.2 Chemical stability

Under normal conditions of use and storage (dry conditions), calcium magnesium oxide is stable.



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10.3 Possibility of hazardous reactions

Calcium magnesium oxide reacts exothermically with acids.

10.4 Conditions to avoid

Minimise exposure to air and moisture to avoid degradation.

10.5 Incompatible materials

Calcium magnesium oxide reacts exothermically with water to form calcium dihydroxide:

CaO.MgO + H₂O \rightarrow Ca(OH)₂ + MgO + 1155 kJ/kg CaO

Calcium magnesium oxide reacts exothermically with acids to form calcium and magnesium salts. Calcium magnesium oxide reacts with aluminium and brass in the presence of moisture under formation (or release) of hydrogen gas:

 $CaO.MgO + 2 \text{ Al} + 7 \text{ H}_2O \rightarrow MgO + Ca \text{ (Al}(OH)_4)_2 + 3 \text{ H}_2$

10.6 Hazardous decomposition products

None.

Further information: Calcium magnesium oxide absorbs moisture and carbon dioxide from air to form calcium magnesium carbonate (dolomite), 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 LD₅₀ > 2000 mg/kg bw (OECD 425, rat)

Dermal no data available

Inhalation no data available

Calcium magnesium oxide is not acutely toxic.

Classification for acute toxicity is not warranted.

b. Skin corrosion/irritation

Calcium dihydroxide is irritating to skin (OECD 404, *in vivo*, rabbit). By read across these results are also applicable to calcium magnesium oxide.

Based on experimental results on similar substances utilized by read-across, calcium magnesium oxide requires classification as irritating to skin [R38, irritating to skin; Skin Irrit 2 (H315 – Causes skin irritation)].

c. Serious eye damage/irritation

CaO causes irreversible lesions in the eye (OECD 405, in vivo, rabbit). By read across these results are also applicable to calcium magnesium oxide.



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Based on experimental results on a similar substance utilized by read-across, calcium magnesium oxide 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 magnesium oxide is considered not to be a skin sensitiser, based on the nature of the effect (pH shift) and the essential requirement of calcium and magnesium for human nutrition.

Classification for sensitisation is not warranted.

e. Germ cell mutagenicity

There is no indication for genotoxic/mutagenic effects of Ca(OH)2 or other calcium or magnesium salts in *in vitro* studies (gene mutation in bacteria).

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

Classification for genotoxicity is not warranted.

f. Carcinogenicity

Both calcium (administered as Ca-lactate) and magnesium (administered as Mg-chloride) are not carcinogenic (experimental results, rat/mouse).

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

Human epidemiological data support lack of any carcinogenic potential of calcium magnesium oxide. Classification for carcinogenicity is not warranted.

g. Reproductive toxicity

Both calcium (administered as Ca-carbonate) and magnesium (administered as Mg-sulphate) are not toxic to reproduction (experimental results, mouse/rat).

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

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

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 magnesium oxide is not toxic for reproduction and/or development.

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



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h. STOT-single exposure

From human data it is concluded that CaO and Ca(OH)2 are irritating to the respiratory tract. This is applicable to calcium magnesium oxide by read-across.

As summarised and evaluated in the SCOEL recommendation (Anonymous, 2008), based on human data calcium magnesium oxide is classified as irritating to the respiratory system by read-across from CaO and Ca(OH)2 [R37, Irritating to respiratory system; STOT SE 3 (H335 – May cause respiratory irritation)].

i. STOT-repeated exposure

Toxicity of calcium and magnesium 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, and UL = 250 mg/d, corresponding to 3.6 mg/kg bw/d (70 kg person) for magnesium.

Toxicity of calcium magnesium oxide 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 calcium magnesium oxide via inhalation (local effect, irritation of mucous membranes) is addressed by an 8-h TWA determined by the Scientific Committee on Occupational Exposure Limits (SCOEL) of 1 mg/m³ respirable dust (read-across from calcium oxide and calcium dihydroxide; see Section 8.1).

Therefore, classification of calcium magnesium oxide for toxicity upon prolonged exposure is not required.

j. Aspiration hazard

Calcium magnesium oxide is not known to present an aspiration hazard.

11.2 Information on other hazards

Not relevant.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute/Prolonged toxicity to fish

LC₅₀ (96h) for freshwater fish: 50.6 mg/l (calcium dihydroxide) LC₅₀ (96h) for marine water fish: 457 mg/l (calcium dihydroxide)

12.1.2 Acute/Prolonged toxicity to aquatic invertebrates

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



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

12.1.3 Acute/Prolonged toxicity to aquatic plants

EC₅₀ (72h) for freshwater algae: 184.57 mg/l (calcium dihydroxide) NOEC (72h) for freshwater algae: 48 mg/l (calcium dihydroxide)

12.1.4 Toxicity to micro-organisms e.g. bacteria

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

12.1.5 Chronic toxicity to aquatic organisms

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

12.1.6 Toxicity to soil dwelling organisms

EC₁₀/LC₁₀ or NOEC for soil macroorganisms: 2000 mg/kg soil dw (calcium dihydroxide) EC₁₀/LC₁₀ or NOEC for soil microorganisms: 12000 mg/kg soil dw (calcium dihydroxide)

12.1.7 Toxicity to terrestrial plants

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

12.1.8 General effect

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

12.1.9 Further information

The results by read across are also applicable to Calcium magnesium oxide, since in contact with moisture calcium hydroxide is formed.

12.2 Persistence and degradability

Not relevant for inorganic substances

12.3 Bioaccumulative potential

Not relevant for inorganic substances



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12.4 Mobility in soil

Calcium magnesium oxide reacts with water and/or carbon dioxide to form respectively calcium dihydroxide and/or calcium carbonate, which are sparingly soluble, and present 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 magnesium oxide 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

14 TRANSPORT INFORMATION

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

14.1 UN-Number or ID number

UN 1910



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14.2 UN proper shipping name

Calcium oxide; Chemical name: Calcium magnesium oxide

14.3 Transport hazard class(es)

Class 8 (Air transport (ICAO/IATA)) UN number 1910 is listed in IMDG (Amendment 34-08).

14.4 Packing group

Group III (Air transport (ICAO/IATA))

14.5 Environmental hazards

None

14.6 Special precautions for user

Avoid any release of dust during transportation, by using air-tight tanks for powders and covered trucks for pebbles.

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 magnesium oxide is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.

National regulations: Water endangering class 1 (Germany)

15.2 Chemical safety assessment

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

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



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H318: Causes serious eye damage

H335: May cause respiratory irritation

16.2 Precautionary Statements

P102:	Keep out of reach of children
P280:	Wear protective gloves/protective clothing/eye protection/face protection
P305+P351:	IF IN EYES: Rinse cautiously with water for several minutes
P310:	Immediately call a POISON CENTRE or doctor/physician
P302+P352:	IF ON SKIN: Wash with plenty of soap and water
P261:	Avoid breathing dust/fume/gas/mist/vapours/spray
P304+P340:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P501:	Dispose of contents/container in accordance with local/regional/national/international regulation

16.3 Abbreviations

- EC₅₀: median effective concentration
- IMO: International Maritime Organization
- LC₅₀: median lethal concentration
- LD₅₀: median lethal dose
- NOEC: no observable effect concentration
- OEL: occupational exposure limit
- PBT: persistent, bioaccumulative, toxic chemical
- PNEC: predicted no-effect concentration
- STEL: short-term exposure limit
- TWA: time weighted average
- vPvB: very persistent, very bioaccumulative chemical

16.4 Key literature references

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

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

16.5 Revision

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



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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.



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APPENDIX: EXPOSURE SCENARIOS

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

Methodology used for environmental exposure assessment

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

1) Industrial uses (local scale)

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

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

2) Professional uses (local scale)

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

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



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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

(<u>http://www.ebrc.de/mease.html</u>) is used to assess inhalation exposure according to the ECHA guidance (R.14).

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

Methodology used for consumer exposure assessment

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

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

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

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

For dermal exposure and exposure to the eye a qualitative approach has been followed, as no DNEL could be derived for this route due to the irritating properties of calcium oxide. Oral exposure was not assessed as this is not a foreseeable route of exposure regarding the uses addressed.



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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 magnesium oxide professional and industrial and consumer uses is performed and organized based on several scenarios. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.



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

				lde use	ntifi es	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)	
9.1	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	х	x	x		х	2	3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b	



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				Identified uses		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)
9.3	Manufacture and industrial uses of medium dusty solids/powders of lime substances	x	x	x		х	3	3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b
9.4	Manufacture and industrial uses of high dusty solids/powders of lime substances	x	x	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	5, 6, 7, 8,	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 11a
9.5	Manufacture and industrial uses of massive objects containing lime substances	х	x	x		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	5, 6, 7, 8,	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b



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



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				Identified uses		Resultin g life cycle stage	entified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)			Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.9	Professional uses of high dusty solids/powders of lime substances		x	x		х	9	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f
9.10	Professional use of lime substances in soil treatment		x	x			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f
9.11	Professional uses of articles/containe rs containing lime substances			х		x	11	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b



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				Identified uses		Resultin g life cycle stage	tified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.12	Consumer use of building and construction material (DIY)				х		х	21	9b, 9a			8
9.13	Consumer use of CO ₂ absorbent in breathing apparatuses				х		х	21	2			8
9.14	Consumer use of garden lime/fertilizer				х		х	21	20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				х		х	21	20, 37			8



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	Exposure scenario title			Identified uses		Resultin g life cycle stage	entified Use			Process	Article	Environmental
		Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	category (SU)		category (PROC)	categor y (AC)	release category (ERC)
9.16	Consumer use of cosmetics containing lime substances				х		x	21	39			8



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers					
1. Title							
Free short title	Manufacture and industrial uses of a	queous solutions of lime substances					
Systematic title based on use descriptor	SU14, SU15, SU16, SU17, SL PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC34, PC35, PC36, PC AC1, AC2, AC3, AC4, AC5, AC6	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 ba	sed on the exposure estimation tool MEASE.					
2. Operational con	ditions and risk management measure	es					
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						
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA					
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).					
PROC 10	Roller application or brushing	Composition System (LOHA-2010-C-00-EN).					
PROC 12	Use of blowing agents in manufacture of foam						
PROC 13	Treatment of articles by dipping and pouring						
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation						
PROC 15	Use as laboratory reagent						
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						



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ERC 10, 11	Wide-dispersive outdoor life articles a							
2.1 Control of wor	kers exposure							
Product characteristic								
is reflected by an assign at ambient temperature t temperature based, takin abrasive tasks are based	E approach, the substance ment of a so-called fugaci the fugacity is based on th ng into account the proces d on the level of abrasion i IC7 and 11) is assumed to	ty class in the MEASE too e dustiness of that substa is temperature and the me instead of the substance in	I. For operations conductonce. Whereas in hot meta lig point of the substance the substance of the substance	ed with solid substances al operations, fugacity is ce. As a third group, high				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential				
PROC 7	not res		aqueous solution	medium				
All other applicable PROCs	not res	stricted	aqueous solution	very low				
Amounts used								
combination of the scale	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 duratio	n of use/exposure							
PROC		Duration o	f exposure					
PROC 7		≤ 240 r	ninutes					
All other applicable PROCs		480 minutes (not restricted)					
Human factors not influenced by risk management								
The shift breathing volur	ne during all process step	s reflected in the PROCs i	s assumed to be 10 m ³ /sł	nift (8 hours).				
Other given operationa	al conditions affecting w	orkers exposure						
	s are not used in hot-met ot considered relevant for							
Technical conditions a	nd measures at process	level (source) to prever	nt release					
Risk management meas required in the processe	sures at the process level s.	(e.g. containment or seg	regation of the emission s	source) are generally not				
Technical conditions a	nd 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	local exhaust ventilation	78 %	-				
PROC 19	"Frequency and duration of exposure". A reduction of exposure duration can	not applicable	na	-				
All other applicable PROCs	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	-				



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Organisational measur	res to prevent /limit relea	ises, dispersion and exp	oosure						
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 magnesium oxide is classified as irritating to	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature					
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.					
breathing resistance and shall be considered that For reasons as given ab the use of RPE), (ii) hav hair). The recommended the contours of the face The employer and self-e devices and the manage policy for a respiratory p	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.								
Amounts used									
The daily and annual a exposure.	mount per site (for point	sources) is not consider	ed to be the main detern	ninant for environmental					
Frequency and duratio	n of use								
Intermittent (< 12 time pe	er year) or continuous use	/release							
Environment factors no	ot influenced by risk ma	nagement							
Flow rate of receiving su	urface water: 18000 m3/day	y							
Other given operationa	al conditions affecting er	nvironmental exposure							
Effluent discharge rate: 2	2000 m³/day								
Technical onsite condi	tions and measures to r	educe or limit discharge	es, air emissions and rel	eases to soil					
to surface water, in case during introduction into c receiving surface waters values in the range of 6-	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 measu	res related to waste								
Solid industrial waste of	lime should be reused or	discharged to the industria	al wastewater and further	neutralized if needed.					



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3. Exposure estimation	ation and reference	to its source							
Occupational exposure	e								
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 magnesium oxide of 1 mg/m ³ (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	MEASE <pre>< 1 mg/m³ (0.001 - 0.66)</pre> Since calcium magnesium oxide 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 exposu	re sure assessment is only re								
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+ and Mg2+ 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 magnesium oxide 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	increase the calcium ma When the pH is not neutri sites may impact the pH	gnesium oxide concentrat ralised, the discharge of e	ion and affect the pH in th ffluent from calcium magn e pH of effluents is norma	e aquatic environment. esium oxide production					
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calciun therefore there is no biological oxide production sites wi	m magnesium oxide produ ogical treatment. Therefor Il normally not be treated	uction is an inorganic wast e, wastewater streams fro in biological waste water t vastewater streams that a	om calcium magnesium reatment plants					
Exposure concentration in aquatic pelagic compartment	When calcium magnesiu sediment will be negligib on the buffer capacity of on pH will be. In general is regulated by the equili carbonate ion (CO32-).	le. When lime is rejected the water. The higher the the buffer capacity prevent brium between carbon diction diction between carbon diction dictio	ace water, sorption to part to surface water, the pH m buffer capacity of the wat nting shifts in acidity or alk xide (CO2), the bicarbona	hay increase, depending er, the lower the effect calinity in natural waters ate ion (HCO3-) and the					
Exposure concentration in sediments		n magnesium oxide is emi	ES, because it is not cons tted to the aquatic compar						
Exposure concentrations in soil and groundwater	be relevant.		exposure scenario, becau						
Exposure concentration in atmospheric compartment	substance: when emitted result of its reaction with calcium(bi)carbonate) are	I to air as an aerosol in wa CO2 (or other acids), into	ecause it is considered no ater, calcium magnesium of HCO3- and Ca2+. Subse and thus the atmospheric up in soil and water.	oxide is neutralised as a equently, the salts (e.g.					
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organ poisoning is therefore no		ne substance: a risk asse	ssment for secondary					



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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 (<u>www.ebrc.de/mease.html</u>) 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 dusty".

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the calcium magnesium oxide 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.

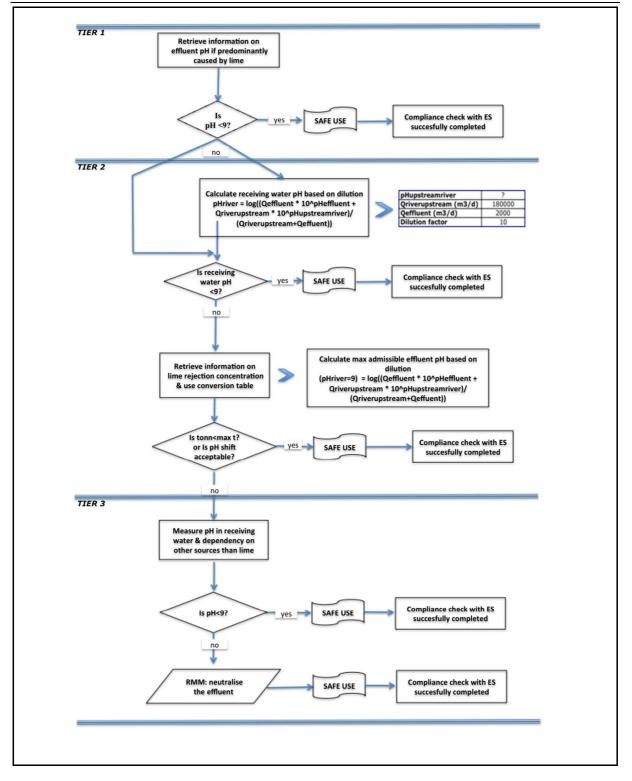
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences 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: 3.0/EN

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

Exposure Scenari	o Format (1) addressing uses carried o	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	SU14, SU15, SU16, SU17, SL PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC34, PC35, PC36, PC AC1, AC2, AC3, AC4, AC5, AC6	6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, J18, SU19, SU20, SU23, SU24 , PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC27, PC28, PC29, PC30, PC31, PC32, PC33, C37, PC38, PC39, PC40 6, AC7, AC8, AC10, AC11, AC13 is 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 ba	used on the exposure estimation tool MEASE.				
2. Operational con	ditions and risk management measure	es				
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					
PROC 7	Industrial spraying					
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	Further information is provided in the ECHA Guidance on information requirements and				
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).				
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					
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					



Version: 2.0/EN				
Version: 3.0/EN Revision date: June/201	7		Drinting [Date: December 10, 2021
PROC 22	Potentially closed proc minerals/metals at e Industria	levated temperature		ate. Detember 10, 2021
PROC 23	Open processing and the minerals/metals at e	ransfer operations with levated temperature		
PROC 24	High (mechanical) energ bound in materia			
PROC 25	Other hot work ope			
PROC 26	Handling of solid inor ambient te			
PROC 27a	Production of metal po	wders (hot processes)		
PROC 27b	Production of metal por	wders (wet processes)		
ERC 1-7, 12	Manufacture, formula industri			
ERC 10, 11	Wide-dispersive outdoor life articles a	and indoor use of long-		
2.1 Control of worl	kers exposure			
Product characteristic				
is reflected by an assign at ambient temperature t temperature based, takir	approach, the substance ment of a so-called fugacit he fugacity is based on th ig into account the proces d on the level of abrasion i	ty class in the MEASE too e dustiness of that substa s temperature and the me nstead of the substance in	I. For operations conducton nce. Whereas in hot meta elting point of the substance	ed with solid substances Il operations, fugacity is ce. As a third group, high
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not res	tricted	solid/powder, molten	high
PROC 24	not res	tricted	solid/powder	high
All other applicable PROCs	not res	tricted	solid/powder	low
Amounts used				
combination of the scale	ndled per shift is not con- e of operation (industrial minant of the process intri	vs. Professional) and lev	exposure as such for thi el of containment/automa	s scenario. Instead, the tion (as reflected in the
Frequency and duratio	n of use/exposure			
PROC		Duration o	f exposure	
PROC 22		≤ 240 n	ninutes	
All other applicable PROCs		480 minutes (not restricted)	
Human factors not influ	uenced by risk managem	nent		
The shift breathing volum	ne during all process steps	s reflected in the PROCs i	is assumed to be 10 m ³ /sl	nift (8 hours).
Other given operationa	I conditions affecting we	orkers exposure		
assessment of the conduction exposure assessment in temperatures are expect	ke process temperature ar ucted processes. In process MEASE is however based ed to vary within the indus us all process temperature	ss steps with considerably d on the ratio of process to stry the highest ratio was t	 high temperatures (i.e. P emperature and melting p aken as a worst case ass 	ROC 22, 23, 25), the oint. As the associated umption for the

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

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



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Technical conditions a	nd 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	general ventilation	17 %	-				
PROC 19	emission source is indicated above under	not applicable	na	-				
PROC 22, 23, 24, 25, 26, 27a	"Frequency and duration of exposure".	local exhaust ventilation	78 %	-				
All other applicable PROCs	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 measur	es to prevent /limit relea	ses, dispersion and exp	oosure					
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 measur	res related to personal p		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 All other applicable PROCs	FFP1 mask not required	APF=4	Since calcium magnesium oxide 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.				
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.								



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Revision date: June/2017

Frequency and duration of use

Printing Date: December 10, 2021

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium magnesium oxide 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)	irritating to skin, derm minimised as far as tech for dermal effects has r	um oxide is classified as al exposure has to be nnically feasible. A DNEL not been derived. Thus, not assessed in this scenario.

Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium magnesium oxide 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+ and Mg2+ 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 magnesium oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium magnesium oxide. 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 magnesium oxide can potentially result in an aquatic emission and locally increase the calcium and magnesium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium magnesium oxide 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 magnesium oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium magnesium oxide 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.



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Exposure concentration in aquatic pelagic compartment	When calcium magnesium oxide 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 magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide 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 magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: 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	
(www.ebrc.de/mease.htm according to the MEASE Method (RDM) are define and substances with a de DNELinhalation: 1 m Important note: The DU I exists at a level of 4 mg/r acute DNEL is therefore term exposure estimates	are not available, the DU may make use of an appropriate scaling tool such as MEASE <u>ml</u>) to estimate the associated exposure. The dustiness of the substance used can be determined i glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum ed as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" ustiness ≥10 % are defined as "high dusty". ug/m ³ (as respirable dust) has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects m ³ . By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long- is by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of
Environmental exposu	re
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 magnesium oxide 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:	
$pHriver = Log \left[\frac{Qd}{dt}\right]$	$\frac{effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent}$ (Eq 1)
Where:	
Q effluent refe	rs to the effluent flow (in m³/day)
	am refers to the upstream river flow (in m³/day)
pH effluent ref	ers to the pH of the effluent

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



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

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

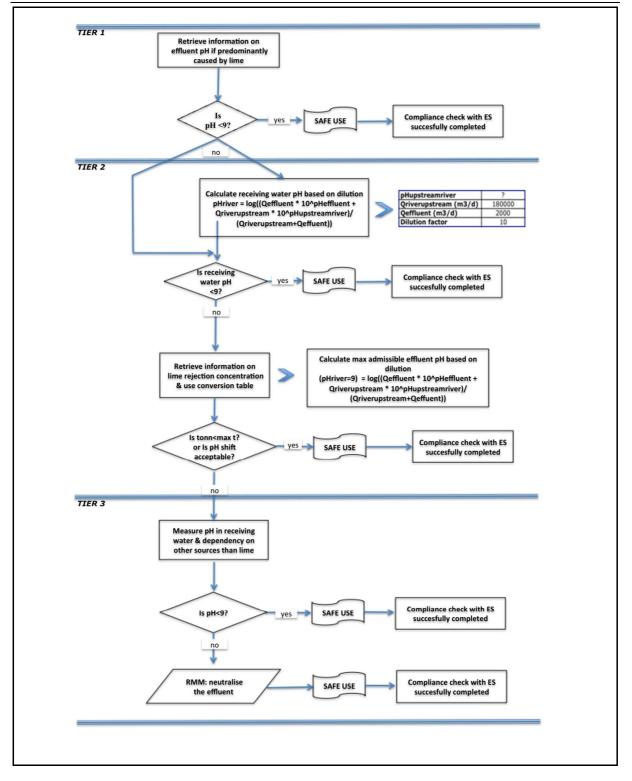
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences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

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



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Revision date: June/2017

Printing Date: December 10, 2021

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

Exposure Scenari	o Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Manufacture and industrial uses of mediu	m 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 cov	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is ba	used on the exposure estimation tool MEASE.		
2. Operational con	ditions and risk management measure	es		
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			
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 Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).		
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			
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			



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/ersion: 3.0/EN				
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PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles			
PROC 25	Other hot work ope	erations with metals		
PROC 26	5	rganic substances at emperature		
PROC 27a	Production of metal po	owders (hot processes)		
PROC 27b	Production of metal po	wders (wet processes)		
ERC 1-7, 12	industri	ation and all types of ial uses		
ERC 10, 11		r and indoor use of long- and materials		
2.1 Control of wor	kers exposure			
Product characteristic				
is reflected by an assign at ambient temperature t temperature based, takin	ment of a so-called fugaci the fugacity is based on th ng into account the proces	 intrinsic emission potenti- ity class in the MEASE toon the dustiness of that substations temperature and the me instead of the substance in 	I. For operations conduct ince. Whereas in hot meta elting point of the substand	ed with solid substances al operations, fugacity is ce. As a third group, high
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not res	stricted	solid/powder, molten	high
PROC 24	not res	stricted	solid/powder	high
All other applicable PROCs	not res	stricted	solid/powder	medium
Amounts used				
combination of the scale		isidered to influence the vs. Professional) and lev insic emission potential.		
Frequency and duratio	n of use/exposure			
PROC		Duration of	f exposure	
PROC 7, 17, 18, 19, 22		≤ 240 n	ninutes	
All other applicable PROCs	480 minutes (not restricted)			
Human factors not infl	uenced by risk managen	nent		
The shift breathing volur	ne during all process step	s reflected in the PROCs i	is assumed to be 10 m³/s	hift (8 hours).
Other given operationa	al conditions affecting w	orkers exposure		
assessment of the conductive exposure assessment in temperatures are expected.	ucted processes. In proces MEASE is however base ted to vary within the indus	nd process pressure are n ss steps with considerably d on the ratio of process te stry the highest ratio was t es are automatically cover	 high temperatures (i.e. F emperature and melting p aken as a worst case ass 	PROC 22, 23, 25), the point. As the associated sumption for the
Technical conditions a	nd measures at process	level (source) to preven	nt release	
Risk management meas	ures at the process level ((e.g. containment or segre	gation of the emission so	urce) are generally not

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



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Technical conditions a	nd 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 separation of	not required	na	-
PROC 3, 13, 14	workers from the	general ventilation	17 %	-
PROC 19	emission source is indicated above under	not applicable	na	-
All other applicable PROCs	"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 measur	es to prevent /limit relea	ses, dispersion and exp	oosure	
These measures involve eating and smoking at the and change clothes at er	e good personal and hous e workplace, the wearing on nd of work shift. Do not we	ekeeping practices (i.e. re if standard working clothes ar contaminated clothing	equired to ensure a safe h egular cleaning with suital s and shoes unless otherw at home. Do not blow dus	ole cleaning devices), no ise stated below. Shower
Conditions and measured	res related to personal p		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) must
All other applicable PROCs	not required	na	Since calcium magnesium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.
(compare with "duration breathing resistance and shall be considered that For reasons as given ab the use of RPE), (ii) have hair). The recommended the contours of the face The employer and self-e devices and the manage policy for a respiratory pr	of exposure" above) shou I mass of the RPE itself, d the worker's capability of ove, the worker should the e suitable facial characteri I devices above which rely properly and securely. mployed persons have leg ment of their correct use i rotective device programm	Id reflect the additional ph ue to the increased therm using tools and of commu erefore be (i) healthy (esp stics reducing leakages b v on a tight face seal will n gal responsibilities for the n the workplace. Therefor he including training of the	implemented in parallel: T aysiological stress for the v aal stress by enclosing the inicating are reduced durir ecially in view of medical etween face and mask (in not provide the required pr maintenance and issue of re, they should define and workers. an be found in the glossar	he duration of work worker due to the head. In addition, it ng the wearing of RPE. problems that may affect view of scars and facial otection unless they fit respiratory protective document a suitable
2.2 Control of envi	ronmental exposur	e		
Amounts used				
The daily and annual an exposure.	mount per site (for point	sources) is not consider	ed to be the main deterr	ninant for environmental



Version: 3.0/EN

Revision date: June/2017

Frequency and duration of use

Printing Date: December 10, 2021

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium magnesium oxide 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)	Since calcium magnesium oxide is classifie irritating to skin, dermal exposure has to l minimised as far as technically feasible. A D for dermal effects has not been derived. Th 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 magnesium oxide 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+ and Mg2+ 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 magnesium oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium magnesium oxide. 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 magnesium oxide can potentially result in an aquatic emission and locally increase the calcium and magnesium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium magnesium oxide 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 magnesium oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium magnesium oxide 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.				



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PRODUCT SAFETY DATA SHEET for CaMgO2 prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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Exposure concentration in aquatic pelagic compartment	When calcium magnesium oxide 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 magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide 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 magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: 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
Occurrentie nel extreeurs	

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 (<u>www.ebrc.de/mease.html</u>) 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 "medium dusty" and substances with a dustiness less than 10 % (RDM) are defined as "medium dusty"

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

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



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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 magnesium oxide 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.

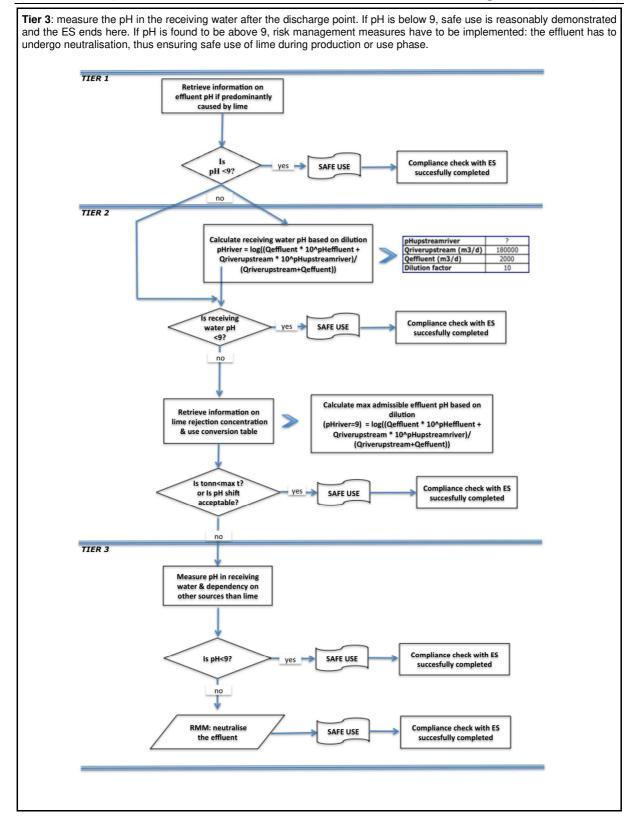
Such equation has to be seen as a worst case scenario, where water conditions are standard and not case specific.

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 magnesium oxide.



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

Exposure Scenari	o Format (1) addressing uses carried o	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 cov	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.		
2. Operational con	ditions and risk management measure	es		
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			
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 Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).		
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			
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			



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Revision date. June/201	-	y work-up of substances		Jate. December 10, 2021
PROC 24	bound in materia			
PROC 25	Other hot work ope	erations with metals		
PROC 26		rganic substances at emperature		
PROC 27a	Production of metal po	wders (hot processes)		
PROC 27b	Production of metal po	wders (wet processes)		
ERC 1-7, 12		ation and all types of ial uses		
ERC 10, 11		r and indoor use of long- Ind materials		
2.1 Control of world	kers exposure			
Product characteristic				
is reflected by an assign at ambient temperature t temperature based, takir	ment of a so-called fugaci he fugacity is based on th ng into account the proces	ty class in the MEASE too the dustiness of that substa the temperature and the me to the substance instead of the substan	al is one of the main expo ol. For operations conduct ince. Whereas in hot meta elting point of the substand ntrinsic emission potential	ed with solid substances al operations, fugacity is ce. As a third group, high
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not res	stricted	solid/powder, molten	high
All other applicable PROCs	not res	stricted	solid/powder	high
Amounts used				
combination of the scale		. Professional) and level of	osure as such for this scer of containment/automatior	
Frequency and duratio	n of use/exposure			
PROC		Duration o	f exposure	
PROC 7, 8a, 17, 18, 19, 22		≤ 240 r	ninutes	
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influ	uenced by risk managen	nent		
The shift breathing volum	ne during all process step	s reflected in the PROCs	is assumed to be 10 m³/sl	hift (8 hours).
Other given operationa	I conditions affecting w	orkers exposure		
assessment of the conductive exposure assessment in temperatures are expected.	ucted processes. In proce MEASE is however base ed to vary within the indus	ss steps with considerably d on the ratio of process t stry the highest ratio was t	not considered relevant for high temperatures (i.e. P emperature and melting p taken as a worst case ass red in this exposure scena	ROC 22, 23, 25), the oint. As the associated umption for the
Technical conditions a	nd measures at process	level (source) to prever	nt release	
D' 1				

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



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Technical conditions a	nd 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 separation of workers from the	not required	na	-
PROC 2, 3	emission source is indicated above under	general ventilation	17 %	-
PROC 7	"Frequency and duration of exposure".	integrated local exhaust ventilation	84 %	-
PROC 19	A reduction of exposure duration can be achieved, for	not applicable	na	-
All other applicable PROCs	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 measur	es to prevent /limit relea	ses, dispersion and exp	oosure	
substance. These measu devices), no eating and s	ures involve good persona smoking at the workplace,	al and housekeeping pract the wearing of standard v	equired to ensure a safe h tices (i.e. regular cleaning working clothes and shoes hinated clothing at home.	with suitable cleaning sunless otherwise stated
Conditions and measu	res related to personal p	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		Eye protection equipment (e.g.
PROC 4, 5, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		goggles or visors) must be worn, unless
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4	Since calcium magnesium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.
(compare with "duration breathing resistance and shall be considered that For reasons as given abo the use of RPE), (ii) have hair). The recommended the contours of the face The employer and self-e devices and the manage policy for a respiratory pin An overview of the APFs	of exposure ⁷ above) shou I mass of the RPE itself, d the worker's capability of ove, the worker should the e suitable facial characteri I devices above which rely properly and securely. mployed persons have leg ment of their correct use i rotective device programm of different RPE (accordi	Id reflect the additional ph ue to the increased therm using tools and of commu erefore be (i) healthy (esp stics reducing leakages b of on a tight face seal will n gal responsibilities for the n the workplace. Therefor he including training of the ng to BS EN 529:2005) ca	implemented in parallel: T sysiological stress for the v lal stress by enclosing the nicating are reduced durin ecially in view of medical etween face and mask (in lot provide the required pr maintenance and issue of re, they should define and e workers. an be found in the glossar	worker due to the head. In addition, it ng the wearing of RPE. problems that may affect view of scars and facial otection unless they fit respiratory protective document a suitable
2.2 Control of envi	ronmental exposur	e		
Amounts used				
The daily and annual a	mount per site (for point	sources) is not consider	ed to be the main deterr	ninant for environmental

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



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Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m3/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium magnesium oxide 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)	Since calcium magnesium oxide is classif irritating to skin, dermal exposure has to minimized as far as technically feasible. A	

Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium magnesium oxide 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+ and Mg2+ 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 very low vapour pressure indicate that calcium magnesium oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium magnesium oxide. 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 performant 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 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 magnesium oxide can potentially result in an aquatic emission and locally increase the calcium and magnesium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium magnesium oxide 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 magnesium oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium magnesium oxide 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.



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Exposure concentration in aquatic pelagic						
compartment	When calcium magnesium oxide 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					
Exposure concentrations in soil and groundwater	s in soil The terrestrial compartment is not included in this exposure scenario, because it is not considered t					
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide 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 magnesium oxide largely end up in soil and water.					
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: 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						
(www.ebrc.de/mease.htm according to the MEASE Method (RDM) are define and substances with a du DNELinhalation: 1 m	are not available, the DU may make use of an appropriate scaling tool such as MEASE <u>ml</u>) to estimate the associated exposure. The dustiness of the substance used can be determined glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum ed as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" ustiness ≥10 % are defined as "high dusty". ug/m ³ (as respirable dust)					
Important note: The DU I exists at a level of 4 mg/i acute DNEL is therefore	has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effect m ³ . By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long					
term exposure estimates	s by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the					
exposure duration should	by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the donly be reduced to half-shift as a risk management measure (leading to an exposure reduction of					
exposure duration should 40 %).	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of					
exposure duration should 40 %). Environmental exposure If a site does not comply	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spec Tier 1: retrieve information the pH be above 9 and b	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of re with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use.					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spec Tier 1: retrieve information the pH be above 9 and b Tier 2a: retrieve information the value of 9. If the mean	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of re with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows:					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spec Tier 1: retrieve information the pH be above 9 and b Tier 2a: retrieve information the value of 9. If the mean	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of re with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows:					
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exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spec Tier 1: retrieve information the pH be above 9 and b Tier 2a: retrieve information the value of 9. If the mean	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of re with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows: $effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}$ $Qriverupstream + Qeffluent$					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spec Tier 1: retrieve information the pH be above 9 and b Tier 2a: retrieve information the value of 9. If the mean $pHriver = Log \boxed{Qe}$ Where:	d only be reduced to half-shift as a risk management measure (leading to an exposure reduction of re with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows: $effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}$ $Qriverupstream + Qeffluent$					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-spece Tier 1: retrieve information the pH be above 9 and b Tier 2a: retrieve information the value of 9. If the mean $pHriver = Log \boxed{\frac{Qe}{Qe}}$ Where: Q effluent refe Q river upstread	with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows: $effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}$ $Qriverupstream + Qeffluent$ $(Eq 1)$ are to the effluent flow (in m ³ /day) are refers to the upstream river flow (in m ³ /day)					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-specent Tier 1: retrieve information the pH be above 9 and be Tier 2a: retrieve information the value of 9. If the mean $pHriver = Log \boxed{\frac{Qe}{Qe}}$ Where: Q effluent refered Q river upstreat pH effluent refered	with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows: $effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}$ $(Eq 1)$ where the effluent flow (in m³/day) are refers to the upstream river flow (in m³/day) ters to the pH of the effluent					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-specent Tier 1: retrieve information the pH be above 9 and be Tier 2a: retrieve information the value of 9. If the mean $pHriver = Log Qe \\ Qe \\ Qe \\ Qe \\ Qe \\ Qe \\ PHere: \\ Qe ffluent refeent pH effluent refeent pH upstream refeent pH upstream refeent pH upstream refeent PH referent PH $	The preduced to half-shift as a risk management measure (leading to an exposure reduction of the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. The predominantly attributable to lime, then further actions are required to demonstrate safe use. The predominantly attributable to lime, then further actions are required to demonstrate safe use. The provide assessment are not available, the pH in the river can be calculated as follows: $\frac{effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent}$					
exposure duration should 40 %). Environmental exposure If a site does not comply perform a more site-specent Tier 1: retrieve information the pH be above 9 and be Tier 2a: retrieve information the value of 9. If the mean $pHriver = Log \left[\underbrace{Qe}_{ret} \right]$ Where: Q effluent refer Q river upstream refer pH upstream refer Please note the	with the conditions stipulated in the safe use ES, it is recommended to apply a tiered approach to cific assessment. For that assessment, the following stepwise approach is recommended. on on effluent pH and the contribution of the calcium magnesium oxide on the resulting pH. Should be predominantly attributable to lime, then further actions are required to demonstrate safe use. tion on receiving water pH after the discharge point. The pH of the receiving water shall not exceed asures are not available, the pH in the river can be calculated as follows: $\frac{effluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent}$ (Eq 1) are to the effluent flow (in m³/day) are refers to the upstream river flow (in m³/day) ters to the pH of the effluent					



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• 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.

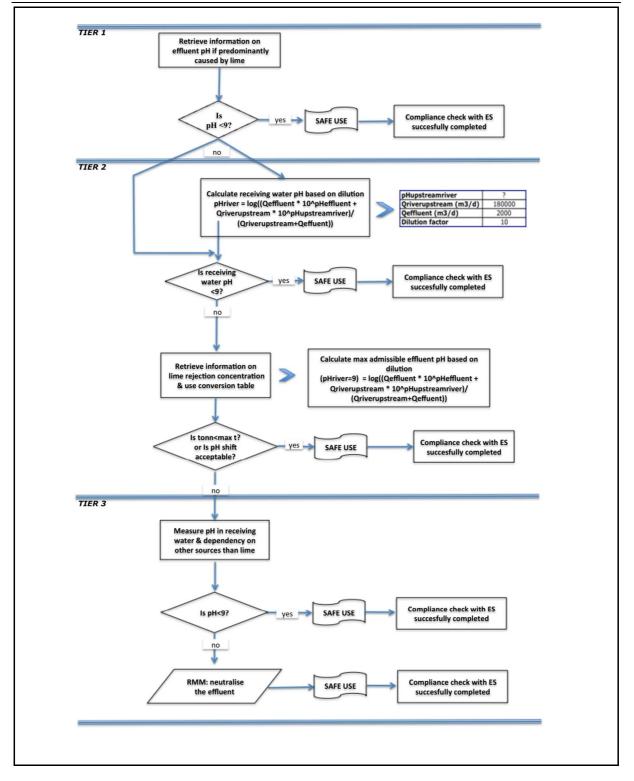
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences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

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



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

1. Title					
Free short title	Manufacture a	and industrial uses of mas	sive objects containing lin		
Systematic title based on use descriptor	Manufacture and industrial uses of massive objects containing lime substances 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 ba	sed on the exposure estin	nation tool MEASE.	
2. Operational con	ditions and risk ma	nagement measure	es		
PROC/ERC	REACH	definition	Involve	d tasks	
PROC 6	Calendering				
PROC 14	tabletting, compression		Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 21		nd/or articles			
PROC 22	minerals/metals at e Industria				
PROC 23	Open processing and t minerals/metals at e	ransfer operations with levated temperature			
PROC 24	High (mechanical) energ bound in materia	y work-up of substances			
PROC 25	Other hot work ope	erations with metals			
ERC 1-7, 12	industri				
ERC 10, 11	Wide-dispersive outdoor and indoor use of long- life articles and materials				
2.1 Control of wor	kers exposure				
Product characteristic					
is reflected by an assign at ambient temperature t temperature based, takir	ment of a so-called fugaci he fugacity is based on th ng into account the proces	ty class in the MEASE too e dustiness of that substa s temperature and the me instead of the substance i	al is one of the main expo ol. For operations conducto ince. Whereas in hot meta elting point of the substance ntrinsic emission potential	ed with solid substance I operations, fugacity is ce. As a third group, hig	
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential	
PROC 22, 23,25	not res	stricted	massive objects, molten	high	
PROC 24	not res	stricted	massive objects	high	
All other applicable PROCs	not res	stricted	massive objects	very low	
Amounts used					
combination of the scale	of operation (industrial vs		osure as such for this scen of containment/automatior		



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compressed air.

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Frequency and duration	n of use/exposure			
PROC		Duration of	f exposure	
PROC 22		≤ 240 n	ninutes	
All other applicable PROCs		480 minutes (not restricted)	
Human factors not influ	uenced by risk managem	ient		
The shift breathing volun	ne during all process steps	s reflected in the PROCs i	s assumed to be 10 m ³ /s	hift (8 hours).
Other given operationa	al conditions affecting wo	orkers exposure		
assessment of the conduction exposure assessment in temperatures are expect	ke process temperature ar ucted processes. In proces MEASE is however based ted to vary within the indus us all process temperature	s steps with considerably d on the ratio of process to try the highest ratio was t	high temperatures (i.e. F emperature and melting p aken as a worst case ass	PROC 22, 23, 25), the point. As the associated sumption for the
Technical conditions a	nd measures at process	level (source) to preven	nt release	
Risk management meas required in the processes	sures at the process level s.	(e.g. containment or segr	regation of the emission s	source) are generally not
Technical conditions a	nd measures to control o	dispersion from source	towards the worker	
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of	not required	na	-
PROC 22, 23, 24, 25	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.	local exhaust ventilation	78 %	-
Organisational measur	es to prevent /limit relea	ses, dispersion and exp	osure	
substance. These measu devices), no eating and s	tion. General occupationa ures involve good persona smoking at the workplace, nge clothes at end of work	I and housekeeping pract the wearing of standard v	ices (i.e. regular cleaning vorking clothes and shoes	with suitable cleaning s unless otherwise stated



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	res related to personal p		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	FFP1 mask	APF=4	Since calcium magnesium oxide 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.	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 <u>appropriate</u> .			
(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.							
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 no	ot influenced by risk ma	nagement					
Flow rate of receiving su	rface water: 18000 m³/day	/					
Other given operationa	I conditions affecting er	nvironmental exposure					
Effluent discharge rate: 2000 m³/day							
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil							
Technical onsite condi	tions and measures to r	educe or limit discharge	s, air emissions and rel	eases to soil			
Risk management measures to surface water, in case during introduction into o receiving surface waters values in the range of 6-9	ures related to the enviror such discharges are expo pen waters is required. In are minimised (e.g. throu 9. This is also reflected in	nment aim to avoid discha ected to cause significant general discharges shoul gh neutralisation). In gene	rging lime solutions into n pH changes. Regular con ld be carried out such that eral most aquatic organisn rd OECD tests with aquati	nunicipal wastewater or trol of the pH value pH changes in ns can tolerate pH			
Risk management measures to surface water, in case during introduction into o receiving surface waters values in the range of 6-9	ures related to the enviror such discharges are expe pen waters is required. In are minimised (e.g. throu 9. This is also reflected in nanagement measure can	ment aim to avoid discha ected to cause significant general discharges shoul gh neutralisation). In gene the description of standar	rging lime solutions into n pH changes. Regular con ld be carried out such that eral most aquatic organisn rd OECD tests with aquati	nunicipal wastewater or trol of the pH value pH changes in ns can tolerate pH			



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3. Exposure estimation and reference to its source								
Occupational exposure	Occupational exposure							
(RCR) is the quotient of 1 to demonstrate a safe mg/m ³ (as respirable dus	tool MEASE was used fo the refined exposure estim use. For inhalation exposu st) and the respective inha ditional safety margin since	nate and the respective D ure, the RCR is based on lation exposure estimate	NEL (derived no-effect lev the DNEL for calcium mag derived using MEASE (as	rel) and has to be below gnesium oxide of 1 inhalable dust). Thus,				
PROC	Method used for inhalation exposure assessment	inhalation exposure Inhalation exposure dermal exposure estimate (BCB)						
PROC 6, 14, 21, 22, 23, 24, 25	MEASE < 1 mg/m³ (0.01 – 0.44) Since calcium magnesium oxide 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 emissio	ons							
STPs/WWTPs, as emissions of calcium magnesium oxide 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+ and Mg2+ 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 magnesium oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium magnesium oxide. 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 magnesium oxide can potentially result in an aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium magnesium oxide 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 magnesium oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium magnesium oxide 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 magnesium oxide 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 magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.							
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.							
Exposure concentration in atmospheric compartment	magnesium oxide: when neutralised as a result of Subsequently, the salts (emitted to air as an aeros its reaction with CO2 (or e.g. calcium(bi)carbonate	ecause it is considered no sol in water, calcium magr other acids), into HCO3- a are washed out from the gnesium oxide largely end	nesium oxide is and Ca2+. e air and thus the				
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in orgar secondary poisoning is th		alcium magnesium oxide:	a risk assessment for				



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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 (<u>www.ebrc.de/mease.html</u>) 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"

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the calcium magnesium oxide 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.

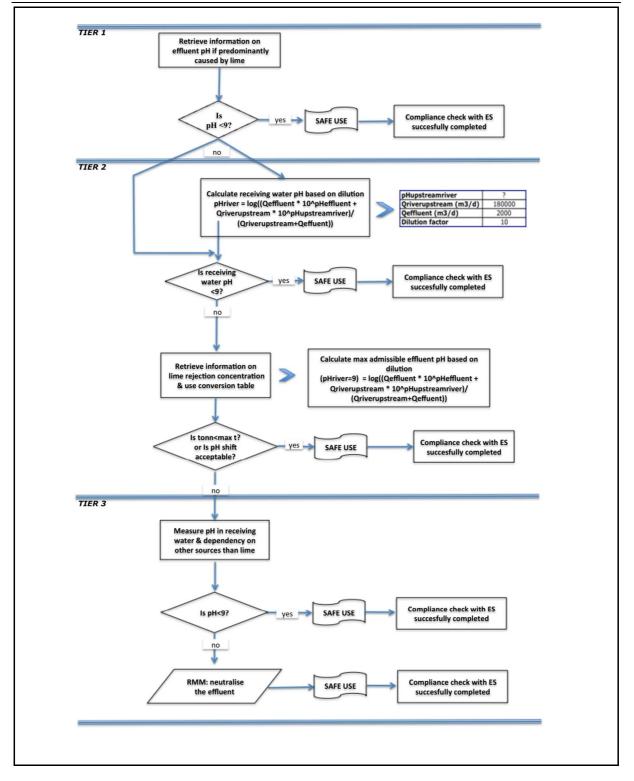
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences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

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



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

Exposure Scenari	o Format (1) addressing uses carried o	out by workers			
1. Title					
Free short title	Professional uses of aqueous	s 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 activities cov	ered are described in Section 2 below.			
Assessment Method		d on the exposure estimation tool MEASE. The sased on FOCUS-Exposit.			
2. Operational con	ditions and risk management measure	es			
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 Guidance on information requirements and chemical safety assessment, Chapter R.12: Use			
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).			
PROC 11	Non industrial spraying				
PROC 12	Use of blowing agents in manufacture of foam				
PROC 13	Treatment of articles by dipping and pouring				
PROC 15	Use as laboratory reagent				
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17	Lubrication at high energy conditions and in partly open process				
PROC 18	Greasing at high energy conditions				
PROC 19	Hand-mixing with intimate contact and only PPE available				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Calcium magnesium oxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.			



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2.1 Control of workers exposure							
Product characteristic							
is reflected by an assign at ambient temperature t temperature based, takin abrasive tasks are based	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 res		aqueous solution	very low			
Amounts used							
combination of the scale	dled per shift is not conside of operation (industrial vs minant of the process intri	. professional) and level o					
Frequency and duratio	n of use/exposure						
PROC		Duration of	f exposure				
PROC 11		≤ 240 n	ninutes				
All other applicable PROCs		480 minutes (not restricted)				
Human factors not influ	uenced by risk managen	nent					
The shift breathing volun	ne during all process steps	s reflected in the PROCs i	is assumed to be 10 m ³ /sl	nift (8 hours).			
• •	I conditions affecting we	• • • • • • • • • • • • • • • • • • •					
	s are not used in hot-met ot considered relevant for						
Technical conditions and measures at process level (source) to prevent release							
Risk management meas required in the processes	sures at the process level s.	(e.g. containment or segr	regation of the emission s	source) are generally not			
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.						
Organisational measures to prevent /limit releases, dispersion and exposure							
substance. These measu devices), no eating and s	Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with						

compressed air.



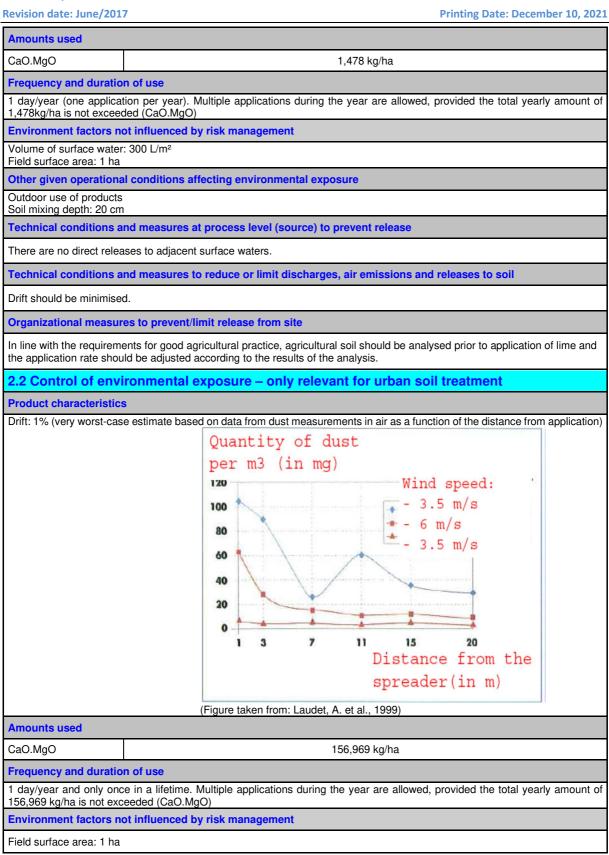
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Conditions and measures related to personal protection, hygiene and health evaluation						
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)		
PROC 11	FFP3 mask	APF=20	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with		
PROC 17	FFP1 mask	APF=4	magnesium oxide is classified as irritating to skin, the use of protective gloves is	the eye can be excluded by the nature and type of application (i.e. closed process).		
All other applicable PROCs	not required	na	mandatory for all process steps.	Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.		
breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE. 2.2 Control of environmental exposure – only relevant for agricultural soil protection Product characteristics Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application) Quantity of dust per m3 (in mg)						
	120 100 80 60 40 20 0 1	aken from: Laudet, A. et al	Distance fro spreader(in	m the		



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Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

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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.

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 magnesium oxide 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)	assessment estimate (RC	
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 magnesium oxide is classified irritating to skin, dermal exposure has to b minimised as far as technically feasible. A DN for dermal effects has not been derived. The 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 magnesium oxide 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	CaO.MgO	4.93	320	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	CaO.MgO	434	712	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium magnesium oxides can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca^{2+} and OH^{-}) in the environment.			



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Environmental exposure for urban soil treatment The urban soil treatment 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 See amounts used emissions Exposure concentration in waste water Not relevant for road border scenario treatment plant (WWTP) Exposure concentration in Not relevant for road border scenario aquatic pelagic compartment Exposure concentration in Not relevant for road border scenario sediments Exposure Substance PEC (mg/L) PNEC (mg/L) RCR concentrations in soil CaO.MgO 462 712 0.65 and groundwater Exposure concentration in This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below atmospheric 10⁻⁵ Pa. compartment Exposure concentration This point is not relevant because calcium can be considered to be omnipresent and essential in the relevant for the food environment. The uses covered do not significantly influence the distribution of the constituents chain (secondary (Ca²⁺ and OH⁻) in the environment. poisoning) 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 urban soil treatment Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water

- Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited
- Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.



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

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

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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of low dusty solids/powders of lime substances			
	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20,			
Systematic title based on use descriptor	SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.			
2. Operational con	ditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)			
PROC 10	Roller application or brushing	Further information is provided in the ECHA		
PROC 11	Non industrial spraying	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).		
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 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,	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			



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Revision date: June/201	n date: June/2017 Printing Date: D			Date: December 10, 2021	
ERC8d, ERC8e, ERC8f					
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 res	tricted	solid/powder, molten	high	
All other applicable PROCs	not res	tricted	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.					
Frequency and duratio	n of use/exposure				
PROC		Duration o	f exposure		
PROC 17	≤ 240 minutes				
All other applicable PROCs	480 minutes (not restricted)				
Human factors not influ	uenced by risk managen	nent			
The shift breathing volum	ne during all process steps	s reflected in the PROCs i	is assumed to be 10 m ³ /sh	nift (8 hours).	
	I conditions affecting we				
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.					
	nd measures at process	level (source) to prever	nt 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 a	nd measures to control	dispersion from source			
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".	not applicable	na	-	
All other applicable PROCs	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	-	



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Organisational measur	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 measu	res related to personal p	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. goggles or visors) must
All other applicable PROCs	not required	na	Since calcium magnesium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	b 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.
(compare with "duration breathing resistance and shall be considered that For reasons as given ab the use of RPE), (ii) hav hair). The recommended the contours of the face The employer and self- devices and the manage policy for a respiratory p	of exposure" above) shou d mass of the RPE itself, d the worker's capability of ove, the worker should the e suitable facial characterid d devices above which rely properly and securely. imployed persons have leg ment of their correct use is rotective device programm	Id reflect the additional ph lue to the increased therm using tools and of commu erefore be (i) healthy (esp stics reducing leakages b v on a tight face seal will n gal responsibilities for the in the workplace. Therefor he including training of the	implemented in parallel: T hysiological stress for the v nal stress by enclosing the unicating are reduced durin ecially in view of medical etween face and mask (in not provide the required pr maintenance and issue of re, they should define and e workers.	worker due to the head. In addition, it ng the wearing of RPE. problems that may affect view of scars and facial otection unless they fit respiratory protective document a suitable

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



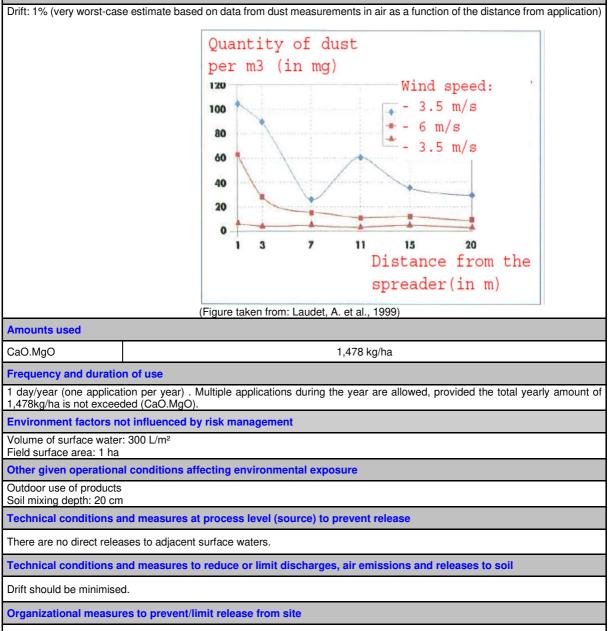
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2.2 Control of environmental exposure - only relevant for agricultural soil protection

Product characteristics

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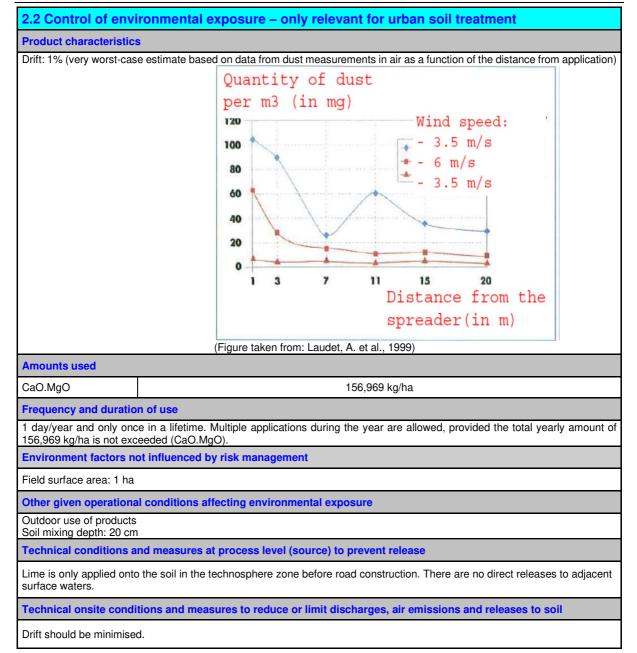
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



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PRODUCT SAFETY DATA SHEET for CaMgO2 prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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Revision date: June/2017

3. Exposure estimation	ation and reference	to its source		
Occupational exposure				
The exposure estimation (RCR) is the quotient of 1 to demonstrate a safe mg/m ³ (as respirable dusting)	tool MEASE was used for the refined exposure estin use. For inhalation exposi st) and the respective inha	nate and the respective D ure, the RCR is based on alation exposure estimate	ation exposure. The risk c NEL (derived no-effect lev the DNEL for calcium may derived using MEASE (as eing a sub-fraction of the i	rel) and has to be below gnesium oxide of 1 inhalable dust). Thus,
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 magnesium oxide 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 exposu	re for agricultural soil p	rotection		
included in the modelling basis of the German EXI applied on the soil, calcit Environmental emissions Exposure concentration in waste water treatment plant	bropriate for agricultural-like application as in this case where parameter as the drift needs to be g. FOCUS is a model typically developed for biocidal applications and was further elaborated on the POSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once um magnesium oxide can indeed migrate then towards surface waters, via drift. See amounts used Not relevant for agricultural soil protection			
(WWTP)				
Exposure concentration in	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
aquatic pelagic compartment	CaO.MgO	4.93	320	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	CaO.MgO	434	712	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution	



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Environmental exposure for urban soil treatment The urban soil treatment 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 See amounts used emissions Exposure concentration in waste water Not relevant for road border scenario treatment plant (WWTP) Exposure concentration in Not relevant for road border scenario aquatic pelagic compartment Exposure concentration in Not relevant for road border scenario sediments Exposure Substance PEC (mg/L) PNEC (mg/L) RCR concentrations in soil CaO.MgO 462 712 0.65 and groundwater Exposure concentration in This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below atmospheric 10⁻⁵ Pa. compartment Exposure concentration This point is not relevant because calcium can be considered to be omnipresent and essential in the relevant for the food environment. The uses covered do not significantly influence the distribution of the constituents chain (secondary (Ca²⁺ and OH⁻) in the environment. poisoning) 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 urban soil treatment Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water

Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited

Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.



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Revision date: June/2017

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

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

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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of medium dusty	v solids/powders of lime substances		
	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20 SU23, SU24			
Systematic title based on use descriptor	PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC34, PC35, PC36, AC1, AC2, AC3, AC4, AC5, AC6	, 5024 , PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC27, PC28, PC29, PC30, PC31, PC32, PC33, , PC37, PC39, PC40 5, AC7, AC8, AC10, AC11, AC13 s are given in Section 2 below)		
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.		
Assessment Method		ed on the exposure estimation tool MEASE. The is based on FOCUS-Exposit.		
2. Operational con	ditions and risk management measure	es		
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			
PROC 4	formulation) Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)			
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and		
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use		
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).		
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 25	Other hot work operations with metals			
PROC 26	Handling of solid inorganic substances at ambient temperature			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			



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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. Content in PROC Use in preparation Physical form Emission potential preparation solid/powder, PROC 25 not restricted high molten All other applicable not restricted solid/powder medium PROCs **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, ≤ 240 minutes 19 All other applicable 480 minutes (not restricted) PROCs 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 Efficiency of LC Localised controls PROC Level of separation (according to Further information (LC) MEASE) Any potentially generic local exhaust **PROC 11. 16** 72 % required separation of ventilation workers from the integrated local emission source is **PROC 17, 18** 87 % exhaust ventilation indicated above under "Frequency and PROC 19 not applicable na duration of exposure". A reduction of exposure duration can be achieved, for example, by the All other applicable installation of ventilated not required na PROCs (positive pressure) control rooms or by removing the worker from workplaces



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Revision date: June/2017 Printing Date: December 10, 2021 involved with relevant exposure. 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 Specification of **RPE** efficiency Further personal Specification of PROC respiratory protective (assigned protection protective equipment gloves <u>(P</u>PE) equipment (RPE) factor, APF) Eye protection PROC 2, 3, 16, 19 FFP1 mask APF=4 equipment (e.g. PROC 4, 5, 8a, 8b, 9, goggles or visors) must FFP2 mask APF=10 10, 13, 17, 18, 25, 26 be worn, unless Since calcium potential contact with magnesium oxide is the eye can be classified as irritating to excluded by the nature skin, the use of and type of application (i.e. closed process). protective gloves is PROC 11 FFP1 mask APF=10 Additionally, face mandatory for all process 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. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.



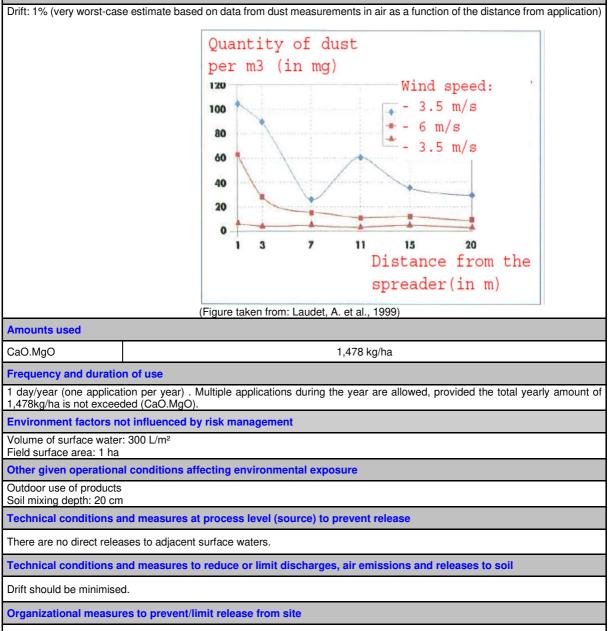
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2.2 Control of environmental exposure - only relevant for agricultural soil protection

Product characteristics

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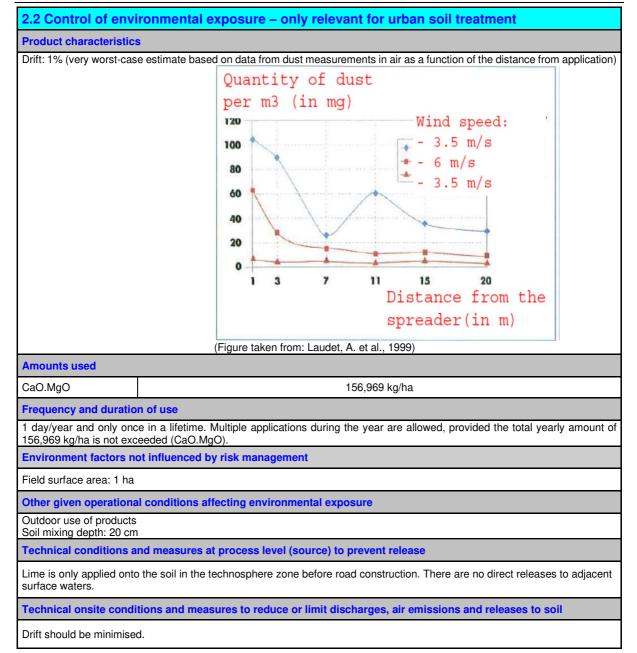
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



Revision date: June/2017

PRODUCT SAFETY DATA SHEET for CaMgO2 prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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3. Exposure estimation	ation and reference	to its source				
Occupational exposure)					
(RCR) is the quotient of 1 to demonstrate a safe mg/m ³ (as respirable dus	the refined exposure estin use. For inhalation exposi st) and the respective inha	nate and the respective D ure, the RCR is based on alation exposure estimate	ation exposure. The risk c NEL (derived no-effect lev the DNEL for calcium may derived using MEASE (as eing a sub-fraction of the i	rel) and has to be below gnesium oxide of 1 inhalable dust). Thus,		
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m³ (0.25 – 0.825)	Since calcium magnesiu irritating to skin, derm minimised as far as tech for dermal effects has r dermal exposure is exposure	al exposure has to be nically feasible. A DNEL not been derived. Thus, not assessed in this		
Environmental exposu	re for agricultural soil pi	rotection				
EUSES as it is more app included in the modelling basis of the German EX	propriate for agricultural-lik g. FOCUS is a model typic POSIT 1.0 model, where p um magnesium oxide can See amounts used	Ater and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the ropriate for agricultural-like application as in this case where parameter as the drift needs to be I. FOCUS is a model typically developed for biocidal applications and was further elaborated on the POSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once Immagnesium oxide can indeed migrate then towards surface waters, via drift. See amounts used				
(WWTP)			Γ			
Exposure concentration in	Substance	PEC (ug/L)	PNEC (ug/L)	RCR		
aquatic pelagic compartment	CaO.MgO	4.93	320	0.015		
Exposure concentration in sediments	natural waters the hydro: by reacting with Ca2+. T	xide ions react with HCO3		CO32- forms CaCO3 the sediment. Calcium		
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	CaO.MgO	434	712	0.61		
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution			



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Environmental exposure for urban soil treatment The urban soil treatment 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 See amounts used emissions Exposure concentration in waste water Not relevant for road border scenario treatment plant (WWTP) Exposure concentration in Not relevant for road border scenario aquatic pelagic compartment Exposure concentration in Not relevant for road border scenario sediments Exposure Substance PEC (mg/L) PNEC (mg/L) RCR concentrations in soil CaO.MgO 462 712 0.65 and groundwater Exposure concentration in This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below atmospheric 10⁻⁵ Pa. compartment Exposure concentration This point is not relevant because calcium can be considered to be omnipresent and essential in the relevant for the food environment. The uses covered do not significantly influence the distribution of the constituents chain (secondary (Ca²⁺ and OH⁻) in the environment. poisoning) 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 urban soil treatment Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water

Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited

Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.



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

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

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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers			
1. Title					
Free short title	Professional uses of high dusty solids/powders of lime substances				
	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24				
Systematic title based on use descriptor	PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC34, PC35, PC36, AC1, AC2, AC3, AC4, AC5, AC6	, 5024 , PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC27, PC28, PC29, PC30, PC31, PC32, PC33, , PC37, PC39, PC40 5, AC7, AC8, AC10, AC11, AC13 s are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.			
Assessment Method		ed on the exposure estimation tool MEASE. The s based on FOCUS-Exposit.			
2. Operational con	ditions and risk management measure	es			
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				
PROC 4	formulation) Use in batch and other process (synthesis) where opportunity for exposure arises				
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)				
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities				
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities				
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)				
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and			
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use			
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).			
PROC 15	Use as laboratory reagent				
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17	Lubrication at high energy conditions and in partly open process				
PROC 18	Greasing at high energy conditions				
PROC 19	Hand-mixing with intimate contact and only PPE available				
PROC 25	Other hot work operations with metals				
PROC 26	Handling of solid inorganic substances at ambient temperature				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems				



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2.1 Control of wor	kers exposure							
Product characteristic								
is reflected by an assign at ambient temperature temperature based, taki	E approach, the substance iment of a so-called fugaci the fugacity is based on th ng into account the proces d on the level of abrasion	ty class in the MEASE too the dustiness of that substa the stemperature and the me instead of the substance in	ol. For operations conduct ince. Whereas in hot meta elting point of the substan	al operations, fugacity is ce. As a third group, high				
PROC	Use in preparation	Use in preparation Content in preparation Physical form Emission potential						
All applicable PROCs	not res	stricted	solid/powder	high				
Amounts used								
combination of the scale	dled per shift is not consid e of operation (industrial ver rminant of the process intr	. professional) and level c						
Frequency and duration	on of use/exposure							
PROC		Duration o	f exposure					
PROC 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26		≤ 240 r	ninutes					
PROC 11		≤ 60 m	ninutes					
All other applicable PROCs		480 minutes (not restricted)					
Human factors not infl	uenced by risk manager	nent						
The shift breathing volu	me during all process step	s reflected in the PROCs i	is assumed to be 10 m ³ /s	hift (8 hours).				
Other given operation	al conditions affecting w	orkers exposure						
assessment of the cond exposure assessment in temperatures are expec	ike process temperature a ucted processes. In proce mMEASE is however base ted to vary within the indus us all process temperature	ss steps with considerably d on the ratio of process to stry the highest ratio was t	 high temperatures (i.e. F emperature and melting p aken as a worst case ass 	PROC 22, 23, 25), the point. As the associated sumption for the				
Technical conditions a	and measures at process	level (source) to prever	nt release					
Risk management meas required in the processe	sures at the process level	e.g. containment or segre	gation of the emission so	ource) are generally not				
	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	generic local exhaust ventilation	72 %	-				
PROC 17, 18	emission source is indicated above under	integrated local exhaust ventilation	87 %	-				
PROC 19	"Frequency and duration of exposure". A reduction of	"Frequency and duration of exposure". not applicable na rooms or outdo A reduction of (efficiency 50 °						
All other applicable PROCs	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	not required	na	-				



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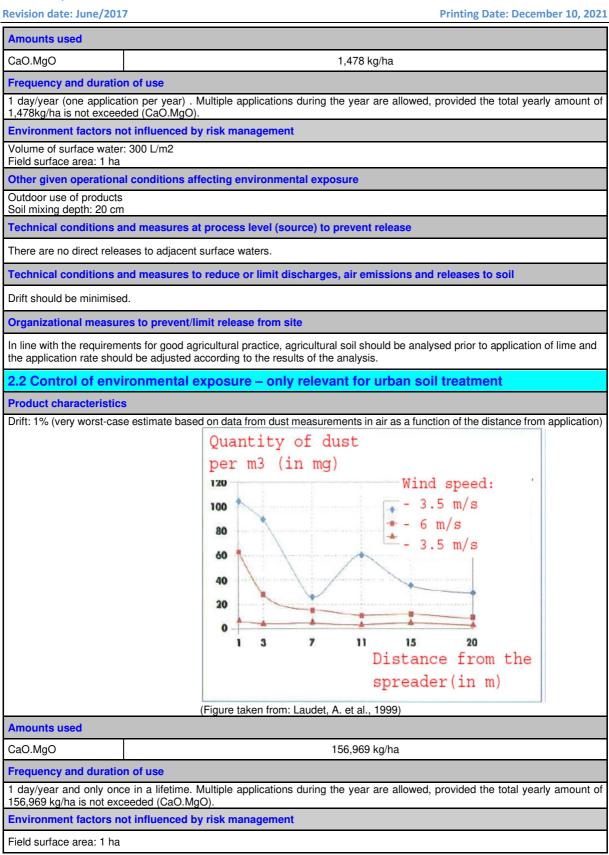
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Organisational measur	es to prevent /limit relea	ises, dispersion and exp	oosure	
substance. These measi devices), no eating and s	tion. General occupationa ures involve good persona smoking at the workplace, nge clothes at end of work	al and housekeeping pract	tices (i.e. regular cleaning working clothes and shoes	with suitable cleaning s unless otherwise stated
Conditions and measu	res related to personal p	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		Eye protection equipment (e.g.
PROC 11, 17, 18, 19	FFP3 mask	APF=20		goggles or visors) mus be worn, unless
PROC 25	FFP2 mask	APF=10	Since calcium magnesium oxide is	potential contact with the eye can be
All other applicable PROCs	FFP2 mask	APF=10	classified as irritating to skin, the use of protective gloves is mandatory for all process steps. exc and and protective 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.
devices and the manage policy for a respiratory p An overview of the APFs 2.2 Control of envi	mployed persons have lease ment of their correct use is rotective device programm of different RPE (according tronmental exposur	in the workplace. Therefor ne including training of the ng to BS EN 529:2005) ca	re, they should define and e workers. an be found in the glossar	document a suitable y of MEASE.
Product characteristics	s e estimate based on data			
	Quar	tity of dust m3 (in mg)	Wind speed - 3.5 m/s - 6 m/s - 3.5 m/s	n the
	(Figure ta	ken from: Laudet, A. et a		



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Other given operationa	I conditions affecting er	nvironmental exposure			
Outdoor use of products Soil mixing depth: 20 cm					
Technical conditions a	nd measures at process	level (source) to prever	nt release		
Lime is only applied onto surface waters.	the soil in the technosph	ere zone before road cons	struction. There are no dir	ect releases to adjacent	
Technical onsite condi	tions and measures to r	educe or limit discharge	es, air emissions and rel	eases to soil	
Drift should be minimise	d.				
3. Exposure estim	ation and reference	to its source			
Occupational exposure	•				
(RCR) is the quotient of 1 to demonstrate a safe mg/m ³ (as respirable due	the refined exposure estin use. For inhalation exposi st) and the respective inha	nate and the respective D ure, the RCR is based on alation exposure estimate	ation exposure. The risk c NEL (derived no-effect lev the DNEL for calcium may derived using MEASE (as eing a sub-fraction of the i	rel) and has to be below gnesium oxide of 1 inhalable dust). Thus,	
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)	Since calcium magnesiu irritating to skin, derm minimised as far as tech for dermal effects has r dermal exposure is exposure	al exposure has to be nically feasible. A DNEL not been derived. Thus, not assessed in this	
Environmental exposu	re for agricultural soil p	rotection			
guidance on the calculat ground water, surface w EUSES as it is more app included in the modelling basis of the German EX applied on the soil, calci	ion of predicted environm ater and sediment (Klosko propriate for agricultural-lik g. FOCUS is a model typic POSIT 1.0 model, where p	ental concentration values wksi et al., 1999). The FC a application as in this ca ally developed for biocida parameters such as drifts	bil group (FOCUS, 1996) a s (PEC) of plant protection OCUS/EXPOSIT modelling se where parameter as th applications and was fur can be improved accordin rds surface waters, via dr	products for soil, g tool is preferred to the e drift needs to be ther elaborated on the g to collected data: once	
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	CaO.MgO	4.93	320	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 CaO.MgO	PEC (mg/L) 434	PNEC (mg/L) 712	RCR 0.61	
Exposure concentration in atmospheric compartment	This point is not relevant 10 ⁻⁵ Pa.	. Calcium magnesium oxi	de is not volatile. The vap	our pressures is below	



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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 (Ca ²⁺ and OH ⁻) in the environment.					
Environmental exposu	re for urban soil treatme	ent				
September 5, 2003), EU can be defined as "the structure, operation and which includes the hard The road authority has re water management". Th purpose of the existing, environmental risk asses	The urban soil treatment 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.					
of predicted environmen sediment (Kloskowksi et for agricultural-like appli model typically develope where parameters such	ntal concentration values (t al., 1999). The FOCUS/E cation as in this case whe ed for biocidal applications	CUS soil group (FOCUS, 1 (PEC) of plant protection p EXPOSIT modelling tool is re parameter as the drift n and was further elaborater according to collected date	products for soil, ground v preferred to the EUSES leeds to be included in the d on the basis of the Gern	water, surface water and as it is more appropriate e modelling. FOCUS is a		
Environmental emissions	See amounts used					
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road bor	der scenario				
Exposure concentration in aquatic pelagic compartment	Not relevant for road bor	der scenario				
Exposure concentration in sediments	Not relevant for road bor	der scenario				
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	CaO.MgO	462	712	0.65		
Exposure concentration in atmospheric compartment		:. Calcium magnesium oxic	de is not volatile. The vap	our pressures is below		
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 $(Ca^{2+} \text{ and OH}^{-})$ in the environment.					
Environmental exposu	re 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 urban soil treatment 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, 			mai impacts beyond (nos			



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

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

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

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



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

Exposure Scenario	o Format (1) addres	sing uses carried o	ut by workers	
1. Title				
Free short title	F	Professional use of lime su	ubstances in soil treatmen	t
Systematic title based on use descriptor	(app	SU opriate PROCs and ERC	I22 s are given in Section 2 be	elow)
Processes, tasks and/or activities covered	Processes, t	asks and/or activities cove	ered are described in Sec	tion 2 below.
Assessment Method		lation exposure is based o tool M environmental assessmer	EASE.	
2. Operational con	ditions and risk ma	nagement measure	S	
Task/ERC	REACH	definition	Involve	d tasks
Milling	PRC)C 5		
Loading of spreader	PROC 8b,	PROC 26	Preparation and use o oxide for so	of calcium magnesium il treatment.
Application to soil (spreading)	PRO	C 11		
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	reactive substances or	or and outdoor use of processing aids in open ems	Calcium magnesium oxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming soil treatment and environmental protection.	
2.1 Control of worl	kers exposure			
Product characteristic				
is reflected by an assign at ambient temperature t temperature based, takir	approach, the substance ment of a so-called fugaci the fugacity is based on th ng into account the proces d on the level of abrasion	ty class in the MEASE too e dustiness of that substa s temperature and the me nstead of the substance in	I. For operations conduct ince. Whereas in hot meta elting point of the substance	ed with solid substances al operations, fugacity is ce. As a third group, high
Task	Use in preparation	Content in preparation	Physical form	Emission potential
Milling	not res	stricted	solid/powder	high
Loading of spreader	not res	stricted	solid/powder	high
Application to soil (spreading)	not res	stricted	solid/powder	high
Amounts used				
combination of the scale	dled per shift is not consid of operation (industrial vs minant of the process intr	. professional) and level of		
Frequency and duratio	n of use/exposure			
Task		Duration o	f exposure	
Milling		240 m	inutes	
Loading of spreader		240 m	inutes	
Application to soil (spreading)		480 minutes (not restricted)	
Human factors not influ	uenced by risk managen	nent		
The shift breathing volum	ne during all process step	s reflected in the PROCs i	is assumed to be 10 m ³ /sł	nift (8 hours).



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Other given operational conditions affecting workers exposure					
	e.g. process temperature a f the conducted processes		not considered relevant	for occupational	
Technical conditions a	and measures at process	level (source) to preven	nt release		
Risk management meas required in the processe	sures at the process level (es.	e.g. containment or segre	gation of the emission so	urce) are generally not	
Technical conditions a	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	not required	na	-	
Loading of spreader	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 measu	res to prevent /limit relea	ises, dispersion and exp	osure		
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 measu	res related to personal p	protection, hygiene and h	nealth evaluation		

Conditions and medsa	obraniono una medodecio related to personal protection, nygiene una neutra 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	O'ana aki wa	Eye protection equipment (e.g. goggles or visors) must be worn, unless		
Loading of spreader	FFP3 mask	APF=20	Since calcium magnesium oxide is classified as irritating to skin, the use of protective gloves is	potential contact with the eye can be excluded by the nature and type of application (i.e. closed process).		
Application to soil (spreading)	not required	na	mandatory for all process steps.	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

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

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



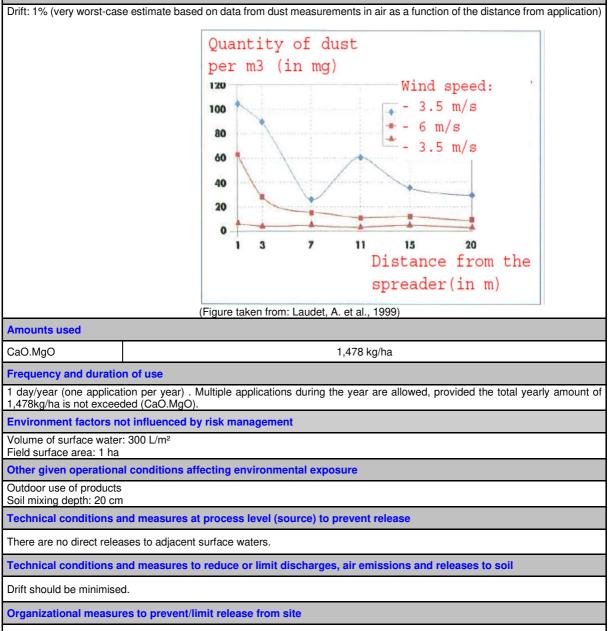
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2.2 Control of environmental exposure - only relevant for agricultural soil protection

Product characteristics

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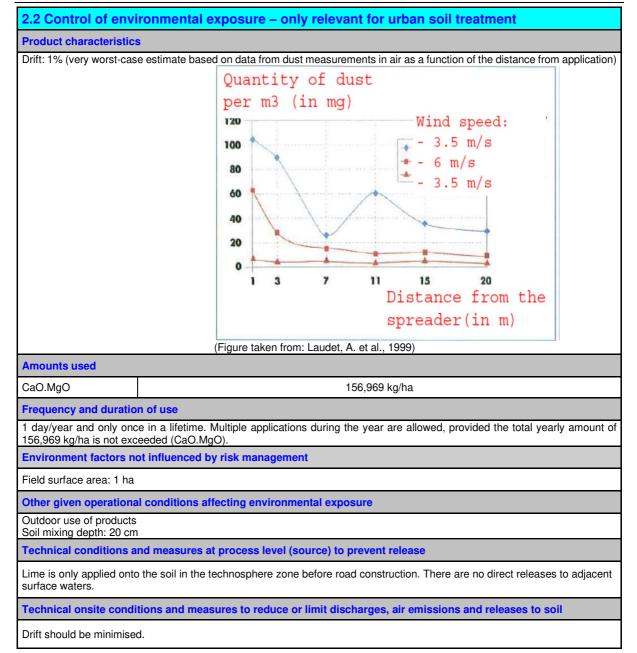
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



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3. Exposure estim	ation and reference	to its source						
Occupational exposure	9							
characterisation ratio (Re and has to be below 1 to	CR) is the quotient of the i	refined exposure estimate	he assessment of inhalatic and the respective DNEL he RCR is based on the D	(derived no-effect level)				
Task	Method used for inhalation exposure assessment	Method used for inhalation exposure Astimate (RCR) Method used for dermal exposure Astimate (RCR)						
Milling	MEASE	0.488 mg/m ³ (0.48)	Since calcium magnesiu					
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m ³ (0.48)	irritating to skin, derm minimised as far as tech for dermal effects has r	nically feasible. A DNEL				
Application to soil (spreading)	measured data	0.880 mg/m ³ (0.88)	dermal exposure is exposure	not assessed in this				
Environmental exposu	re for agricultural soil p	rotection						
ground water, surface w EUSES as it is more app included in the modelling basis of the German EX applied on the soil, calcin	ater and sediment (Klosko propriate for agricultural-lik g. FOCUS is a model typic POSIT 1.0 model, where p	wksi et al., 1999). The FC e application as in this ca ally developed for biocida parameters such as drifts	S (PEC) of plant protection DCUS/EXPOSIT modelling se where parameter as th applications and was fur can be improved accordin rds surface waters, via dri rds surface waters, via dri	tool is preferred to the e drift needs to be ther elaborated on the g to collected data: once				
Environmental emissions	See amounts used							
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultu	ral soil protection						
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR				
concentration in aquatic pelagic compartment	CaO.MgO	4.93	320	0.015				
Exposure concentration in sediments	Exposure concentration in 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.							
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR				
concentrations in soil and groundwater	CaO.MgO	434	712	0.61				
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.							
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipres y influence the distribution					



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Environmental exposure for urban soil treatment The urban soil treatment 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 See amounts used emissions Exposure concentration in waste water Not relevant for road border scenario treatment plant (WWTP) Exposure concentration in Not relevant for road border scenario aquatic pelagic compartment Exposure concentration in Not relevant for road border scenario sediments Exposure Substance PEC (mg/L) PNEC (mg/L) RCR concentrations in soil CaO.MgO 462 712 0.65 and groundwater Exposure concentration in This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below atmospheric 10⁻⁵ Pa. compartment Exposure concentration This point is not relevant because calcium can be considered to be omnipresent and essential in the relevant for the food environment. The uses covered do not significantly influence the distribution of the constituents chain (secondary (Ca²⁺ and OH⁻) in the environment. poisoning) 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 urban soil treatment Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water

Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited

Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.



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

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

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

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



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

	o Format (1) addres	sing uses carried o	ut by workers				
1. Title	[
Free short title	Professional uses of articles/containers containing lime substances SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20,						
Systematic title based	SU22, SU1, SU5, SU6a,	SU6b, SU7, SU10, SU11 SU23,		17, SU18, SU19, SU20,			
on use descriptor		C2, AC3, AC4, AC5, AC6	5, AC7, AC8, AC10, AC11 s are given in Section 2 be				
Processes, tasks and/or activities covered	Processes, t	asks and/or activities cove	ered are described in Sec	tion 2 below.			
Assessment Method	The assessment of	inhalation exposure is ba	sed on the exposure estin	nation tool MEASE.			
2. Operational con	ditions and risk ma	nagement measure	S				
PROC/ERC	REACH d	efinition	Involve	d tasks			
PROC 0	Other p (PROC 21 (low emission exposure e	n potential) as proxy for	Use of containers contain oxide/preparations as breathing a	CO ₂ absorbents (e.g.			
PROC 21	Low energy manipulation materials an		Handling of substanc	es bound in materials articles			
PROC 24	High (mechanical) energ bound in materia	y work-up of substances	Grinding, mec				
PROC 25	Other hot work ope	rations with metals	Welding, soldering				
ERC10, ERC11, ERC 12	Wide dispersive indoor a life articles and mater		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 worl	kers exposure						
Product characteristic							
is reflected by an assign at ambient temperature t temperature based, takin abrasive tasks are based	approach, the substance ment of a so-called fugacit the fugacity is based on th ing into account the proces d on the level of abrasion i	y class in the MEASE too e dustiness of that substa s temperature and the me	I. For operations conduct ince. Whereas in hot meta elting point of the substanc ntrinsic emission potential	ed with solid substances al operations, fugacity is ce. As a third group, high			
PROC	Used in preparation?	preparation	Physical form	Emission potential			
PROC 0	not res	tricted	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 res	tricted	massive objects	very low			
PROC 24, 25	not res	tricted	massive objects	high			
Amounts used							
combination of the scale	lled per shift is not conside of operation (industrial vs minant of the process intri	. professional) and level o					



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Frequency and duration	on of use/exposure							
PROC		Duration of exposure						
PROC 0		occupational exposure to o	ninutes calcium magnesium oxide er instructions of the actua					
PROC 21		480 minutes ((not restricted)					
PROC 24, 25		≤ 240 r	minutes					
Human factors not infl	uenced by risk managen	nent						
The shift breathing volu	me during all process steps	s reflected in the PROCs	is assumed to be 10 m ³ /s	hift (8 hours).				
Other given operation	al conditions affecting we	orkers exposure						
assessment of the cond exposure assessment in temperatures are expec	ike process temperature ar ucted processes. In process n MEASE is however based ted to vary within the indus uus all process temperature	ss steps with considerably d on the ratio of process t stry the highest ratio was t	/ high temperatures (i.e. F emperature and melting p taken as a worst case ass	PROC 22, 23, 25), the point. As the associated sumption for the				
Technical conditions a	and measures at process	level (source) to preven	nt release					
Risk management meas required in the processe	sures at the process level (e.g. containment or segre	egation of the emission so	urce) are generally not				
	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 PROC 0, 24, 25 PROC 0, 24, 24, 24, 25 PROC 0, 24, 24, 24, 24, 24, 24, 24, 24, 24, 24								
Organisational measu	res to prevent /limit relea	ses, dispersion and exp	oosure					
substance. These meas devices), no eating and	stion. General occupationa ures involve good persona smoking at the workplace, nge clothes at end of work	I and housekeeping pract the wearing of standard v	tices (i.e. regular cleaning working clothes and shoes	with suitable cleaning s unless otherwise stated				

compressed air.



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Conditions and measu	res related to personal p		health evaluation			
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE) Eye protection		
PROC 0	not required	. gog				
PROC 21	not required	na	Since calcium magnesium oxide is classified as irritating to	be worn, unless potential contact with the eye can be excluded by the nature		
PROC 24, 25	FFP1 mask	APF=4	implemented in parallel: T	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.		
breathing resistance and shall be considered that For reasons as given ab the use of RPE), (ii) have hair). The recommended the contours of the face The employer and self-e devices and the manage policy for a respiratory pl	I mass of the RPE itself, d the worker's capability of ove, the worker should the e suitable facial characteri I devices above which rely properly and securely. mployed persons have leg ment of their correct use i rotective device programm	lue to the increased therm using tools and of commu erefore be (i) healthy (esp istics reducing leakages b v on a tight face seal will n gal responsibilities for the in the workplace. Therefor he including training of the	hysiological stress for the what stress by enclosing the inicating are reduced durin ecially in view of medical petween face and mask (in not provide the required promaintenance and issue of re, they should define and a workers.	head. In addition, it ng the wearing of RPE. problems that may affect view of scars and facial otection unless they fit respiratory protective document a suitable		
2.2 Control of envi	ronmental exposur	е				
Product characteristics	5					
Lime is chemically bound	d into/onto a matrix with ve	ery low release potential				
3. Exposure estimation	ation and reference	to its source				
Occupational exposure)					
(RCR) is the quotient of 1 to demonstrate a safe mg/m ³ (as respirable dus	the refined exposure estin use. For inhalation exposi st) and the respective inha	nate and the respective D ure, the RCR is based on alation exposure estimate	ation exposure. The risk c NEL (derived no-effect lev the DNEL for calcium mag derived using MEASE (as eing a sub-fraction of the i	rel) and has to be below gnesium oxide of 1 inhalable dust). Thus,		
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/m³ (0.5)	Since calcium magnesi			
PROC 21	MEASE	0.05 mg/m³ (0.05)	irritating to skin, derm minimised as far as tech	al exposure has to be inically feasible. A DNEL		
PROC 24	MEASE	0.825 mg/m ³ (0.825)	for dermal effects has r	not been derived. Thus,		
			dermal exposure is not assessed in th exposure scenario.			
PROC 25	MEASE	0.6 mg/m ³ (0.6)	exposure			
PROC 25 Environmental exposu		0.6 mg/m ³ (0.6)	exposure			



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

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

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



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

Exposure Scenario	Forma	t (2) add	lressin	g uses carried out l	by consu	mers	
1. Title							
Free short title				Consumer use of buil	ding and co	onstruction materi	al
Systematic title based	l on use	descript	or	SU21, PC9a, PC9b, E			
Processes, tasks acti				Handling (mixing and Application of liquid, p	filling) of p	owder formulatior	
Assessment Method*			Human health: A qualitative assessm	ent has be xposure to Dutch mo	en performed for the eye. Inhalatic del (van Hemmer	on exposure to dust has	
2 Operational co	nditior	is and i	risk m				
2. Operational conditions and risk m RMM No product integ				ated risk management		are in place	
				ctivity referring to arti			vironmental release
PC/ERC					ole oulege		
PC 9a, 9b Application of lime Post-application e Wide dispersive in Wide dispersive of			g of powder containing lime substances. e plaster, putty or slurry to the walls or ceiling.				
Wide dispersive			persive c	outdoor use resulting in	inclusion in	nto or onto a matr	ix
2.1 Control of cor	Isume	rs expo	sure				
Product characteristic							
Description of the		entration	of the	Physical state of	Dustine	ss (if relevant)	Packaging design
preparation	subst	substance in the preparation		the preparation		,	
Lime substance	100 %			Solid, powder		edium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%		Solid, powder	of lime s (indicati	ng on the kind substance ve value from t sheet see 9 0 3)	35 kg.	
Plaster, Mortar	20-40	2/2		Pasty	-	0.0.0)	_
Putty, filler	30-55			Pasty, highly	-		In tubes or buckets
r utty, mor	00 00	/0		viscous, thick liquid			
Pre-mixed lime wash	~30%			Solid, powder	High - Ic	NA/	Bulk in bags of up to
paint	~30%				(indicati	ve value from t sheet see	35 kg.
Lime wash paint/milk ~ 30 % of lime preparation				Milk of lime preparation	-	/	-
Amounts used					1		I
Description of the preparation		Amour	t used	per event			
Filler, putty 250 g – 1 kg pc				ount is hear		the depth and size of	
		ding on the size of the room, wall to be treated.					
Floor/wall equalizer		~ 25 kg	depend	ling on the size of the ro			
Frequency and durati	on of us						
Description of task				on of exposure per ev	ent	frequency of e	events
Mixing and loading of li powder.	me conta	aining	1.33 m	in (DIY ¹ -fact sheet, RIV er 2.4.2 Mixing and loac	act sheet, RIVM,		
Application of lime plas slurry to the walls or ce		' or		al minutes - hours 2/year (DIY ¹ fact sheet)			



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Human factors not inf	luenced b	y risk manage	ment				
Description of the task	Populat	ion exposed	Breathing rat	te	Exposed body part		Corresponding skin area [cm²]
Handling of powder	Adult		1.25 m ³ /hr		Half of both hands		430 (DIY ¹ fact sheet)
Application of liquid, pasty lime preparations.	Adult		NR		Hands and forearms		1900 (DIY ¹ fact sheet)
Other given operation	al conditi					1	
Description of the tas	K	Indoor/outdo	or		volume		exchange rate
Handling of powder		indoor		small a	ersonal space, rea around the user)		hr ⁻¹ (unspecified room)
Application of liquid, par preparations.	sty lime	indoor		NR		NR	
Conditions and measu							
 Protect uncov should be use 	clothing, sh vered area ad in accor	noes and gloves s of skin (arms,	s immediately. legs, face): the kin protection pla	re are va	rious effective skin pro	otectio	on products which
Conditions and measu				humina			
 wear protective Choose work environment, 	ing or mixi ve goggles gloves ca cotton glo	ng building mat as well as face refully. Leather ves with plastic	erials, during de masks during d gloves become covering (nitrile	emolition dusty wo wet and are bet	or caulking and, above rk. can facilitate burns. W ter. Wear gauntlet glov	e all, d /hen v /es di	during overhead work, working in a wet uring overhead work
				numidity	which permeates the w	Vorkin	ig clothes.
2.2 Control of env		ntal exposu	re				
Product characteristic							
Not relevant for exposu	re assessr	nent					
Amounts used*	***	nont					
Not relevant for exposu Frequency and duration		nent					
Not relevant for exposu		nont					
Environment factors r			anagement				
Default river flow and di			anagement				
Other given operation		ons affecting e	environmental of	exposure	9		
Indoor							
Direct discharge to the							
Conditions and measu							
Default size of municipa						_	
Conditions and measu			treatment of w	aste for	disposal		
Not relevant for exposu							
Conditions and measu			recovery of wa	ste			
Not relevant for exposu							
3. Exposure estim The risk characterisatio effect level) and is giver substances of 4 mg/m ³ RCR includes an additio EN 481. Since limes are classifie	n ratio (RC n in parent (as respira onal safety	CR) is the quotie heses below. F able dust) and th margin since th	ent of the refined or inhalation exp ne respective in ne respirable fra	d exposu posure, th halation e action is a	he RCR is based on the exposure estimate (as a sub-fraction of the inf	ie acu inhal halab	ute DNEL for lime able dust). Thus, the le fraction according to
and exposure to the eye		-					'



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Human exposure

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Handling of po		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 μg/cm² (-) 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 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 DIY ¹ -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).
	iquid, pasty lime preparations.	
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.
dioxide from the	osure will be assumed as the aqueous atmosphere.	s lime preparation will quickly convert to calcium carbonate with carbor
the pH of the infl biological activity used beneficially of the municipal	OC/RMMs related to the environment luent of a municipal wastewater treatn y. The influent of a municipal wasteway of or pH control of acid wastewater stru	to avoid discharging lime solutions directly into municipal wastewater, nent plant is circum-neutral and therefore, there is no exposure to the ter treatment plant is often neutralized anyway and lime may even be earns that are treated in biological WWTPs. Since the pH of the influer pH impact is negligible on the receiving environmental compartments,



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

Exposure Scenario	Format (2) ad	dressin	g uses carried out b	y consui	ners	
1. Title						
Free short title			Consumer use of CO ₂	absorbent	in breathing app	aratuses
Systematic title based	on use descrip	tor	SU21, PC2, ERC8b	4000.00.0		
Processes, tasks activ			Filling of the formulatic Use of closed circuit b Cleaning of equipment	reathing ap		
Assessment Method*			Human health A qualitative assessme exposure. The inhalati model (van Hemmen, Environment A qualitative justificatio	ent has be on exposu 1992).	re has been asse	oral and dermal essed by the Dutch
2. Operational c	onditions a	nd risk				
RMM The soda lime is a 18%) is added wh cycle calcium dihu			available in granular forn nich will further reduce th ydroxide will be quickly r ctivity referring to artic	n. Furtherr ne dustines reacting wi	more, a defined a ss of the absorber th CO_2 to form the	nt. During the breathing e carbonate.
		ies (ERC		no outogo		
PC 2 Use of closed circ CO ₂ absorbent. T (catalysed by wat carbonate. The C			uit breathing apparatus he breathed air will flow er and sodium hydroxid O ₂ -free air can be re-bre bsorbent: The absorben	through th e) with the eathed aga	ne absorbent and calcium dihydrox ain, after addition	CO_2 will quickly react tide to form the
			ndoor use resulting in in	clusion inte	o or onto a matrix	
2.1 Control of consumers exposu						
Product characteristic						
Description of the	Concentration	of the	Physical state of Dustines		ss (if relevant)	Packaging design
preparation	substance in t		the preparation			· · ·····g ····g·
CO ₂ absorbent	78 - 84% Depending on application the component has different additiv A specific amo water is always (14-18%).	main s ves. unt of	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 ₂ -Absorbent used in			1-3 kg depending on th	ne kind of l	preathing apparat	tus
Frequency and duration						
Filling of the formulation into the Ca. 1.3 cartridge min		on of exposure per events 33 min per filling, in sum			ve (up to 4 times)	
Use of closed circuit breathing 1-2 h apparatus				Up to 4 dives a	day	
Cleaning and emptying of equipment < 15 m Human factors not influenced by risk manage					After each dive	(up to 4 times)
Human factors not infl Description of the task	Population ex		ment Breathing rate	Expose	d body part	Corresponding skin area [cm²]
Filling of the formulation into the cartridge Use of closed circuit	adult		1.25 m ³ /hr (light working activity)	hands -		840 (REACH guidance R.15, men)
breathing apparatus Cleaning and emptying of equipment				hands		840 (REACH guidance R.15, men)



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Other given operati	onal condition	ons affecting consume	ers exposure	
Description of the t		Indoor/outdoor	Room volume	Air exchange rate
Filling of the formula cartridge		NR	NR	NR
Use of closed circuit apparatus	breathing	-	-	-
Cleaning and emptyi equipment	ng of	NR	NR	NR
	acurae rolate	d to information and h	ehavioural advice to consu	more
		clothing. Do not breathe		
Keep container tightl Keep out of reach of Wash thoroughly after	y closed as to children. er handling. th eyes, rinse	avoid the soda lime to		lvice.
			to assure a proper use of the l	preathing apparatus.
Conditions and me	asures relate	d to personal protection	on and hygiene	
Wear suitable gloves 149).	, goggles and	d protective clothes durin	ng handling. Use a filtering hal	f mask (mask type FFP2 acc. to EN
		nental exposure		
Product characteris		t		
Not relevant for expo	sure assessr	nent		
Amounts used*				
Not relevant for expo		nent		
Frequency and dura				
Not relevant for expo				
Environment factor	s not influen	ced by risk manageme	ent	
Default river flow and	d dilution			
		ons affecting environm	ental exposure	
Indoor				
	asures relate	d to municipal sewage	treatment plant	
			and sludge treatment techniqu	8
				e
			nt of waste for disposal	
Not relevant for expo				
		d to external recovery	of waste	
Not relevant for expo	sure assessn	nent		
3. Exposure e	stimation	and reference to	o its source	
				d the respective DNEL (derived no-
effect level) and is gi substances of 4 mg/r	ven in parent m³ (as respira	heses below. For inhalat ble dust) and the respec	tion exposure, the RCR is bas stive inhalation exposure estin	ed on the acute DNEL for lime nate (as inhalable dust). Thus, the of the inhalable fraction according to
-	e aro classifi	ed as irritating to skin a	nd eves a qualitative assessm	ent has been performed for dermal
exposure and exposi-				ient has been performed for dermai
			a thair own CO, corubbar) it a	an be assumed that instructions will
be taken into account				
		cposure		
Human exposure	lation into th			
Filling of the formu				
Route of exposure	Exposure	estimate	Method used, comments	
Oral	-		Qualitative assessment	
				ur as part of the intended product
			use.	
Dermal	-		Qualitative assessment	
				re taken into account no human
				ever, dermal contact to dust from
				le or direct contact to the granules
				otective gloves are worn during
				ionally result in mild irritation easily



Revision date: June/2017

Dust

PRODUCT SAFETY DATA SHEET for CaMgO2 prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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Eye

	Printing Date: December 10, 2021
	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.
g/m³ (3 × 10 ⁻⁴) g/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

Environmental		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.
Inhalation	Small task: 0.3 μg/m³ (7.5 × 10 ⁻⁵) Large task: 3 μg/m³ (7.5 × 10 ⁻⁴)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section
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.
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.
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Route of exposure	Exposure estimate	Method used, comments
	mptying of equipment	
		finishing the assembly of the scrubber. Divers filling their own CO_2 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.
Inhalation	negligible	existent. Qualitative assessment Instructional advice is provided to remove any dust before
Eye	-	Qualitative assessment Due to the product characteristics, it can be concluded that eye exposure to the absorbent in breathing apparatuses is non-
Dermal	-	use. Qualitative assessment Due to the product characteristics, it can be concluded that dermal exposure to the absorbent in breathing apparatuses is non-existent.
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product
Route of exposure	Exposure estimate	Method used, comments
	ircuit breathing apparatus	
Inhalation	Small task: 1.2 μg/m ³ (3 × 10 ⁻⁴) Large task: 12 μg/m ³ (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.
		exposure is advisable.



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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.



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ES number 9.14: Consumer use of garden lime/fertilizer

					•				
Exposure Scenario	o Forma	at (2) ad	dressin	ig uses carrie	ed out l	by consu	mers		
1. Title									
Free short title				Consumer us	e of gard	len lime/fer	tilizer		
Systematic title base	d on us	e descrip	tor	SU21, PC20,					
Processes, tasks act	tivities o	covered		Manual applic Post-applicati	ation of	garden lim	e, fertilizer		
Assessment Method*	t .			Human health		Suie			
Assessment Method						ent has be	en nerforme	ed for	oral and dermal
				exposure as v	well as fo	or the expo	sure to the	eve.	The dust exposure has
				been assesse					
				Environment					
	A qualitative j	ustificatio	on assessr	nent is prov	ided.				
2. Operational co	nditio	ns and	risk m	anagement	measu	ures			
RMM				ated risk mana					
PC/ERC					g to arti	cle catego	ries (AC) a	nd e	nvironmental release
		categor							
PC 20							id (worst ca	se) a	nd soil incorporation.
DO 10		Post-app	blication (exposure to play	ying child	dren.		>	and a still the same should be
PC 12				g of the garden exposure to pla			nu (worst Ca	ase) a	and soil incorporation.
ERC 8e		Wide die	persive	outdoor use of r	eactive of	substances	in onen sv	stem	S
2.1 Control of co	neum				Cacilve	substances	я порел зу	Stern	5
Product characteristi		or o exp	Joure						
Description of the		entratior	of the	Physical stat	te of	Dustine	ss (if releva	ant)	Packaging design
preparation		tance in		the preparati	ion	Bustine		anty	r uokuging ucoign
r . F		aration							
Garden lime	100 %			Solid, powder High d		High dus	High dusty		Bulk in bags or
						• •		containers of 5, 10 and	
									25 kg
Fertilizer	Up to	20 %		Solid, granular Lov		Low dus	ty		Bulk in bags or
									containers of 5, 10 and
								25 kg	
Amounts used Description of the pre	onoratio			Amountuood	1		Cour		information
Garden lime	eparatio						and direction of use		
Fertilizer				100g /m ² (up to 1kg/m ² (compos					
Frequency and durat	ion of u	se/exnos	ure	Toog /III (up)		(composi		allon	rand direction of use
Description of the tas		3C/CAP03	Durati	ion of exposure per event frequency of events			vents		
Manual application				es-hours		1 tasks per year			
				iding on the size of the treated					
			area						
Post-application						for up	to 7 days after		
				ure factors hand	dbook)		applicatio	n İ	
Human factors not in						-			· · · · ·
Description of the	Popu	lation ex	posed	Breathing ra	te	Exposed	d body par	τ	Corresponding skin
task Manual application	Adult			1.05 m ³ /br 11		Handa a	Hands and forearms		area [cm ²] 1900 (DIY fact sheet)
Post-application		/Toddlers				NR	and torearms		NR
Other given operation			fecting		nosure				
Description of the tas			or/outdo			volume		Air	exchange rate
Manual application outdoor		-		personal sp	ace.	NR	<u> </u>		
1.12					N	area aroun	· ·		
user)									
Post-application		outde			NR			NR	
Conditions and meas									
					Use a fil	tering half	mask (masl	< type	e FFP2 acc. to EN 149).
Keep container closed									
In case of contact with			diately w	ith plenty of wa	iter and s	seek medic	al advice.		
Wash thoroughly after			noo to	otor and not	tor to line				
Do not mix with acids a Incorporation of the ga							vill facilitata	the c	offect
Conditions and meas							miacilitate	ine e	
Wear suitable gloves.					anygier				
	4044103								



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2.2 Control of e	environmental exposu	re	
Product characteris	stics		
Drift: 1 % (very wors		a from dust measure	ments in air as a function of the distance from
application)			
Amounts used		1	
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
	CaO.MgO	1,478 kg/ha	or the corresponding amount of 2244 kg
	Ca(OH)2.Mg(OH)2	2,030 kg/ha	Ca(OH) ₂ /ha. This rate is three times the amount
	CaCO3.MgO	2,149 kg/ha	needed to compensate the annual losses of
	Ca(OH)2.MgO	1,774 kg/ha	lime by leaching. For this reason, the value of
	Natural hydraulic lime	2,420 kg/ha	1700 kg CaO/ha or the corresponding amount
			of 2244 kg Ca(OH) ₂ /ha is used in this dossier as the basis for the risk assessment. The amount
			used for the other lime variants can be
			calculated based on their composition and the
			molecular weight.
Frequency and dur	ation of use		molecular weight.
		polications during th	e year are allowed, provided the total yearly amount of
1,478kg/ha is not ex		pp.ioutiono during ti	is year are another, provided the total yearly amount of
	s not influenced by risk ma	anagement	
Not relevant for expo	osure assessment		
	onal conditions affecting e	nvironmental expos	sure
Outdoor use of produ			
Soil mixing depth: 20			
	ns and measures at process	s level (source) to p	revent release
	eleases to adjacent surface v		
			, air emissions and releases to soil
Drift should be minin		or mill aloonargoo	
	easures related to municipa	l cowago treatment	nlant
Not relevant for exp		i sewaye i calificiti	plant
	easures related to external	treatment of waste	for disposal
Not relevant for exp		treatment of waste	
	easures related to external	recovery of waste	
Not relevant for exp			
	timation and reference	o to ite couroo	
			osure estimate and the respective DNEL (derived no-
effect level) and is g substances of 1 mg, RCR includes an ad EN 481. Since lime substance	iven in parentheses below. F /m ³ (as respirable dust) and ti ditional safety margin since t es are classified as irritating	or inhalation exposu he respective inhalat he respirable fractior	ion exposure estimate (as inhalable dust). Thus, the is a sub-fraction of the inhalable fraction according to valitative assessment has been performed for dermal
exposure and expos	sure to the eye.		
Human exposure			
Manual application			and comments
Route of	Exposure estimate	Method u	sed, comments
oral	-	Qualitativ	e assessment
Urai	-		sure does not occur as part of the intended product
Dermal	Dust, powder		e assessment
	, portaoi		uction measures are taken into account no human
			is expected. However, dermal contact to dust from
			n of lime substances or by direct contact to the limes
			excluded if no protective gloves are worn during
			n. Due to the relatively long application time, skin
		application	
			ould be expected. This can easily be avoided by
		irritation w	rould be expected. This can easily be avoided by e rinsing with water. It would be assumed that
		irritation w immediate	
		irritation w immediate consumer	e rinsing with water. It would be assumed that
		irritation w immediate consumer themselve	e rinsing with water. It would be assumed that s who had experience of skin irritation will protect



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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 lime)	Small task: 12 μg/m³ (0.0012) Large task: 120 μg/m³ (0.012)	Quantitative assessment 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).
Inhalation (fertilizer)	Small task: 0.24 μg/m ³ (2.4 * 10 ⁻⁴) Large task: 2.4 μg/m ³ (0.0024)	Quantitative assessment 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	•	•
for products which a case exposure of cl model predicts the treated area and als Garden lime or ferti	are applied in parks or amateur produc hildren, who may have access to these post-application exposure to products so via the oral route through hand-to-n lizer including lime is used to treat acid I driving effect of lime (alkalinity) will be	ow called CRD) post-application exposure need to be addressed ets used to treat lawns and plants grown in private gardens. In this e areas soon after treatment, needs to be assessed. The US EPA used in private gardens (e.g. lawns) by toddlers crawling on the nouth activities. dic soil. Therefore, after application to the soil and subsequent e 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.



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

Exposure Scenario	Form	at (2) ado	Iressin	uses carried out b	v consu	mers		
		ut (2) uuu	103511	g uses curred out b	<i>y</i> consu			
	1. Title							
Free short title Systematic title based on use descriptor			Consumer use of lime substances as water treatment chemicals					
Processes, tasks activities covered			SU21, PC20, PC37, ERC8b Loading, filling or re-filling of solid formulations into container/preparation of lime milk Application of lime milk 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 c	ondit	tions an	ld risk	c management m	leasure	es		
RMM				t integrated risk manage				
PC/ERC		categorie	es (ERC		•			
PC 20/37	PC 20/37 Filling and re-fillin Transfer of lime s		g (transfer of lime subst ubstances (solid) into co tion of lime milk to water	ontainer fo				
ERC 8b				ndoor use of reactive su		in open systems		
2.1 Control of co								
Product characteristic Description of the		ontrotion	of the	Dhysical state of	Ducting	(if relevant)	Dookoging dooign	
preparation	subs	Concentration of the substance in the preparation		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 E		Bulk-tank lorry or in "Big Bags" or in sacks		
Amounts used								
Description of the pre				Amount used per eve				
Water treatment chemic aquaria				depending on the size of the water reactor to be filled (~ 100g /L)				
Water treatment chemic drinking water			for	depending on the size of the water reactor to be filled (~up to 1.2 kg/L)				
Lime milk for further app				~ 20 g / 5L				
Frequency and duration	on of u	se/exposu				1 Aug		
Preparation of lime milk (loading, filling 1.33 mi and refilling) (DIY-fa		on of exposure per even in act sheet, RIVM, Chapte and loading of powders	I task/month NVM, Chapter 2.4.2		events			
		Il minutes - hours	1 tasks/ month					
Human factors not infl	luence	d by risk r	nanage					
Description of the task	Population exposed		Breathing rate	Exposed body part		Corresponding skin area [cm ²]		
Preparation of lime milk (loading, filling and refilling)		adult		1.25 m³/hr	Half of both hands		430 (RIVM report 320104007)	
Dropwise application adult of lime milk to water		NR	Hands		860 (RIVM report 320104007)			
Other given operation Description of the task			ecting of pr/outdo		volume	Air	exchange rate	



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Preparation of lime (loading, filling and		Indoor/outdoor	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room indoor)
Dropwise application milk to water	n of lime	indoor	NR	NR
	easures relate	ed to information and b	ehavioural advice to consumers	
Keep container clos Use only with adequ	ed and out of ate ventilatior	n.	dust of water and seek medical advice.	
Wash thoroughly aff Do not mix with acid	ter handling. Is and always	add limes to water and r	not water to limes.	
Conditions and me	easures relate	ed to personal protection	on and hygiene	
			a filtering half mask (mask type FFP2	2 acc. to EN 149).
		nental exposure		
Product characteri				
Not relevant for exp	osure assessr	nent		
Amounts used*				
Not relevant for exp	osure assessr	nent		
Frequency and du				
Not relevant for exp				
		nced by risk manageme	ent	
Default river flow an				
Indoor	lional condition	ons affecting environm	iental exposure	
		ad to municipal cowork	treatment plant	
		ed to municipal sewage	and sludge treatment technique	
			nt of waste for disposal	
Not relevant for exp				
		ed to external recovery	of waste	
Not relevant for exp				
		and reference to	a ite source	
effect level) and is g substances of 4 mg. RCR includes an ac EN 481. Since lime substance exposure and expos	iven in parent /m ³ (as respira Iditional safety es are classifi	theses below. For inhalat able dust) and the respec margin since the respira- ied as irritating to skin an	refined exposure estimate and the re- tion exposure, the RCR is based on the ctive inhalation exposure estimate (as able fraction is a sub-fraction of the ini- and eyes a qualitative assessment has	e acute DNEL for lime inhalable dust). Thus, the nalable fraction according to
Human exposure		<u>,</u>		
Preparation of lime Route of			Mothed used as mercents	
Route of exposure	Exposure	esumate	Method used, comments	
Oral	-		Qualitative assessment Oral exposure does not occur as pa use.	art of the intended product
Dermal (powder)		0.1 μg/cm² (-) 1 μg/cm² (-)	Qualitative assessment If risk reduction measures are taker exposure is expected. However, de loading of limes or direct contact to if no protective gloves are worn dur occasionally result in mild irritation rinsing with water. Quantitative assessment The constant rate model of ConsEx contact rate to dust formed while po taken from the DIY-fact sheet (RIVI granules the exposure estimate will	rmal contact to dust from the lime cannot be excluded ing application. This may easily avoided by prompt po has been used. The buring powder has been <i>I</i> report 320104007). For
Eye	Dust		Qualitative assessment If risk reduction measures are taker exposure is expected. Dust from loa excluded if no protective goggles at water and seeking medical advice a advisable.	ading of the limes cannot be re used. Prompt rinsing with

advisable.



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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.
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

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.



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ES number 9.16: Consumer use of cosmetics containing lime substances

Exposure Scenario Format (2) addr	essing uses carried out by consumers				
1. Title					
Free short title	Consumer use of cosmetics containing limes				
Systematic title based on use descriptor					
Processes, tasks activities covered	3021, F039, En00a				
Processes, tasks activities covered	Human health:				
Assessment Method*	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 conditions and ris	sk management measures				
ERC 8a Wide dispersive indoor use of processing aids in open systems					
2.1 Control of consumers expos					
· · · · · · · · · · · · · · · · · · ·					
Product characteristic	and this was done not used to be someidened				
	om this use does not need to be considered.				
Amounts used					
	om this use does not need to be considered.				
Frequency and duration of use/exposure					
	om this use does not need to be considered.				
Human factors not influenced by risk ma					
	om this use does not need to be considered.				
Other given operational conditions affect					
Not relevant, as the risk to human health from	om this use does not need to be considered.				
	rmation and behavioural advice to consumers				
Not relevant, as the risk to human health fro	om this use does not need to be considered.				
Conditions and measures related to personal protection and hygiene					
Not relevant, as the risk to human health from this 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					
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					
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 c	ompartments, such as surface water, sediment and terrestrial compartment.				

End of the safety data sheet